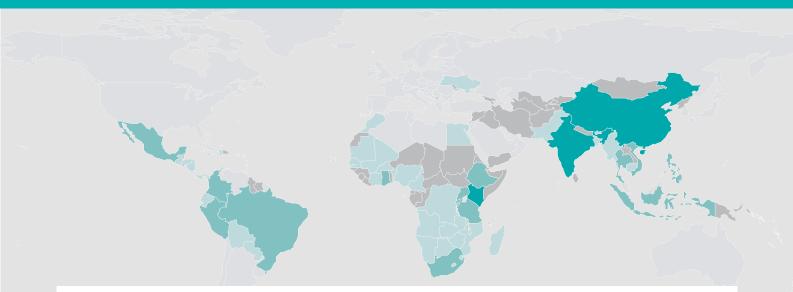
Improving access to cancer care

A first analysis of pharmaceutical company actions in low- and middle-income countries



Companies are addressing access to cancer care - can efforts be channelled to where they will have most impact?

Pharmaceutical companies are addressing access to cancer care in developing countries: 16 of the world's largest pharmaceutical companies are engaged in 129 diverse access initiatives in low- and middle-income countries. The largest proportion (55%) are related to building local capacity, followed by pricing actions on specific products. There is large variety in the scope, breadth, location and scale of the initiatives, as well as in the cancers being addressed. Impact per initiative is rarely disclosed, and warrants structured monitoring and evaluation. Treatment is only one element of cancer care, which also comprises, for example, prevention, diagnosis and palliative care. Although the 16 companies together address most elements in some form, in some countries, efforts are not evenly spread, varying by cancer and country/region. Health systems in lower income countries need strengthening in order to support and sustain cancer care. Governments shoulder the main responsibility in this regard. Pharmaceutical companies share an opportunity to address all elements of cancer care, through tailored multi-sector partnerships that take a systems-level approach to making lasting improvements.

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ACCESS TO MEDICINE FOUNDATION

access to medicine Foundation

The Access to Medicine Foundation is a non-profit organisation. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access to medicine. For ten years, the Foundation has been building consensus on the role for the pharmaceutical industry in improving access to medicine and vaccines. It published its first benchmark of industry activity in this area in 2008, in the first Access to Medicine Index. The fifth Access to Medicine Index was published in 2016. In 2017, the Foundation published the first Access to Vaccines Index.

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Ministry of Foreign Affairs of the Netherlands

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ACCESS TO MEDICINE FOUNDATION

22 May 2017

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About this study

Cancer is one of the greatest health challenges of our time, and a leading cause of death in every corner of the world. Currently, around 65% of all cancer deaths occur in developing countries. Governments bear the greatest responsibility for improving access to cancer care. Pharmaceutical companies have a unique role to play.

The first landscape of company activities on cancer care

This study is the first assessment of whether and how large pharmaceutical companies are improving access to cancer care in low- and middle-income countries (LMCs). It reports on the actions of 16 of the world's largest research-based pharmaceutical companies. It analyses data collected by the Access to Medicine Foundation, directly from the companies measured and extensively supplemented through publically available information.

The Access to Medicine Foundation has found that 16 companies are taking some action to improve access to cancer medicine, implementing 129 initiatives. There is large variety in the reported initiatives, as well as in the cancers being addressed.

FINDINGS: 16 COMPANIES, 129 ACCESS INITIATIVES

The findings of this study are presented in five main sections:

Landscape analysis

Analysis of where companies are focusing their access efforts for cancer care, looking at location, cancer type, access focus (IP, pricing or capacity building) and activity (e.g., awareness-raising, diagnosis, treatment).

Companies' oncology footprints

Overview of each company's therapeutic focus, sales and oncology products, including products that are on the WHO Model Essential Medicines List 2015.

Oncology pricing – 36 access initiatives

Discussion of 36 separate initiatives that each address the price of one or more cancer medicines in at least one country in scope.

Intellectual Property Policies – 12 companies publish IP policies

Discussion of the IP policies of the companies in scope toward patent rights in poor countries.

Capacity building – 71 initiatives

Discussion of how each company approaches capacity building, plus 21 other initiatives for health system strengthening:

- Initiatives linked to specific products
- General capacity building
- e-Health or m-Health initiatives
- Funding for initiatives



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Landscape study | Access to cancer care

Executive Summary

Cancer is one of the greatest health challenges of our time, and a leading cause of death in every corner of the world. World Health Organisation (WHO) estimates that the number of people dying from cancer globally will increase by 45%, to 11.5 million, by 2030. Currently, around 65% of cancer deaths occur in developing countries, where cancer rates are also rising. Typically, the infrastructure and resources needed to ensure access to cancer care in poorer countries are limited, despite the majority having national cancer control plans.

Treatment is only one element of cancer care. It also includes prevention, diagnosis and palliative care. National governments shoulder the main responsibility for improving cancer care. Pharmaceutical companies also have a unique role to play. They have the ability and opportunity to improve the accessibility and affordability of products, to meet the specific needs of people with cancer in developing countries. Such companies also have valuable expertise for supporting the development of resilient health systems for cancer care.

Figure 1. By the numbers: pharma company activity to address access to cancer care

COMPANIES

16 companies are taking action, including market leaders in oncology

IP POLICIES

12 companies have published IP policies; 2 companies are discussing potential licensing terms

PRICING 36 initiatives, mainly patient access/support programmes

CAPACITY BUILDING

71 initiatives, including 13 linked to specific products This landscape study is the first assessment of whether and how large pharmaceutical companies are improving access to cancer care in low- and middle-income countries (referred to here as LMCs). It reports on the actions of 16 of the world's largest research-based pharmaceutical companies.

16 companies; 129 access initiatives

The Access to Medicine Foundation has found that 16 of the world's largest pharmaceutical companies are taking some action to improve access to cancer care, implementing a diverse range of 129 initiatives. These involve pricing, capacity building and other activities, such as stakeholder engagement. There is large variety in the scope, scale and geographic focus of the reported initiatives, as well as in the cancers being addressed.

Where cancer type is specified, female cancers, haematological cancers and colorectal cancer gain most attention, with more initiatives aimed at breast cancer (42 initiatives) and cervical cancer (27) than other cancer types. The highest numbers of initiatives are found in Kenya, China, India, Indonesia and the Philippines. This perhaps in part reflects the presence of more developed healthcare systems and networks of active partners, or opportunities for having more impact. At the regional level, Latin America is the only region with initiatives in all countries; while sub-Saharan Africa has more initiatives overall.

Focus on capacity building

Most initiatives (71 out of 129) involve local capacity building. They include projects to raise awareness or reduce the stigma of cancer; programmes that support screening, diagnosis, treatment, and/or palliative care; as well as initiatives that focus on infrastructure and equipment and/or improving administrative activities. At least 65 initiatives involve multiple partners, such as international organisations, local or international NGOs, governments, private sector partners, foundations, universities or non-profit organisations.

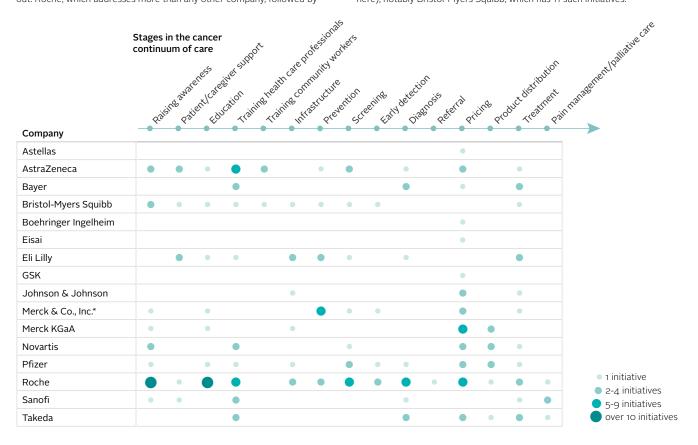
It is difficult to rank different types of capacity building in terms of merit. Initiatives can vary in investment and results. For instance, initiatives to raise awareness by distributing educational materials may reach a wider range of people than initiatives aimed at improving infrastructure, equipment, staffing a hospital or training healthcare professionals. But they may also be less challenging, less demanding in terms of human resources and capital, and have a less direct impact on patient health. The role that the pharmaceutical industry plays in addressing access to cancer care globally is often heavily debated, particularly with regard to the affordability of cancer medicines (for example, in recent discussions of compulsory licences granted, towards products such as Nexavar® (sorafenib), and about the price of Herceptin® (trastuzumab) and other cancer medicines). The global oncology market is expected to grow from around USD 105 billion to USD 150 billion by 2020,¹ and is led in terms of revenues by a relatively small group of companies. Companies active in oncology, particularly market leaders, can invest in access to affordable, quality cancer medicines and contribute to the development of resilient health systems around the world.

WHO Model EML

The 16 companies evaluated here have a total of 11 detailed initiatives linked to medicines on the WHO Model Essential Medicines List (EML) 2015. The EML identifies the medicines that any basic healthcare system needs in order to function. That only 11 EML oncology products are currently reported to be included in access programmes points towards the need for governments and their partners to strengthen health systems so that they can receive such critical cancer products – and for companies (including manufacturers of cancer products not included in this study) to bring more essential and affordable products to more of the countries that need them.

Figure 2. Which companies' access initiatives address more stages of cancer care?

Effective cancer management requires a sequence of health services, referred to as "the cancer continuum of care". While many companies address multiple stages of the cancer care continuum, six companies stand out: Roche, which addresses more than any other company, followed by AstraZeneca, Pfizer, Bristol-Myers Squibb, Eli Lilly, and Merck & Co., Inc. Several initiatives address multiple stages. No company addresses all stages. A few companies support capacity building through philanthropy (not shown here), notably Bristol-Myers Squibb, which has 11 such initiatives.



Not all health systems are strong or resilient enough, or have appropriate guidelines, monitoring and treatment options to be able to offer patients proper cancer care. Health systems in developing countries need to be sufficiently strengthened by governments and their partners to ensure that people's needs can be met and sustainable health outcomes achieved.

The cancer continuum of care

When it comes to delivering effective cancer care, a sequence of health services is required – including cancer awareness, prevention, screening, early detection, diagnosis (testing), referral, (affordability of and access to) treatment, follow-up, pain management and palliative care. This sequence is often referred to as the cancer continuum of care.

The pharmaceutical companies evaluated together address all health services across this continuum, albeit unevenly, varying by cancer type and country. Some companies stand out by addressing multiple service areas through their various initiatives (i.e., AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Merck & Co., Inc., Pfizer and Roche). None of the companies evaluated address all services. Many initiatives improve access to a range of health service levels, yet few specifically address access to necessary products or medicines. The majority of capacity building initiatives are focused on raising cancer awareness, or on training and education, across all types of cancer. The diversity of activities allows more partnerships to be formed, where lessons learned from one system can be shared with others. However, what works in one country or context may not always work in another; tailored approaches are required. The total impact of the initiatives captured in this study is as yet largely unknown, highlighting the need for more organised, structured and transparent monitoring and evaluation of initiatives.

Pharmaceutical companies, together with their partners, have the opportunity to contribute more to all levels of health services across the cancer continuum of care in low-income countries. This can best be done through multi-sector partnerships that address cancer care at a health systems level. Companies also share an opportunity to offer affordable, quality oncology products to more people who need them globally. For companies to be able to contribute, health systems must be capable of supporting and providing cancer care.

Main findings

1

Pharmaceutical companies engage in 129 initiatives to improve access to cancer care in poorer countries

The majority of initiatives (71) relate to capacity building, with a little over a quarter of initiatives addressing pricing (36). Four companies have each launched an initiative relating to mobile health and/or online training programmes on cancer care. Companies are also bringing their financial reserves to bear: the study found 17 cases of companies providing philanthropic financial support for capacity building activities. The remaining initiatives cover other areas, such as stakeholder engagement. Roche leads numerically with the highest number of initiatives across the board. Roche is also the market leader in oncology revenues globally.

2

Capacity building initiatives are very diverse in their scope, type and focus

Capacity building programmes are very varied in nature. Most combine various elements of capacity building, such as awareness-raising (28 initiatives) and education/training (45). A sizeable group of initiatives aim to build capacity in either cancer diagnosis (16), screening (14) and/or early detection (5). A small core of capacity building initiatives (13) also include programmes designed to increase access to specific products, for example by addressing pricing (e.g., AstraZeneca, Novartis, Roche). The most comprehensive access initiatives either combine different access strategies, multiple types of capacity building activity per project, or address several forms of cancer

3

Most companies have pricing initiatives in place for at least some of their products

Out of 16 companies, 13 have one or more access initiatives addressing pricing: reporting 36 pricing initiatives for cancer medicine in total. Many of these are organised in patient access or support programmes (PAPs and PSPs), which generally provide some form of discount or donation directly to patients enrolled in the programme. It is not possible in this study to evaluate whether pricing programmes truly reflect the local community's ability to pay for cancer treatments.

4

More than half of pharmaceutical companies (12) report their policies on IP filing and enforcement

Many companies state that they do not intend to file or enforce patents in (at least some) low- and middle-income countries. GSK and Merck KGaA report the most comprehensive approaches: they both have IP policies that apply in the majority of low and lower-middle-income countries (LICs and LMICs, as classified by the World Bank). Both companies have also started discussing future licensing arrangements for cancer medicines with the Medicines Patent Pool (MPP).

5

Companies address access to some cancer medicines on WHO Model EML

The Model EML identifies those medicines necessary for a basic health system to function. The companies evaluated together have 56 products that match medicines on the Model EML. Only 11 of these (from three companies: AstraZeneca, Novartis and Roche) are targeted by access initiatives captured in this study. EML medicines are not specified or included in access strategies reported by Bayer, Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, Merck & Co., Inc., Pfizer, Sanofi and Takeda. Eli Lilly may also have an initiative for one EML product; details of the initiative and whether it is ongoing are unavailable.

6

At least half of initiatives involve partnerships

Out of 129 initiatives in total, companies report 65 initiatives that involve some sort of partnership with international organisations, including the United Nations, the Union for International Cancer Control (UICC) and WHO, as well as with local and/or international NGOs, governments, private-sector partners, foundations, universities and/or non-profit organisations.

8

Geographically, companies' activities are focused on areas with high cancer mortality rates

Initiatives are being implemented in 63 countries (out of 107 assessed). Kenya, China and India have more initiatives than other countries. Regionally, sub-Saharan Africa has the most initiatives overall: it has 50 initiatives, most of which involve general capacity building (23) followed by funding (14).

Female cancers, haematological and colorectal cancers gain most attention

Many initiatives identified in this study are linked to general or unspecified cancers. Where cancer type is specified, female cancers, haematological cancers and colorectal cancer gain most attention. Breast cancer leads with 42 initiatives, followed by cervical cancer (27), haematological (14) and colorectal cancer (10). Among women in developing countries, this distribution reflects the leading cancer types by incidence. Among men, however, the leading cancers by incidence in developing countries are lung and liver cancer, which seem less represented.

Introduction

Cancer is one of the greatest health challenges of our time, and a leading cause of death in every corner of the world. According to World Health Organisation (WHO), the number of people dying from cancer globally is projected to increase by 45% to 11.5 million by 2030 (up from 7.9 million deaths in 2007). New cases of cancer are estimated to jump from 11.3 million in 2007 to 22 million in 2035.² As part of WHO's Global Action Plan for the Prevention and Control of NCDs,³ countries around the world are now working towards a 25% relative reduction in deaths from non-communicable diseases, which include premature mortality from cancer, by 2025. This is extended to 30% by the UN 2030 Agenda for Sustainable Development, in particular Sustainable Development Goal (SDG) 3: Ensure healthy lives and promote well-being for all at all ages.⁴

Low- and middle-income countries carry the heaviest cancer burden

Currently, around 65% of all cancer deaths occur in low- and middle-income countries² – and this figure rising. Although high-income countries continue to have the highest overall cancer incidence rates, for the most common cancers, the figures are either plateauing or decreasing. This is largely due to decreases in known risk factors, early detection rates and improved treatment.⁵ In contrast, cancer rates in low- and middle-income countries (in this paper referred to as LMCs) are rising due to an increase in life expectancy and in risk factors typically associated with cancers, such as smoking, excess body weight, physical inactivity and changing reproductive patterns. For example, the Indian National Cancer Registry Program estimates that the number of cancers in India will rise from 946,172 in 2008 to 1,148,758 in 2020⁶ (these figures reflect a growing demand for cancer care in a country with high levels of inequality). Low- and middle-income countries also shoulder an excessive burden of infection-related cancers affecting stomach, liver and cervix.² Without adequate treatment and prevention, the disproportionate majority of cancer deaths will continue to occur in LMCs.

Reflecting the rising cancer burden in LMCs

In May 2015, WHO added 16 new medicines for treating cancers to its Model Essential Medicines List (EML).^{7*} The Model EML 2015 includes a total of 46 cytotoxic, adjuvant and hormonal agents that address cancer. In addition, the WHO Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013-2020 recommends the Hepatitis B vaccines and the human papillomavirus (HPV) vaccine for cervical cancer prevention, following recommendations made by the WHO Strategic Advisory Group of Experts on Immunization (SAGE), as well as a basic palliative care package for cancer patients.^{7*}

How can LMCs deliver along the cancer care continuum? Effective cancer management requires a sequence of health services, together referred to as "the cancer continuum of care". The care continuum for cancer patients⁸ (Figure 3) outlines the sequence of health services that are needed for effective cancer management: awareness of cancer symptoms and risks, preventive measures, screening, early detection, diagnosis (testing), referral, access to treatment, pain management, supportive care (and/or palliative care) and follow-up. Typically, in LMCs, the infrastructure and resources needed for ensuring access to cancer care at each step of the care continuum are limited. However, the majority of countries do now have a national cancer control plan (NCCP).9 Enhancing awareness of behaviour change for modifiable cancer risk factors, signs and symptoms of cancers, and the opportunity provided by early detection and treatment as well as improving the accessibility, availability and affordability of cancer medicines and preventative vaccines in LMCs is especially important.

National governments have a substantial role and responsibility for improving access to cancer care: starting with the need to prioritise the inclusion of cancer care as they strengthen their health systems and to publish their NCCP. Governments must also ensure that all healthcare workers complete their education with a basic understanding of cancer facts, as well

Figure 3. The cancer continuum of care

Effective cancer management requires a sequence of health services, referred to as "the cancer continuum of care". It involves many steps, including several at the primary healthcare level – the first level of contact individuals, families and communities will have with their healthcare system.



as developing the necessary oncology expertise and formal disciplines. Similarly, governments can encourage communities to take an active role in improving their own cancer health literacy. Governments can also lead in driving the right type of engagement with pharmaceutical companies: engage-

ROLE FOR PHARMACEUTICAL COMPANIES

In strengthening the cancer care continuum in LMCs, pharmaceutical companies have a unique role to play: they have the ability and opportunity to improve the accessibility and affordability of the oncology products they produce in ways that meet the specific needs of people living with cancer in developing countries. In addition, such companies can provide locally tailored capacity building activities that address different stages of the care continuum, working on their own or with partner organisations. They can also support infrastructure development, or provide other forms of financial or on-the-ground support.

When pharmaceutical companies take steps to improve access to cancer care in LMCs, both the company and the country in question can benefit. Such actions can provide the country (and its populations) with improved community health by addressing local care and support needs. At the same time, such steps can enable companies to further develop their oncology businesses in key emerging markets. Such situations – often referred to as providing shared value – are to be welcomed, provided that conflicts of interest are actively prevented, and the public health goals are prioritised over the business goals.

This landscape study comprises the first assessment of what large pharmaceutical companies are doing to improve access to cancer care in low- and middle-income countries. It reports the actions of 16 of the world's largest research-based pharmaceutical companies. The aim is to give an overview of the scale, scope and types of activities being undertaken by research-based pharmaceutical companies to improve access to cancer care in low- and middle-income countries. The study identifies where activities are being concentrated and where gaps remain for further action from the industry and their partners. It looks at the distribution of company activities in geographic terms, by disease and along the cancer care continuum. Where possible, the study also identifies the main perceived strengths and limitations of these approaches. icine through sharing responsibilities, and whereby activities are aligned with the NCCP and have a positive impact on local healthcare needs.

ments that have a maximum impact on access to cancer med-



Dr. Dolendo treats a child with cancer at her clinic in the Philippines, where Novartis supports training for local staff.



AstraZeneca provides medicine and information to postmenopausal breast cancer patients at the Center of Hope in Phnom Pen, Cambodia.

*The WHO Model Essential Medicines List (EML) is updated every 2 years. The next update is expected later in 2017.

METHODS AND LIMITATIONS

This study analyses data collected by the Access to Medicine Foundation on large research-based pharmaceutical companies – namely, the 20 companies ranked in the 2016 Access to Medicine Index. The Access to Medicine Index is published every two years by the Foundation, and evaluates 20 of the world's largest pharmaceutical companies (by market capitalisation) according to their efforts to improve access to medicine in developing countries.

Data for this study was collected directly from the companies analysed via a questionnaire, and extensively supplemented by independent, publicly available sources. These include company websites, the IFPMA partnership directory, sites of non-governmental organisations, news releases by companies and others, and independent media and journal articles. Company products were sourced through corporate websites. The targeted cancer type or indication for the product was summarised. There may be differences in the exact registered indication for each product in different countries and situations. The period of analysis for company-submitted data runs from June 2014 up until May 2016, and to February 2017 for supplemental public data. Company data for this study was gathered alongside data for the 2016 Access to Medicine Index. Companies were given an opportunity in 2017 to fact check and update the information used. Data provided to the Foundation and used in this study were not subject to non-disclosure agreements. Companies were asked to describe their activities in addressing access to cancer care for all cancer types in the 107 low- and middle-income countries in the scope of the 2016 Access to Medicine Index (see appendix). Companies were not asked for initiatives per oncology product: as a result, in some cases, some details were not consistently available, e.g., about related products, geographic scope, the responsibilities of partners and outcomes reported. Where companies report that an initiative applies to a region, such as sub-Saharan Africa, the authors have assumed that the initiative is available in all countries in that region.

Regarding pricing initiatives for cancer products, it was not possible to analyse the affordability of the products in question using the data obtained; the cost of treatments in different circumstances and different markets is also unknown, and limited data is available to validate this. Further, no attempt was made to assess either the presence or nature of any conflicts of interest relating to the company initiatives identified. The Foundation recommends that the potential for such analyses be explored. All conclusions drawn in this paper thus reflect these limitations.

About the Access to Medicine Foundation

The Access to Medicine Foundation is an independent nonprofit organisation based in the Netherlands. Its mission is to stimulate and guide pharmaceutical companies to do more for the people living in low- and middle-income countries without access to medicine. The Foundation is independently funded by the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs and UK AID.

How are pharma companies addressing access to cancer care?

The Access to Medicine Foundation has found that 16 of the world's largest pharmaceutical companies are taking some action to improve access to cancer medicine in developing countries. They are implementing a diverse range of initiatives, including pricing actions and a variety of capacity building activities. A smaller group of companies also carries out additional stakeholder engagement activities. There is large variation in the scope, and in the therapeutic and geographic focus of the reported access to cancer care initiatives.

The 16 companies have a total of 171 cancer medicines and two preventive vaccines in their portfolios. Eleven companies have a cancer or cancer-related product on the WHO Model Essential Medicines List (EML) 2015. Together, these match 37 of the 46 unique cancer products on the EML. As multiple companies can produce the same EML medicine, 56 out of the companies' 171 cancer medicines are on the WHO Model EML (see Figure 4). Together, these medicines can target at least 43 different types of cancer. The cancers with the most products are breast cancer, lung cancer, prostate cancer and haematological malignancies (in that order).

The 16 companies are implementing 129 initiatives to address access to cancer care in the countries in scope. The largest group pertain to capacity building (71, or 55 %), followed by pricing (36, or 29%) (see Figure 5). Most capacity building initiatives are focused on awareness-raising, training and education.

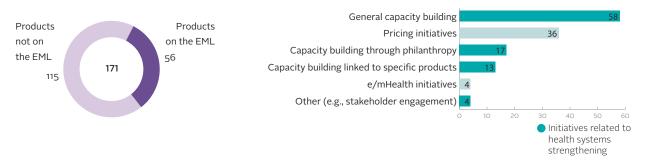
Most initiatives (80 out of 129) are not linked to a specific product. The remaining 49 are linked to 26 oncology medicines. This includes initiatives linked to preventive vaccines in scope, other products such as biomarkers, or unnamed products. The 129 initiatives are present in 63 out of 107 lowand middle-income countries (LMCs) included in the analysis (for a full list, see the appendix). Only 11 EML products are linked to access programmes. This points to the need for governments and others to strengthen health systems, and for oncology companies to bring more essential, affordable products to countries that need them.

Figure 4. One third of cancer products in scope on WHO EML

Approximately one third of cancer products produced by the companies evaluated are on the WHO Model Essential Medicines List (EML) 2015. The EML identifies medicines needed for a basic healthcare system to function. In total, 11 companies in scope have one or more oncology products that matches an item on the EML.

Figure 5. Companies' cancer access initiatives are very diverse

16 pharmaceutical companies are involved in a diverse range of cancer access initiatives in lowand middle-income countries – reporting 129 initiatives in total. The largest proportion relate to some form of health system strengthening.



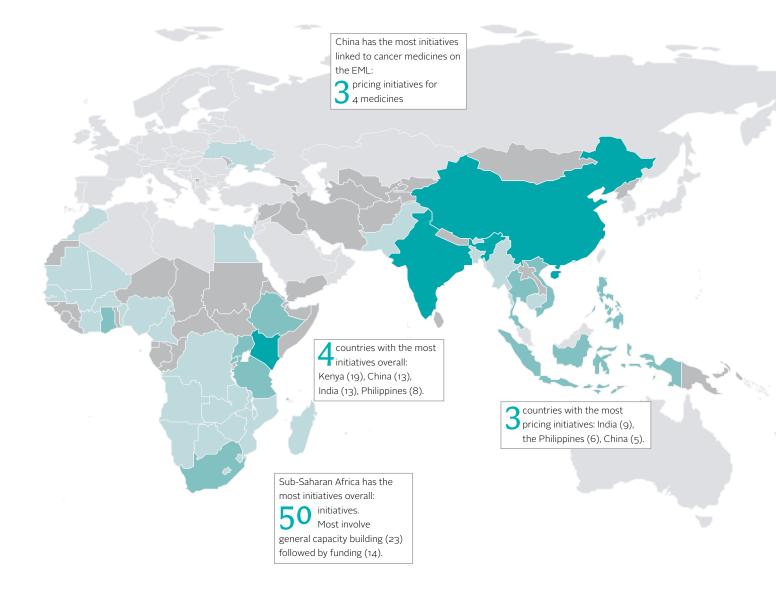
COMPANIES ARE MORE ACTIVE IN KENYA, CHINA AND INDIA

Pharmaceutical companies focus their cancer access initiatives on 63 countries. The countries gaining most attention by number of initiatives are Kenya, China and India, with 19, 13 and 13 initiatives, respectively. They are followed by Indonesia and the Philippines, with 9 and 8 initiatives, respectively. Where companies report that an initiative applies to a region, such as sub-Saharan Africa, this study has assumed that the initiative is running in all countries in that region. In India and the Philippines, the majority of initiatives involve pricing. This could be due to the fact that these countries are among the fastest growing emerging markets in scope and have health systems that are better equipped to address access to cancer care. In Indonesia and Kenya, initiatives are mostly capacity building projects. Looking at geographic regions, Latin America & Caribbean has the highest proportion of countries targeted by at least one initiative: 24 initiatives in all 18 countries in scope. Sub-Saharan Africa follows, with 50 initiatives addressing access to cancer care across 25 out of 46 countries in scope (including five initiatives that are specifically reported to cover the whole region). This is followed by East Asia & Pacific, with 35 initiatives in 7 out of 18 countries in scope. Overall, sub-Saharan Africa is the geographic region with the highest number (50) of initiatives (see Figure 6).



Activity maps onto high mortality

In general, companies are taking more action in geographic areas with the highest cancer mortality rates. Gaps do remain. Companies can increase their activities in two regions: in Europe & Central Asia, Ukraine is the only LMC in scope (out of 9) with initiatives in place; in North Africa & Middle East, Egypt and Morocco are the only countries (out of 8 in scope) served. Within sub-Saharan Africa, countries such as Sierra Leone, Somalia and Burundi currently have no access initiatives in place of any kind, despite having high cancer mortality rates. Limited company activity in these areas can partly be explained by the fact that these countries have weaker health systems, have markets that are less attractive for pharmaceutical companies, and therefore activities are likely to be philanthropic in nature, with little incentive to engage. Island nations are often forgotten, with small populations and unique challenges that need innovative approaches.¹⁰



MORBIDITY DISTRIBUTION: FEMALE CANCERS GAIN MOST ATTENTION

When diseases are specified, the cancers that gain most attention are high-impact female cancers, haematological cancers and colorectal cancers (in terms of burden). This broadly reflects the needs of people living in LMCs, the priority actions on early detection recommended by WHO, the companies' cancer product portfolios and the need for prevention of cancers by vaccination against human papillomavirus (HPV). The majority of company activities identified in this study are connected to breast cancer (42 initiatives), cervical cancer (27), haematological cancer (14) and colorectal cancer (10) (see Figure 7).

Among women, this distribution reflects the leading cancers (by incidence) in developing countries, where breast and cervical cancer have the highest incidence and are the most common cause of cancer death in females and overall. Among men in LMCs, however, leading cancers (by incidence) are lung and stomach cancer, and (by mortality) lung and liver cancer. These seem to be less represented in companies' efforts to improve access to cancer care. This study identified five initiatives for lung cancer, seven for hepatocellular (liver) cancer and only four for stomach cancer (one for stomach; three for gastrointestinal stromal tumours (GIST)). This also reflects the limited opportunities to identify these patients in LMCs and improve patient outcomes in these cancer types.^{2,11}

Many lung cancer products

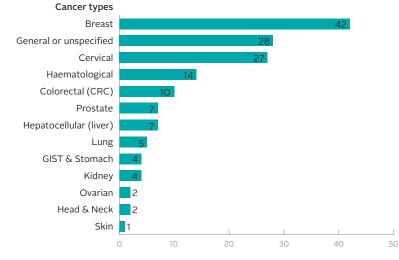
This does not completely correspond to the spread of products in companies' portfolios. Hepatocellular cancer and stomach cancer are indeed less represented in companies' medicine portfolios. However, for lung cancer, no such correspondence exists. On the contrary, lung cancer is among the cancers targeted most frequently by companies' oncology portfolios. To better reflect the needs of male cancer patients in LMCs, pharmaceutical companies with products for stomach, hepatocellular and lung cancers could focus more on improving research to identify patients with these cancers and support earlier detection as well as access to these cancer medicines.

Companies in scope have 38 initiatives for infection-related cancers: targeting prevention of the human papillomavirus (HPV) infection that causes cervical cancer (27 initiatives), prevention of the hepatitis B and C (HBV and HCV) infections that cause hepatocellular cancer (7 initiatives), and targeting stomach cancer, which is also often infection-related (5 initiatives). For cervical and hepatocellular cancer, two companies (Merck & Co., Inc. and Roche) account for all initiatives. These two companies and the partners involved could engage with others on initiatives to address access to treatment for patients affected by these cancers. Stomach cancer, which is also infection-related, is not currently preventable via vaccination. Three companies, however, are addressing stomach cancer: Novartis, with two pricing initiatives for Glivec® (imatinib); Pfizer, through two pricing initiatives for Sutent® (sutinib), and Roche, through one capacity building initiative.

Four companies in scope are implementing an initiative addressing paediatric cancer: Bristol-Myers Squibb, Novartis, Roche and Sanofi. Novartis, Roche and Sanofi do not specify which childhood cancer they currently address; Bristol-Myers Squibb is addressing paediatric haemato-oncology. Seventeen initiatives do not specify the type of cancer they address.

Figure 7. Female cancers gain most attention

Where initiatives address a specified cancer type, breast cancer and cervical cancer gain most attention, followed by haemotological and colorectal cancer. Among women, this reflects the leading cancer types. Among men, however, the leading cancers in developing countries are lung and liver cancer.





COVERING THE CARE CONTINUUM: MOST COMPANIES ADDRESS MANY HEALTH SERVICES

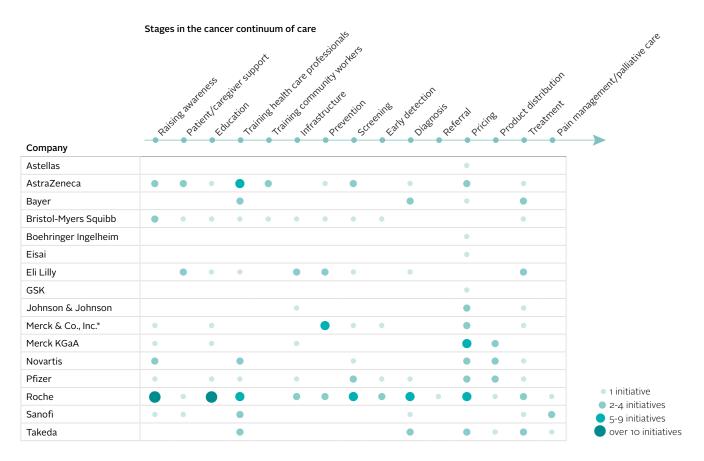
Effective cancer management requires a sequence of health services, together referred to as "the cancer continuum of care".8 The sequence comprises raising awareness of cancer symptoms and risks, preventive measures, screening, early detection, diagnosis (testing), referral, access to treatment, pain management (and/or palliative care), and follow-up. To provide access to cancer care and bring down cancer deaths in LMCs, all stages of the cancer care continuum need to be addressed. Together, the 16 companies have initiatives that target most stages in the care continuum (albeit for different diseases and in different countries/regions). Multiple initiatives address a range of health services across the continuum (see Figure 2), and some companies stand out by addressing multiple service areas (i.e.,

Roche, followed by AstraZeneca, Pfizer, Eli Lilly, Bristol-Myers Squib, and Merck & Co.., Inc.). No company addresses all levels of cancer care through its initiatives. Pharmaceutical companies share an opportunity to address all levels of health service across the cancer care continuum. Companies are encouraged to achieve this through multi-sector partnerships to help address specific needs in cancer care at the local health-systems level.

Roche is the company with the highest cancer revenues worldwide and the most initiatives for access to cancer care, all focusing on either capacity building or pricing. At least 40% of the initiatives are linked to awareness-raising, some in combination with other service areas. Roche has the most initiatives linked to medicines on the WHO Model Essential Medicines List (Model EML), notably for Herceptin® (trastuzumab), Pegasys® (pegylated interferon), MabThera®/Rituxan® (rituximab) and Avastin® (bevacizumab). Sanofi has the broadest capacity building initiative by the number of countries served: it reports that its initiative on childhood cancer serves 28 countries (and names these countries individually). Novartis reports a single patient assistance programme (PAP) for Glivec[®] covering 80 countries, not naming them individually. Bristol-Myers Squibb reports the longest standing initiatives and partnerships. One of its initiatives has been in place since 1999. Merck & Co., Inc. has the most projects linked to specific products.

Figure 2. Which companies' access initiatives address more stages of cancer care?

Effective cancer management requires a sequence of health services, referred to as "the cancer continuum of care". While many companies address multiple stages of the cancer care continuum, six companies stand out: Roche, which addresses more than any other company, followed by AstraZeneca, Pfizer, Bristol-Myers Squibb, Eli Lilly, and Merck & Co., Inc. Several initiatives address multiple stages. No company addresses all stages. A few companies support capacity building through philanthropy (not shown here), notably Bristol-Myers Squibb, with 11 such initiatives.



Palliative care

Only two companies, Roche and Sanofi, have initiatives in place that directly address access to palliative care and/or pain management, an area that is critically needed. Takeda also addresses pain management and palliative care as part of its training programme for primary healthcare providers in Kenya.

While several companies address advance and metastatic disease, this information was not consistently available for analysis. GSK, Eli Lilly, Novartis and Takeda are the only companies that report activity in R&D capacity building for oncology in an LMC in scope: GSK through its Africa Open Lab activities and its partnership with the South African MRC, Eli Lilly through its initiative for gynaecological cancers, having founded an oncology research institute in Kenya, Novartis through its Next Generation Scientist intensive internship programme for promising scientists from LMCs, and Takeda through several partners in sub-Saharan Africa.

Eli Lilly reports the highest numbers of people made available for capacity building projects related to oncology: in 2016, it deployed 13 employees to the non-government organisation AMPATH for a project in Eldoret, Kenya.

Are product-linked initiatives more impactful?

Certain companies run more or broader initiatives than others. Their relative value or merit is linked to the product types being made accessible and health services addressed (e.g., whether the initiative relates to awareness-raising, screening or testing, or aims to improve affordability or access to treatment). Ideally, product-linked initiatives should support health systems by making diagnostics and treatments more available in a safe, effective manner designed to ensure better treatment outcomes. A good example would be an initiative to make receptor testing more available in order to ensure treatment with Herceptin® is more effective (provided that Herceptin® is affordable and widely available).

Having an impact on cancer care depends on many factors, such as health systems' readiness to accept treatment. A tailored approach is needed for access initiatives, customised to match needs, the health system, the population's ability to pay for cancer care and several other factors. Ensuring countries are aware of initiatives is also important: it allows governments to make broader and more impactful plans relating to cancer management. Companies can support health systems to become resilient and ready to absorb more effective treatments, ensuring patients receive appropriate testing before treatment. Providing greater access to diagnostics can be a marketing tactic. Nevertheless, having access to accurate diagnostic tools is critical for delivering effective care. In turn, it is critical that follow-on care and key products and services are accessible and available. Without this, providing access to screening, early detection and diagnosis can have only limited impact on patient outcomes. The health system has to prioritise affordable cancer care. As the producers of cancer medicines, pharmaceutical companies are particularly well positioned to contribute their products and expertise to impactful initiatives.

Pharmaceutical companies with the highest numbers of oncology products in their portfolios are Pfizer, Roche and Novartis (in that order). Although they have only a few product-linked initiatives, both Roche and Novartis report initiatives that include several EML products. Pfizer's off-patent portfolio project may include more products, but details are limited. Other companies have product-linked initiatives for larger proportions of their (admittedly smaller) portfolios: AstraZeneca has access initiatives linked to four out of eight cancer medicines; Johnson & Johnson has initiatives for five out of 11 medicines.

Products on the WHO EML are considered the core products of any basic health system. For all companies, these products should be a priority for access in low- and middle-income countries. This applies to research-based companies as covered in this paper, as well as to generic medicine manufacturers. There is still a lot to do: e.g., to support the many countries who need health systems strengthening, by focusing on the highest burden cancers, on countries with the highest cancer burdens, on cancers with a high chance of successful treatment or a high chance of palliation.

For example, in paediatric cancers, there is a lack of ability to diagnose and provide curative treatments, despite such treatments being available in industrialised countries. Bristol-Myers Squibb, Novartis, Roche and Sanofi stand out for being active in access to paediatric oncology medicine: Bristol-Myers Squibb's Global HOPE project is a paediatric haematology-oncology initiative in Botswana, Malawi, and Uganda; Novartis' World Child Cancer Initiative in the Philippines will support the improvement of cancer care for children through education and medical capacity building; Roche has an education programme that covers multiple cancers in Indonesia; and Sanofi has My Child Matters, an initiative focused on improving childhood cancer survival rates in low-resource countries.



A technician views a tissue sample, supported by Roche's SPHERE programme in Asia Pacific.

CAPACITY BUILDING: MOST INITIATIVES INVOLVE PARTNERS, MANY COMBINE MULTIPLE ACTIVITIES

The majority of companies' access initiatives represent some form of capacity building. Capacity building initiatives can come in various shapes and forms from initiatives that support health systems (e.g., through awareness-raising, stigma reduction, patient support, education, training of community members and healthcare personnel) to activities that support different stages of medical management (e.g., prevention, screening, early detection, diagnosis, treatment, palliative care), and to practical and technical activities (e.g., investments in infrastructure, equipment, or improving administrative activities such as registries or medical records).

Almost all of the capacity building initiatives identified in this study combine two or more different activities. Initiatives that are linked to specific products will often also include elements of general capacity building. Most Patient Assistance/Access Programmes (or PAPs), for instance, combine pricing actions such as discounts or donations with activities such as awareness-raising, training or education. The most comprehensive access initiatives are marked by multi-pronged approaches to access in a single programme: some combine multiple approaches for improving access or multiple types of capacity building activity. Others address multiple stages of the continuum of care and/or address several forms of cancer.

The more comprehensive programmes – examples

AstraZeneca's Project Phakamisa in South Africa aims to improve access to a range of hormonal treatments for breast and prostate cancer through pricing actions, awareness-raising, providing patient support and training volunteers and healthcare professionals. Bristol-Myers Squibb and Pfizer are working together as well as with a range of partners in a Women's Cancer Initiative in the Americas. This initiative focuses on breast and cervical cancer and aims to improve national treatment programmes, patient registries and education, while also addressing cancer awareness, screening and early detection. The initiative is being run in partnership with the PAHO Foundation, IFPMA, Ministry of Health in Chile, International Agency for Research on Cancer and the National Cancer Institute of Argentina. Eli Lilly is working with NGO AMPATH in Kenya to address access to gynaecology-oncology and general oncology. Its objective is to equip an oncology outpatient centre, hire medical staff, train local healthcare professionals and create a research and training institute focused on cancer. Roche stands out not because of the type of health service levels addressed in individual programmes, but because its 22 initiatives together address the majority of health service levels in the cancer care continuum, albeit for different types of cancer. Some of Roche's initiatives also combine pricing initiatives with capacity building activities.

Pharmaceutical companies partner to improve access to cancer medicine At least 65 initiatives involve some sort of partnership (see Figure 8). The partners range from international organisations (e.g., the UN, Union for International Cancer Control, Gavi the Vaccine Alliance, and WHO), to



Eli Lilly works with NGO AMPATH to equip an oncology outpatient centre in Eldoret, Kenya.



These volunteers in South Africa have been trained via AstraZeneca's Phakamisa project.

local and/or international NGOs (e.g., Pink Ribbon Red Ribbon, and Max Foundation), to governments, private-sector partners, foundations, universities and/or non-profit organisations (e.g., Axios International, V Care, and Cervicusco). The partnerships aim to achieve a diverse range of goals, including product development through PDPs. For example, Merck KGaA is working with India-based Dr. Reddys Laboratories to develop monoclonal antibody products for cancer treatment. Companies also engage in on-theground partnerships to improve local capacities. For example, Eli Lilly is working with AMPATH in Western Kenya to equip a new oncology outpatient center, hire additional staff, train local healthcare professionals, and create a research and training institute focused on cancer prevention.

Partnerships that involve public sector organisations may be more likely to improve access, provided public sector interests are paramount and the contribution and engagement of the pharmaceutical company can be maintained. In turn, this facilitates the sharing of responsibilities and alignment of activities with local needs.

Figure 8. Almost all capacity building initiatives involve partnerships

Pharmaceutical companies work with a range of partners in their capacity building initiatives, including international organisations, local and national NGOs, governments and other private sector partners. At least 65 initiatives involve partnerships.



MOST COMPANIES IN SCOPE HAVE PRICING INITIATIVES IN PLACE

Thirteen companies have implemented a total of 36 pricing initiatives for cancer medicine, covering 19 types of cancer or cancer-related diseases. Pricing initiatives have been implemented in 45 different countries, with India, China and the Philippines gaining most attention (8, 6 and 6 initiatives respectively). The majority of pricing initiatives are organised in patient access or support programmes

More pricing initiatives (8) focus on breast cancer, haematologic cancers (7), lung cancer (5), prostate cancer, renal cancer and colorectal cancer (4 initiatives each), than other cancer types. For breast cancer, four companies (AstraZeneca, Eisai, Novartis and Roche), have pricing initiatives in place, covering five medicines in a selected range of LMCs: Roche has five pricing initiatives for Herceptin® (trastuzumab), AstraZeneca has one for Arimidex® (anastrozole), Eisai has one for Halaven® (eribulin), and Novartis addresses prices for Femara® (letrozole) and generic medicines anastrozole and tamoxifen (both are on the EML).

There is a slight over-representation of prostate cancer medicines covered through pricing initiatives, when comparing the distribution of initiatives to disease burdens in LMCs. Three companies (Astellas, AstraZeneca, Johnson & Johnson) have pricing initiatives for five medicines for prostate cancer: Astellas has one pricing initiative for Xtandi®, AstraZeneca has one for both Zoladex® and Casodex®, and Johnson & Johnson has one for both Zytiga® and Sylvant®.

Prices of cancer products for which pricing initiatives are in place were not available for analysis. As a result, it is not possible to assess whether initiatives lead to affordable prices for specific communities. Some may argue that the need for some PAPs and PSPs arises because listed prices for cancer medicines are unaffordable. Cancer medicines are often unaffordable for patients in poverty or with limited access to healthcare financing. Recent reports estimate that, although the US pays the most for cancer medicines, treatments are least affordable in lower-income countries. In India, median monthly prices start at USD 1,515 for branded products, and at USD 159 for generic medicines (not taking into account drug costs paid by governments, insurers or patients themselves). Where companies are implementing pricing initiatives on cancer medicines,



Women in Kenya queue for cervical cancer screening offered by the Novartis Healthy Family programme, known as "Familia Nawiri"

companies need to demonstrate how and the extent to which they accommodate the ability of specific populations to pay for cancer medicines, and ensure that the price of the medicines does not hamper access. In this landscape study, Novartis' Access programme is the only programme where the company offers a price of USD 1 per treatment per month.

The majority of pharmaceutical companies disclose IP policies

When studying intellectual property management of companies, 12 out of 16 companies have published their IP policies: they will not file or enforce patents in either all lower middle-income countries (LMICs) or subsets of LMICs. While many patent policies are applied generally to all products in the portfolio, two companies, GSK and Merck KGaA, report the most comprehensive approaches to IP non-enforcement: their IP policies apply in the majority of LICs and LMICs and they are engaging with the Medicines Patent Pool to explore opportunities for licensing specifically cancer medicines.

Compulsory licences have recently been issued for cancer medicines by some countries, and certain patent filings have been denied. These cases highlight that there is more companies can do in terms of adjusting patent-filing and enforcement policies, and in issuing non-exclusive voluntary licences for cancer products.

PHARMACEUTICAL COMPANIES ADDRESS ACCESS TO SOME OF THEIR CANCER MEDICINES ON THE MODEL EML

The most relevant product lines for cancer care in low- and middle-income countries are those included on the WHO Model Essential Medicines List (EML). The EML identifies the basic set of medicines needed by every public health system. Several companies in scope – including high earners – have many such products: Bristol-Myers Squibb, Novartis, Pfizer and Roche (see Figure 9) This study includes five of the six largest players in the global oncology market: Roche, Novartis, Bristol-Myers Squibb, Johnson & Johnson and Pfizer (in order of revenue). The only one of the six not in scope is Celgene. For several of these high-earning companies, there are long-running and ongoing discussions surrounding the affordability of their cancer medicines. Once again, the recent issuance of compulsory licences by countries for cancer products highlights that there are unresolved questions surrounding the affordability of cancer medicines. It can be argued that companies with larger revenues from oncology medicines have an obligation to invest more in improving access to cancer care in poorer countries.

As pharmaceutical companies engage with access to medicine, they must strike a balance between acting on business opportunities and improving public-health outcomes. Higher-earning companies may have expensive cancer medicines in their portfolios and/or cancer medicines that offer considerable health benefits. Access initiatives should focus on ensuring affordable access to products that offer significant health benefits, exemplified by products on the Model EML. In addition. companies may run access initiatives that address other health services across the cancer care continuum, such as health system development, awareness-raising and patient education.

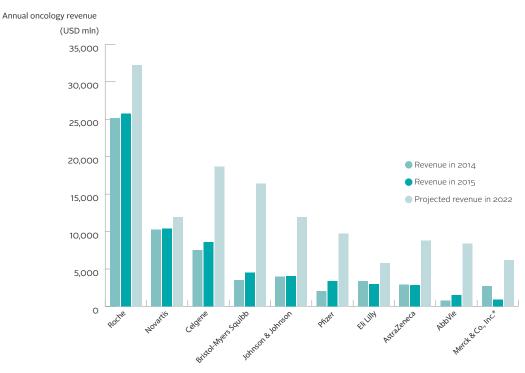
For instance, Roche has at least 17 oncology medicines in its portfolio, five of which are linked to access initiatives. Four of these are on the Model EML. Roche and Novartis have the highest number of EML medicines (4 each) linked to access initiatives. Roche also has the most initiatives overall that address access to cancer care. Roche offers hormone receptor (Her2) testing and the medicine Herceptin® (trastuzumab) to patients. For oncologists, having access to both diagnostics and treatment is critical, as are strong health services, to their ability to offer quality care. Any inherent conflict of interest must be mitigated by the companies and public partners in such relationships. Discussions continue on the need for Herceptin® to be made more affordable in many markets.

Bristol-Myers Squibb has at least 15 cancer medicines in its portfolio, eight of which are on the Model EML; only one, which is not on the Model EML, is specified in an access initiative. However, the company has a high number of initiatives for cancer: 18 capacity building initiatives, including 14 funding initiatives. Conversely, Pfizer has a portfolio of at least 36 cancer medicines, including 20 on the Model EML, making it a company that has the potential to have a tremendous impact on bringing access to cancer care in LMCs. Pfizer has two access initiatives, one of which pertains to both capacity building and pricing, linked to four products: Sutent® (sunitinib) for GIST, renal cancer, etc., Xalkori® (crizotinib) for lung cancers with specific genetic mutations, Torisel® (temsirolimus) for advanced renal cancer, and Bosulif® (bosutinib) for CML. These medicines are not on the Model EML.

Three companies link access initiatives to products on Model EML Eleven pharmaceutical companies in scope manufacture 37 cancer (or cancer-related) medicines that are on the Model EML. This study identified 13 out of 129 access initiatives that are linked to specific cancer products: 11 initiatives are linked to 11 products on the Model EML (see Figure 9). Three companies (AstraZeneca, Novartis and Roche) are responsible for these initiatives. Of these initiatives, only a small subset is aimed at improving access in developing countries through pricing and capacity building initiatives. There may be one additional EML product covered by an access initiative of Eli Lilly. But, the

Figure 9. Which companies lead the global oncology market?

Several oncology market leaders are engaged in access initiatives, although the total impact of these projects is unknown. Roche is the global oncology market leader by revenue.



Source: pmlive; statista

*Merck & Co., Inc. is known as MSD outside of the USA and Canada.

details of this initiative and whether this is ongoing are unknown.

The company performing best in this regard is AstraZeneca, with initiatives for all three of its cancer medicines on the Model EML; Novartis has access initiatives for 4 out of its 6 EML medicines; Roche for 4 out of 7. At the other end of the spectrum, Bayer, Bristol Myers-Squibb, Johnson & Johnson, Merck & Co., Inc., Pfizer, Sanofi and Takeda report no EML products linked to their initiatives.

Some companies have reported access initiatives without disclosing more details, such as whether or not they were aimed at developing countries. One such example is an initiative by Eli Lilly, which reports that it has an access initiative currently addressing 120 cancer patients, projected to reach 193 patients over the next 5 years. The project is linked to Gemzar® (gemcitabine), which is on the Model EML, and may be used for the treatment of breast, lung, pancreatic and biliary tract



Bayer's Go West programme helps train local physicians in rural hospitals such as this one in China

cancer. However, Eli Lilly neither reports nor publishes further details about this initiative.

Eleven pharmaceutical companies in scope currently produce 56 (oncology or oncology-related) medicines that are on the Model EML, covering 37 out of the 46 products listed on the EML (multiple companies can produce the same EML product). There are 36 (out of 56) EML products specified and included in the access initiatives from these companies, leaving the remainder (20) unaddressed. There is a dire need for health systems to be strengthened to be ready to receive more of the essential medicines for cancer care from the pharmaceutical industry. For this to happen, one needs support, capacity and infrastructure development in countries and an engaged and willing pharmaceutical industry (both innovative and generic) to bring effective affordable treatments to these health systems.

Country governments need to prioritise cancer care, and pharmaceutical companies, especially those producing products listed on the EML, whether research-based (as evaluated here) or generic medicine manufacturers, could include more of those medicines in their future access strategies for developing countries. There is also room to expand existing initiatives to more countries, where they have been shown to be effective. Strong monitoring and evaluation metrics and transparency in reporting outcomes is necessary for scale-up and impact.

Figure 10. Three companies stand out for linking EML products to access initiatives

All 16 companies have one or more access initiatives for cancer. Most also link some access initiatives to a specific product. Only AstraZeneca, Novartis and Roche link access initiatives to cancer products on the EML and provide details of these initiatives. Eli Lilly may also have an initiative for one EML product, details of the initiative and whether it is ongoing is unavailable.

Company	Cancer products	On the EML	Covered by access initiatives	On the EML and in access initiatives
Astellas	3	0	1	0
AstraZeneca	8	3	4	3
Bayer	7	2	2	о
Bristol-Myers Squibb	16	7	1	о
Boehringer Ingelheim	2	0	2	0
Eisai	5	0	1	0
Eli Lilly	8	3	1	1
GSK*	1	0	1	0
Johnson & Johnson	11	2	5	0
Merck & Co., Inc. *	9	1	1	0
Merck KGaA	1	0	1	0
Novartis	27	6	6	4
Pfizer	36	20	4	0
Roche	17	7	5	4
Sanofi	13	4	о	0
Takeda	7	1	1	0
Totals	171	56	36	12

Oncology portfolios and access initiatives

The detailed results of this study are presented in four main sections, each includes an overview of the section's main findings, descriptions of each company's performance, and a discussion.

26 Companies' oncology footprints

An overview of each company's therapeutic focus, sales, geographic presence and oncology products, including whether those products are on the WHO Model Essential Medicines List (EML) 2015.

38 Oncology pricing – 34 access initiatives

Discussion of 34 separate initiatives that each address the price of one or more cancer medicines in at least one country in scope, including a description of each initiative.

52 Intellectual Property Policies – 12 companies publish IP policies Assessment of the IP policies of the companies in scope toward patent rights in poor countries, which are assumed to apply to companies' oncology pipelines and portfolios.

55 Capacity building initiatives – 71 in total, 13 linked to specific products Breakdown of how each company approaches capacity build-

ing for cancer care, plus 21 other initiatives for health system strengthening:

- 57 Initiatives linked to specific products
- 60 General capacity building
- 74 e-Health or m-Health initiatives
- 76 Funding for initiatives

COMPANIES' ONCOLOGY FOOTPRINTS

16 companies have 171 cancer products

CONTEXT

This study maps the actions of 20 of the world's largest research-based pharmaceutical companies to improve access to cancer care. All 20 companies were asked to report their strategies for improving access to cancer medicine in developing countries: 16 companies submitted data in relation to such strategies. For these 16 companies, this data has been extensively supplemented with data from independent, publicly available sources.

SUMMARY

19 out of 20 pharmaceutical companies have oncology products in their portfolios. 16 companies have reported strategies for improving access to cancer medicine in developing countries. These 16 companies have at least 168 cancer medicines and two preventive vaccines for cancer in their portfolios. The cancers targeted most frequently by the products from these companies are breast, lung and prostate cancer, and haematological malignancies.

Companies with the largest portfolios are Pfizer, Novartis, Roche, Bristol-Myers Squibb, and Johnson & Johnson (with 36, 27, 17, 15 and 11 cancer medicines respectively). It may be argued that, because of their larger sales, these companies might be expected to dedicate a proportion of their revenues to improving access to cancer medicine in developing countries. Currently, however, only Johnson & Johnson has access strategies linked to a substantial portion of its cancer medicines (5 out of 11). Pfizer, Novartis, Roche and Bristol-Myers Squibb have access initiatives for only 4 out of 36; 6 out of 27; 5 out of 17; and 1 out of 15, respectively. This supports the view that, although all companies can take action to improve access to cancer care, many healthcare systems need to be further strengthened before companies can significantly improve access to specific products.

MAIN FINDINGS

11 companies produce 56 products on the WHO Model Essential Medicines List (EML)

11 companies produce oncology medicines on the Model EML. Together, these companies produce medicines that match 34 of the 46 unique oncology medicines listed on the EML. They also produce medicines matching a further three oncology-related medicines: one anti-emetic, one antiviral medicine and one medicine for haemoglobinopathies. Currently 11 EML products (from three companies: AstraZeneca, Novartis and Roche) are linked to specific detailed access initiatives.

Cancer portfolios vary in size

Cancer portfolios vary between one and 36 products in total, and up to 20 products on the Model EML.

Pfizer, Novartis and Roche have the most cancer products

Pfizer, Novartis and Roche have the most cancer products, with 36, 27, and 17 cancer medicines, respectively. These three companies and Bristol-Myers Squibb also have the most products on the EML.

AstraZeneca, Johnson & Johnson link to larger proportion of products

AstraZeneca and Johnson & Johnson have access initiatives linked to the largest proportions of their cancer products: AstraZeneca has initiatives for four out of eight cancer medicines; Johnson & Johnson for 5 out of 11.

WHICH COMPANIES HAVE THE LARGEST ONCOLOGY PORTFOLIOS, INCLUDING PRODUCTS ON THE EML?

For each of the 16 companies active in access to cancer care, this section provides: an overview of its therapeutic focus, sales and geographic presence, and oncology products, including whether those products are on the WHO Model Essential Medicines List (EML), 2015. Indications listed here are from company websites. Specific indications and details of recommended usage are not included in the descriptions here. Moreover, registered indications may vary in different countries. Counts are based on listed products. Variants of each product (different doses, strengths, formulations and other var-

iants) are not counted separately. Companies thus have *at least* the numbers of products listed here. Company initiatives may also include more products, however data is either unavailable or under confidentiality and thus not included.

N / 11		All	On EML
Astellas	Oncology products	3+	0
Stock Exchange: XTKS • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 17,113 (FY2014)	Products linked to initiatives	1	0

GENERAL INFORMATION

The company is active in 5 therapeutic areas: urology, oncology, immunology, nephrology and neuroscience.

SALES

In approximately 50 countries in scope, with most sales coming from the Americas and Japan. Astellas is present in 10 countries in Asia which includes many developing markets as well as few countries in Africa.

ONCOLOGY PRODUCTS

Astellas has at least 3 oncology products. None are on the EML.

- Tarceva® (erlotinib) for metastasized non-small cell lung cancer (NSCLC)
- Eligard® (leuprolide acetate) for prostate cancer
- Xtandi® (enzalutamide) for prostate cancer.

ONCOLOGY ACCESS INITIATIVES

Astellas has 1 out of 3 medicines linked to access initiatives:

• Xtandi® (enzalutamide) for prostate cancer.

AstraZeneca

Stock Exchange: XLON • Ticker: AZN • HQ: London, UK • Employees: 61,500

GENERAL INFORMATION

The company is active in 4 main areas: cardiovascular and metabolic diseases; oncology; respiratory, inflammation and autoimmunity; infection and neuroscience.

SALES

AstraZeneca is present in a majority of countries in Africa, particularly in sub-Saharan Africa.

ONCOLOGY PRODUCTS

AstraZeneca has at least 8 cancer medicines, three of which are on the EML:

- Arimidex® (anastrozole) (EML+) for breast cancer
- Casodex® (bicalutamide (EML+) for prostate cancer
- Faslodex (fulvestrant) for breast cancer
- Iressa (gefitinib) for lung cancer
- Lynparza (olaparib) for ovarian, fallopian tube or primary peritoneal cancer and approved in the US for treatment of advanced ovarian cancer
- Nolvadex® (tamoxifen) (EML+) for early and advanced breast cancer
- Tagrisso (osimertinib) for lung cancer
- Zoladex (goserelin) for prostate and breast cancer.

ONCOLOGY ACCESS INITIATIVES

AstraZeneca has 4 out of 8 medicines linked to access initiatives, including all three on the EML:

- Arimidex® (anastrozole) for breast cancer
- Casodex® (bicalutamide) for prostate cancer
- Nolvadex® (tamoxifen) for breast cancer
- Zoladex® (goserelin) for prostate and breast cancer

Bayer

Stock Exchange: XFRA • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 116,800

GENERAL INFORMATION

Bayer is active in 6 main areas: cardiology, women's healthcare, oncology, haematology, ophthalmology and radiology.

SALES

Its largest sales are in Europe and North America. Bayer is present in most of the Middle East and North Africa, all of sub-Saharan Africa, Asia and Pacific, and Latin America.

ONCOLOGY PRODUCTS

Bayer has at least 7 oncology medicines. Two medicines, DTIC-Dome(r) (dacarbazine) and Prednosine for CLL are listed on the EML.

Oncology products

Products linked to initiatives

- Campath® (alemtuzumab) for B-cell CLL
- DTIC-Dome® (dacarbazine) (EML+) for Hodgkin's lymphoma
- Nexavar® (sorafenib) for hepatocellular carcinoma, renal cell carcinoma and thyroid carcinoma
- Raloxifene for breast cancer
- Prednisone for acute lymphoblastic leukemia, CLL (EML+), Hodgkin's lymphoma, mycosis fungoides, non-Hodgkin lymphoma
- Stivarga® (regorafenib), for colorectal cancer (CRC) and gastrointestinal stromal tumour (GIST)
- Xofigo® (radium Ra 223 dichloride) for metastatic prostate cancer.

ONCOLOGY ACCESS INITIATIVES

Bayer has 2 out of 7 medicines linked to access initiatives (neither is on the EML).

- Nexavar® (sorafenib) for hepatocellular carcinoma and renal cell carcinoma
- Stivarga® (regorafib)

	All	On EML	
Oncology products	8+	3	
Products linked to initiatives	4	з	

All

7+

2

On EML

2

0

Bristol-Myers Squibb

Stock Exchange: XNYS • Ticker: BMY • HQ: New York, NY, US • Employees: approx. 25,000

	All	ONEML
Oncology products	16+	7
Products linked to initiatives	1	0

GENERAL INFORMATION

The company is active in 6 main areas: oncology, immune-oncology, immunoscience, cardiovascular, fibrotic diseases, and genetically defined diseases.

SALES

Bristol-Myers Squibb has most revenues in the USA and Europe, and is active in a few countries in Latin America, Africa, East Asia and the Pacific.

ONCOLOGY PRODUCTS

Bristol-Myers Squibb has at least 16 medicines for various types of cancer, of which 7 are on the Model EML.

- Paraplatin® (carboplatin) (EML+) for ovarian cancer
- Taxol® (paclitaxel) (EML+) for ovarian, breast, lung, cervical and pancreatic cancer and Kaposi's sarcoma
- Platinol® (cisplatin) (EML+) (off-patent, meaning no company has the exclusive right to manufacture it) for various types of cancer, including testicular, ovarian, breast, bladder, cervical, lung and esophageal cancer, HNSCC, mesothelioma, brain tumours, and neuroblastoma
- Vepesid®, Etopophos® (etoposide) (EML+) for testicular and lung cancer
- Yervoy® (ipilimumab) for melanoma
- Opdivo® (nivolumab) for melanoma, renal cell carcinoma, Hodgkin lymphoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck and urothelial carcinoma
- Sprycel® (dasatinib) for chronic myeloid leukaemia (CML), acute lymphoblastic leukaemia, and melanoma
- · Lysodren® (mitotane) for adrenal cancer
- Hydrea® or Droxia® (hydroxyurea) (EML+) for CML and HNSCC
- Empliciti™ (elotuzumab) for multiple myeloma
- Cytoxan® (cyclophosphamide) (EML+) for multiple cancers, including Burkitt's lymphomabladder, bone, cervical, endometrial, lung, prostate, testicular and adrenal cancer
- Blenoxane® (bleomycin) (EML+) for Hodgkin lymphoma, non-Hodgkin lymphoma, penile, cervical and vulvar cancer, squamous cell carcinoma of the head and neck squamous cell cancer (HNSCC) and testicular cancer
- Becenum®, BiCNU®, Carmubris®(carmustine) for brain tumours, Hodgkin lymphoma, multiple myeloma, and non-Hodgkin lymphoma
- Megace® (megestrol) for breast cancer and endometrial cancer
- Mitozytrex®, Mutamycin® (mitomycin C) for stomach and pancreatic cancer.

ONCOLOGY ACCESS INITIATIVES

Bristol-Myers Squibb has 1 product linked to an access initiative:

• Sprycel® for people living with CML in specified low-income countries.

Boehringer Ingelheim

Stock Exchange: Privately held • Ticker: - • HQ: Ingelheim, Germany • Employees: 47,501 (average 2015) Products linked to initiatives

Oncology products

ΔII On EML 2+ 2

GENERAL INFORMATION

Boehringer Ingelheim's key areas of focus are respiratory diseases, cardio-metabolic diseases, oncology, immunology, and central nervous system diseases.

SALES

The company's highest net sales are in the Americas. Boehringer Ingelheim is present in Europe, North America, large parts of Latin and South America, in Australia, Asia as well as in North Africa, the Middle East and a few countries in sub-Saharan Africa.

ONCOLOGY PRODUCTS

Boehringer Ingelheim has 2 oncology medicines. Neither is on the EML.

- · Giotrif® (afatinitb) for lung cancer
- Vargatef® (nindetanib) for lung cancer

ONCOLOGY ACCESS INITIATIVES

The company has 2 products linked to access initiatives:

- · Giotrif® (afatinitb) for lung cancer
- Vargatef® (nindetanib) for lung cancer

0

0

Eisai

Stock Exchange: XTKS • Ticker: 4523 • HQ: Tokyo, Japan • Employees: 9,877 (consolidated)

	All	On EML
Oncology products	5+	0
Products linked to initiatives	1	0

GENERAL INFORMATION

Eisai's focus areas are oncology and neurology

SALES

Eisai earns about half of its revenues in Japan (as end of Fiscal Year 2015). Eisai's marketing activities have expanded beyond developed countries such as Japan, the U.S. and Europe to emerging and developing countries. It is present in Central and South America, the Middle East, Russia, Oceania, Asia (including China, South Korea, Taiwan, India and ASEAN) and a few countries in Africa.

ONCOLOGY PRODUCTS

Eisai has at least 5 oncology products, none of which are on the EML.

- Halaven® (eribulin) for breast cancer and soft tissue sarcoma
- Lenvima® (lenvatinib) for thyroid and renal cell carcinoma
- Aloxi
 (palonosetron hydrochloride)
- Akynzeo® (netupitant and palonosetron) for chemotherapy-induced nausea and vomiting (CINV), postoperative nausea and vomiting (PONV)
- Gliadel® (carmustine) for malignant glioma

ONCOLOGY ACCESS INITIATIVES

Eisa has 1 out of its 5 oncology medicines linked to an access initiative:

• Halaven® (eribulin), used for the treatment of metastatic breast cancer

		All	On EML
Eli Lilly	Oncology products	8+	3
Stock Exchange: XNYS • Ticker: LLY • HQ: Indianapolis, IN, US • Employees: 41,275	Products linked to initiatives	1	1

GENERAL INFORMATION

Eli Lilly focuses on oncology, neuroscience, men's health, immunology, endocrinology and diabetes.

SALES

The company's revenues are highest in Europe. Eli Lilly is present in the majority of countries in Latin America, North Africa and the Middle East, sub-Saharan Africa, Central Asia, East Asia and the Pacific.

ONCOLOGY PRODUCTS

Eli Lilly has at least 8 oncology medicines, 3 of which are on the EML.

- Gemzar® (gemcitabine) (EML+) as a stand-alone treatment for pancreatic cancer, and a combination agent for metastatic breast, ovarian and lung cancer
- Elimta® (pemetrexed) for non-small-cell lung cancer and mesothelioma
- Cyramza® (ramucirumab) for CRC, lung and stomach cancer
- Erbitux® (cetuximab)* and Portrazza® (necitumumab) for lung cancer
- Lartruvo® (olaratumab) for soft tissue sarcoma
- Evista® (raloxifene) for breast cancer
- Velban®, Velsar® (vinblastine) (EML+) for breast cancer, choriocarcinoma, Hodgkin lymphoma, non-Hodgkin lymphoma, Kaposi sarcoma, mycosis fungoides, and testicular cancer
- Vincasar® (vincristine) (EML+) for Hodgkin lymphoma, neuroblastoma, non-Hodgkin lymphoma, rhabdomyosarcoma, and Wilms tumour.

*Erbitux is manufactured by Eli Lilly for the US and Canada, and by Merck KGaA for territories outside the US and Canada, including Japan.

ONCOLOGY ACCESS INITIATIVES

Eli Lilly has 1 out of 8 medicines linked to access initiatives. This medicine is on the EML. However, for the initiative in question, no details are reported on the countries served or initiative specifics.

• Gemzar® (gemcitabine) for pancreatic cancer

On EML

2

0

All

11+

5

0.01/		All	ON EML
GSK	Oncology products	1+	0
Stock Exchange: XLON • Ticker: GSK • HQ: Brentford, UK • Employees: 101,255	Products linked to initiatives	1	0

GENERAL INFORMATION

GSK is active in 6 main areas: HIV/ AIDS and infectious diseases, oncology, immune-inflammation, respiratory and rare diseases.

In 2014, GSK acquired Novartis' vac-

oncology portfolio to Novartis.

cine business and divested its marketed

ONCOLOGY PRODUCTS

GSK currently has at least 1 marketed oncology product, which is not on the EML but is on the WHO SAGE list.

• Cervarix®, an human papillomavirus (HPV) vaccine for the prevention of cervical cancer.

ONCOLOGY ACCESS INITIATIVES

GSK has 1 product linked to an access initiative:

• Cervarix®, an HPV vaccine for the prevention of cervical cancer,

Johnson & Johnson

Stock Exchange: XNYS • Ticker: JNJ • HQ: New Brunswick, NJ, US • Employees: 127,100

GENERAL INFORMATION

The company is active in 7 main areas. Johnson & Johnson is active in the areas of cardiovascular and metabolism, immunology, infectious diseases and vaccines, neuroscience and oncology.

SALES

SALES

The company's highest sales are in the USA. The company is present in 69 countries in scope, covering most of Latin America, sub-Saharan Africa, Central Asia, East Asia and the Pacific, and some countries in North Africa and the Middle East.

ONCOLOGY PRODUCTS

Johnson & Johnson has at least 11 oncology medicines, 2 of which are on the EML.

Oncology products

Products linked to initiatives

- Zytiga® (abiraterone acetate) and Sylvant® (siltuximab) for prostate cancer
- Imbruvica ® (ibrutinib) for haematologic cancers
- Dacogen ® (decitabine) for myelodysplastic syndrome
- Darzalex® or Dalinvi ® (daratumumab) for multiple myeloma
- Velcade ® (bortezomib) for multiple myeloma
- Caelyx® or Doxil® (doxorubicin hydrochloride) (EML+) for ovarian and breast cancer, myeloma and AIDS-related Kaposi's sarcoma
- Eprex®, Eprex Protecs®, Erypo®, Erypo FS® (epoetin-alfa) for replacement of eryhtropoetin in patients receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma
- Leustat, Leustatin, Leustatine (cladribine) for haematological malignancies such as hairy cell leukaemia and certain types of CLL
- Ribobustan, Ribomustin or Ribomustine (bendamustine hydrochloride) (EML+) for treatment of lymphoma
- · Yondelis® (trabectedin) for leiomyosarcoma and liposarcoma

ONCOLOGY ACCESS INITIATIVES

Johnson & Johnson has 5 out of its 11 products linked to access initiatives. It has committed to expanding initiatives to include one further medicine (Darzalex® (daratumumab) for multiple myeloma).

- Zytiga® (abiraterone acetate)
- Sylvant® (siltuximab) for prostate cancer
- Imbruvica® (ibrutinib) for haematologic cancers
- Dacogen ® (decitabine) for myelodysplastic syndrome
- Velcade
 (bortezomib) for multiple myeloma

Merck & Co., Inc

Stock Exchange: XNYS • Ticker: MRK • HQ: Kenilworth, NJ, US • Employees: 68,000

	All	On EML
Oncology products	9+	1
Products linked to initiatives	1	0

GENERAL INFORMATION

The company is active in 4 main areas: Merck & Co., Inc.'s core areas of focus are endocrinology, oncology, infectious diseases and vaccines.

SALES

The company has sales in 81 developing countries. Its largest sales are in the USA. The company serves most countries in Latin America, North Africa and the Middle East, sub-Saharan Africa, Central Asia and East Asia and the Pacific.

ONCOLOGY PRODUCTS

*Merck & Co., Inc. is known as MSD outside the US and Canada

Merck & Co., Inc. has at least 9 oncology products, including a preventive vaccine for human papillomavirus (HPV). One of these medicines, Dexamethasone, is on the Model EML.

- Gardasil®, an HPV vaccine for the prevention of cervical cancer
- Dexamethasone (EML+) for leukemia, lymphoma, and mycosis fungoides
- Emend® (aprepitant/fosaprepitant dimeglumine) for chemotherapy-related nausea and vomiting (not strictly an oncology product, but classified as such on the company's website)
- Intron®A (Interferon alfa-2b) for hairy cell leukaemia, melanoma, follicular lymphoma, Kaposi's sarcoma, hepatitis B virus (HBV) and hepatitis C virus (HCV) (both important etiologic factors for hepatocellular carcinoma
- Keytruda® (pembrolizumab) for lung cancer, melanoma, HNSCC and Hodgkin lymphoma
- Sylatron ™ (peginterferon alfa-2b) for melanoma
- Temodar $\ensuremath{\mathbb{R}}$ (temozolomide) for brain tumours
- Tice® (BCG LIVE vaccine) for carcinoma in situ of the bladder
- Zolinza® (vorinostat) for cutaneous T-cell lymphoma.

ONCOLOGY ACCESS INITIATIVES

Merck & Co., Inc. reports 1 out of its 9 products linked to access initiatives.

• Gardasil®, a HPV vaccine for the prevention of cervical cancer

Merck KGaA

Stock Exchange: XFRA • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 49,613

 All
 On EML

 Oncology products*
 1+
 0

 Products linked to initiatives
 1
 0

GENERAL INFORMATION

The company is active in 5 main areas: Merck KGaA focuses on oncology, immunology, neurology, endocrinology and cardiovascular diseases. In November 2014, the company announced a partnership with Pfizer to jointly develop and commercialise immune-oncology products.

SALES

Net sales are highest in Europe and Asia-Pacific. Merck KGaA is present in 77 developing countries, in large parts of Latin America, North Africa, sub-Saharan Africa, Central Asia and East Asia and the Pacific.

ONCOLOGY PRODUCTS

Merck KGaA's has at least 1 oncology medicine, not on the EML. Merck KGaA also produces biomarker tests for metastasized CRC (mCRC).

• Erbitux® (cetuximab) for CRC and HNSCC**

ONCOLOGY ACCESS INITIATIVES

Merck KGaA has access initiatives linked to both Erbitux® (cetuximab) and its biomarker tests.

• Erbitux® (cetuximab) for CRC and HNSCC**

* Biomarker tests are not included in this statistic.

**Erbitux is manufactured by Eli Lilly for the US and Canada, and by Merck KGaA for the territories outside the US and Canada, including Japan.

Novartis

Stock Exchange: XSWX • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 122,966

	All	On EML
Oncology products	27+	6
Products linked to initiatives	6	4

GENERAL INFORMATION

The company is active in 6 main areas. Novartis focuses on cardiovascular disease, respiratory diseases, neuroscience, immunology, dermatology, ophthalmology and oncology.

SALES

Novartis' largest net sales are in the Americas, and the company has sales in 77 developing countries. The company is present in almost all countries in Latin America, North Africa and the Middle East, sub-Saharan Africa, Central Asia and East Asia and the Pacific.

ONCOLOGY PRODUCTS

Novartis has at least 27 oncology medicines, 6 of which are on the Model EML. Seven of Novartis' medicines do not directly target cancer (Dexamethasone, Exjade®, Zometa®, Zarxio®, Sandostatin LAR®, Signifor®, and Zofran®).

- Zarxio® (filgrastim) (EML+) for neutropenia associated with cancer
- Glivec®(imatinib) (EML+) for haematologic malignancies (CML, ALL, myelodysplastic syndrome and myeloproliferative diseases, hypereosinophilic syndrome and/or chronic eosinophilic leukaemia), GIST, and dermatofibrosarcoma protuberans
- Exjade® (deferasirox) (EML+), Afinitor® (everolimus) for breast cancer, pancreatic neuro-endocrine tumours (pNET), and renal cell carcinoma
- Aredia (pamidronate) for breast cancer and multiple myeloma
- Arzerra® (ofatumumab) for chronic lymphocytic leukaemia
- Atriance® (nelarabine) for the treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL)
- Dexamethasone (EML+) for leukemia, lymphoma, and mycosis fungoides
- Farydak® (panobinostat), part of a combination treatment (with bortezomib and dexamethasone) for multiple myeloma
- Femara®(letrozole) for treatment following surgery for postmenopausal women with breast cancer
- Hycamtin® (topotecan) for ovarian and lung cancer
- Jakavi® (ruxolitinib) for haematologic malignancy polycythemia vera
- Mekinist® (trametinib) for melanoma
- Promacta® (eltrombopag) for thrombocytopenia which may be associated with certain types of cancer
- RevoladeTM (eltrombopag) for aplastic anaemia, which may be associated with certain types of cancer such as leukaemia
- Sandostatin® LAR® (octreotide acetate) for acromegaly associated with (neuro)endocrine tumours
- Signifor® (pasireotide) for Cushing's disease or acromegaly, which may be associated with cancer
- Tafinlar® (dabrafenib) for unresectable or metastatic melanoma
- Tasigna® (nilotinib) for CML
- Tykerb® (lapatinib) for advanced breast cancer
- Votrient® (pazopanib) for advanced renal cell carcinoma and soft tissue cancers
- Votubia® (everolimus) for renal angiomyolipoma associated with tuberous sclerosis, and subependymal giant cell astrocytoma in patients aged 3 years and older
- Zofran® (ondansetron) for nausea and vomiting associated with chemotherapy
- Zometa® (zoledronic acid) for the prevention of pathologic fractures in patients with advanced malignancies involving bone, and tumour-induced hypercalcaemia
- Zykadia® (ceritinib) for lung cancer
- Generic medicines anastrozole (EML+) and tamoxifen (EML+) for breast cancer.

ONCOLOGY ACCESS INITIATIVES

Novartis has access initiatives linked to 6 of its total of 27 oncology medicines. This includes 4 of its 6 medicines on the Model EML.

- Exjade® (deferasirox) for iron overload
- Glivec® (imatinib) for haematologic malignancies, GIST, and dermatofibrosarcoma protuberans
- $\ensuremath{\mathsf{Femara}}\xspace$ (letrozole), anastrozole, and tamoxifen for breast cancer
- Tasgina® (nilotinib) for CML.

Pfizer

Stock Exchange: XNYS • Ticker: PFE • HQ: New York, NY, US • Employees: 97,900

GENERAL INFORMATION

Pfizer is active in 9 main areas: Pfizer Innovative Health (PIH) includes six business groups – Consumer Healthcare, Inflammation & Immunology, Internal Medicine (neuroscience and pain, and cardiovascular and metabolic), Oncology, Rare Disease and Vaccines. Pfizer Essential Health (PEH) – formerly known as the Global Established Pharma business – is active in non-viral anti-infectives, biosimilars and sterile injectable medicines.

All On EML Oncology products 36+ 20 Products linked to initiatives 4 0

SALES

Pfizer is present in almost all of Latin America, North Africa and the Middle East, Central Asia, East Asia and the Pacific.

ONCOLOGY PRODUCTS

Pfizer has at least 36 oncology medicines, including approx. 20 that are on the EML.

- Aredia® (pamidronate) for breast cancer, multiple myeloma
- Aromasin® (exemestane) for breast cancer in postmenopausal women
- Treanda® (bendamustine) (EML+) for CLL
- Bleomycin (EML+) for palliative treatment of HNSCC, cervical, penile and vulvar cancer, Hodgkin's lymphoma, non-Hodgkin's lymphoma, testicular cancer and malignant pleural effusion
- Bosulif® (bosutinib) for CML
- Camptosar® (Irinotecan) (EML+) for (metastatic) CRC
- Carboplatin (EML+) for ovarian cancer
- Cortef® or Solu-Cortef® (hydrocortisone) (EML+) for palliative management of leukaemias and lymphomas in adults and acute leukaemia of childhood
- Cytarabine (EML+) for acute non-lymphocytic leukaemia, ALL and CML, meningeal leukaemia
- Dacarbazine (EML+) metastatic melanoma
- Depo-Medrol®, Medrol® or Solu-Medrol, (methylprednisolone) (EML+) for palliative management of leukaemias and lymphomas
- Docetaxel (EML+) for breast, lung, prostate and gastric cancer, HNSCC
- Doxorubicin (EML+) for axillary lymph node involvement in breast cancer, haematologic cancers (ALL, AML, Hodgkin's lymphoma, non-Hodgkin's lymphoma), metastatic cancer of the breast, ovary, bladder, thyroid, stomach and lung, metastatic Wilms' tumour, metastatic neuroblastoma, metastatic soft tissue sarcoma, and metastatic bone sarcomas
- Ellence® (epirubicin) for axillary involvement in breast cancer
- Fludarabine (EML+) for B-cell CLL
- Gemcitabine (EML+) for ovarian cancer in combination with carboplatin, breast cancer in combination with paclitaxel, lung cancer in combination with cisplatin and pancreatic cancer as a single agent
- Ibrance® (palbociclib) as part of a combination therapy for advanced or metastatic breast cancer
- Idamycin® (idarubicin) for AML, ALL and advanced breast cancer after failure of first-line chemotherapy not including anthracyclines
- Inlyta® (axitinib) for renal cancer

- Methothrexate, Rheumatrex, Trexall®, Abitrexate, Folex PFS®, Folex®, Methotrexate LPF, Mexate-AQ or Mexate (methothrexate) (EML+) for gestational choriocarcinoma, ALL, breast cancer, epidermoid cancers of the head and neck, advanced mycosis fungoides (cutaneous T cell lymphoma), osteosarcoma, and lung cancer, and as part of a combination treatment in non-Hodgkin's lymphoma
- Mitoxantrone for pain-related to advanced prostate cancer, acute non-lymphocytic leukaemia
- Neosar® (cyclophosphamide) (EML+) for breast cancer
- Neumega® (oprelvekin) for the prevention of severe thrombocytopenia and reducing the need for platelet transfusions following myelosuppressive chemotherapy patients with haematologic nonmyeloid cancers,
- Oxaliplatin (EML+) for CRC
- Paclitaxel (EML+) for ovarian, (metastatic) breast, lung cancer, and AIDSrelated Kaposi's sarcoma
- Sutent® (sunitinib) for renal cancer, Gastrointestinal Stromal Tumour (GIST), and pancreatic neuroendocrine tumor (PNET)
- Toposar® (etoposide) (EML+) for testicular and lung cancer (manufactured by Pharmacia &Upjohn, now part of Pfizer)
- Topotecan for lung cancer
- Torisel® (temsirolimus) for advanced renal cancer
- Vinorelbine (EML+) for advanced lung cancer, Vincristine (EML+) for acute leukaemia, as a combination therapy for Hodgkin's and non-Hodgkin's lymphomas, rhabdomyosarcoma, neuroblastoma, and Wilms' tumour
- Xalkori® (crizotinib) for lung cancers with specific genetic mutations
- · Zinecard® Totect (dexrazoxane) for cardioprotection with chemotherapy
- Zofran® (ondansetron) (EML+) for chemotherapy-induced nausea and vomiting
- Zometa® (zoledronic acid) for multiple myeloma.

ONCOLOGY ACCESS INITIATIVES

Pfizer has access initiatives for 4 of its 36 oncology medicines:

- Sutent® (sunitinib) for renal cell cancer
- Xalkori® (crizotinib) for lung cancers with specific genetic mutations
- Torisel® (temsirolimus) for advanced renal cancer
- Bosulif® (bosutinib) for CML

Roche

Stock Exchange: XSWX • Ticker: ROG • HQ: Basel, Switzerland • Employees: 91,747

	All	On EML
Oncology products*	17+	7
Products linked to initiatives	5	4

GENERAL INFORMATION

Roche is active in 5 main areas: Roche is focused on oncology, immunology, ophthalmology, infectious diseases and neuroscience.

SALES

Roche has sales in 90 developing countries. Roche's highest sales are in North America. Roche is present in many countries in Latin America, North Africa and the Middle East, sub-Saharan Africa, Central Asia, East Asia and the Pacific.

ONCOLOGY PRODUCTS

Roche has at least 17 oncology medicines, 7 of which are on the Model EML. Three of Roche's oncology medicines are being considered for inclusion in the 2017 WHO Essential Medicines List: Perjeta® (pertuzumab), Kadcyla® (trastuzumab-emtansine) and Tarceva® (erlotinib). Three medicines are strictly speaking not oncology medicines, but are relevant to cancer aetiology and (treatment) complications: Pegasys® (pegylated interferon) for chronic HCV infection, Kytril, Kevatril (granise-tron) for chemotherapy induced nausea and vomiting, and Neupogen® (filgrastim) for prevention of chemotherapy induced neutropenia.

- Avastin® (bevacizumab) (EML+) for colorectal, breast and lung cancer and in combination treatment for advanced renal cancer
- Bondronat® (ibandronate) for bone metastasis in breast cancer
- Erivedge® (vismodegib) for metastatic basal cell carcinoma
- Gazyva/GazyvaroTM (obinutuzumab) for leukaemia and lymphoma
- Herceptin® (trastuzumab) (EML+) for breast cancer and metastatic stomach cancer
- Kadcyla® (trastuzumab-emtansine) for unresectable locally advanced or metastatic breast cancer, previously treated with Herceptin® (trastuzumab) and/or a taxane
- Kytril®, Kevatril® (granisetron) for chemotherapy-induced nausea and vomiting
- ${\sf Neupogen} \otimes$ (filgrastim) (EML+) for the prevention of chemotherapy-induced neutropenia
- Perjeta® (pertuzumab) for combination therapy with Herceptin® (trastuzumab) for metastatic breast cancer
- Roferon-A® (interferon alfa-2a) for chronic hepatitis C, hairy cell leukaemia, and AIDS-related Kaposi's sarcoma
- Tarceva® (erlotinib) for lung and pancreatic cancer
- Tecentriq (atezolizumab) for lung cancer, and urothelial cancer
- Vesanoid® (all trans retinoic acid) (EML+) for acute promyelocytic leukaemia
- Xeloda® (capecitabine) (EML+) for colorectal and breast cancer
- MabThera®/Rituxan® (rituximab) (EML+) for lymphatic cancer
- Pegasys® (pegylated interferon) (EML+) for chronic HCV infection
- Zelboraf® (vemurafenib) for inoperable or metastatic melanoma.

ONCOLOGY ACCESS INITIATIVES

Roche has access initiatives for 5 out of its 17 medicines, including 4 on the EML:

- MabThera®/Rituxan® (rituximab) for lymphatic cancer
- Herceptin® (trastuzumab) for breast cancer
- Avastin® (bevacizumab) for cervical, renal, lung, and primary peritoneal cancer, CRC, and glioblastoma
- Tarceva® (Erlotinib) for lung cancer
- Pegasys® (pegylated interferon) for HCV

*Her2 HBV and HCV tests are not included in this statistic.

Sanofi

Stock Exchange: XPAR • Ticker: SAN • HQ: Paris, France • Employees: 115,631

Sanofi is active in 6 main disease areas. Sanofi focuses on diabetes and cardiovascular diseases, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases and consumer healthcare.

SALES

Sanofi has sales in 96 developing countries. Highest net sales are in North America. Sanofi is present in almost all countries in Latin America, North Africa and the Middle East, sub-Saharan Africa, Central Asia, East Asia and the Pacific.

ONCOLOGY PRODUCTS

Sanofi has at least 13 oncology medicines, 4 of which are on the Model EML.

- Caprelsa® (vandetanib) for medullary thyroid cancer (MTC)
- Cerubidine® (daunorubicin) (EML+) for acute lymphoid leukemia and acute myeloid leukemia
- Clolar®/Evoltra® (clofarabine) for acute lymphoid leukemia
- Elitek® (Rasburicase) for management of plasma uric acid levels in paediatric and adult patients with leukemia, lymphoma, and solid tumour malignancies who are receiving anticancer therapy expected to result in tumour lysis and subsequent elevation of plasma uric acid
- Jevtana® (cabazitaxel) for prostate cancer
- Taxotere® (docetaxel) (EML+) for breast and prostate cancer, HNSCC, CRC, , gastric cancer and NSCLC
- Fludara® (fludarabine) (EML+) for B cell chronic lymphoid leukemias
- Eloxatin® (oxaliplatin) (EML+) for CRC and other gastrointestinal cancers
- Leukine® (sargamostim) for use following induction chemotherapy in older patients with acute myelogenous leukemia (AML)
- Mozobil ®(plerixafor) in combination with granulocyte-colony stimulating factor (G-CSF) lymphoma and multiple myeloma
- Thyrogen $\ensuremath{\mathbb{B}}$ (thyrotropin alfa for injection) for thyroid cancer
- Granocyte® (Lenograstim) for non myeloid malignancy
- Zaltrap® (aflibercept) as part of a combination therapy for metastatic CRC.

ONCOLOGY ACCESS INITIATIVES

Sanofi has not specified or included any products in its access initiatives.

- 1 1		All	On EML
Takeda	Oncology products*	7+	1
Stock Exchange: XTKS • Ticker: 4502 • HQ: Osaka, Japan • Employees: 31,168	Products linked to initiatives	1	0
(consolidated)			

GENERAL INFORMATION

Takeda is active in 4 main areas: gastrointestinal diseases, oncology, central nervous system diseases, and vaccines. It also has several broad-spectrum antibiotics.

SALES

Most of the company's revenues are earned in Japan, the United States, Europe and Canada. The company has sales in 29 developing countries. Takeda is present in large parts of Latin America, one country in North Africa and the Middle East, two countries in sub-Saharan Africa, and the majority of countries in Central and East Asia and the Pacific.

ONCOLOGY PRODUCTS

Takeda has at least 7 oncology medicines, one of which is on the Model EML

- $\ensuremath{\mathsf{Velcade}}\xspace{\mathbbmath{\mathbb{R}}}$ (bortezomib) for multiple myeloma and mantle cell lymphoma
- Vectibix $\ensuremath{\mathbb{R}}$ (Panitumumab) for CRC
- Adcetris® (brentuximab vedotin) for Hodgkin's lymphoma and aggressive T-cell lymphoma
- Mepact® (mifamurtide) for osteosarcoma
- Ninlaro® (ixazomib) for multiple myeloma
- Iclusig® (ponatinib) for chronic myeloid leukemia and Philadelphia-chromosome positive acute lymphoblastic leukemia
- Enantone® (leuprorelin) (EML+) for prostate and breast cancer

ONCOLOGY ACCESS INITIATIVES

Takeda has has access initiatives reported for 1 of its 7 oncology medicines. This medicine is not on the Model EML.

• Adcetris® (brentuximab vedotin) for Hodgkin's lymphoma

	All	On EML
Oncology products*	13+	4
Products linked to initiatives	ο	0

THREE COMPANIES WITH CANCER MEDICINES REPORT NO ACTIVITIES

Four out of the 20 pharmaceutical companies in scope report having no initiatives for improving access to cancer medicine: AbbVie, Daiichi Sankyo, Gilead and Novo Nordisk. Of these, only Novo Nordisk is not active in oncology. **AbbVie** has at least 2 oncology products, one of these is on the Model EML:

- Venclexta[™] (venetoclax) for relapsed or refractory chronic lymphocytic leukemia (CLL) (co-developed with Genentech, member of Roche group)
- Lupron® (leuprolide acetate) for prostate cancer. This medicine is on the Model EML.

Daiichi Sankyo has at least two oncology products, one is on the Model EML:

- Zelboraf® (vemurafenib) for skin cancer (co-developed with Genentech, member of Roche group).
- Camptosar® (irinotecan) for CRC. This medicine is on the Model EML.

Gilead has at least one oncology product, not on the Model EML:

• Zydelig® (Idelalisib) for haematologic cancers.

Patient assistance/support programmes account for highest proportion of pricing actions

CONTEXT

Affordability is a cornerstone of ensuring access to medicine. While pharmaceutical companies can take various approaches to improve affordability, the two main approaches are tiered (differential) pricing and Patient Assistance/ Access Programmes (PAPs) or Patient Support Programmes (PSPs). Tiered pricing involves setting different prices for the same product depending on the territory or population (e.g., a single price per country or prices for different populations within a country). To be considered 'equitable pricing', these prices must take account of the ability of different population segments to pay. PAPs and PSPs can effectively lead to tiered pricing within a country (intra-country tiered pricing).

However, the presence of either approach does not automatically assume affordable pricing. For example, in 2014, GSK's Revolade® (eltrombopag) and Votrient®(pazopanib) were priced at USD 444 and USD 954 per month in India.¹⁴ Yet India's GNI per capita is only USD 318 per month. These prices are clearly unaffordable for many, particularly considering most people in India pay for medicines on an out-of-pocket basis.14 These products have since been transferred to Novartis. Similarly, Bayer's PAP for Nexavar® (sorafenib), also in India, offers the patient a per-month price that is reported to be 4.5 times higher than the cost of the generic alternative.¹⁴ In short, pricing initiatives can improve the affordability of cancer medicines - but only if the resulting prices take adequate account of people's differing abilities to pay and ensure all patients that need affordable products can access them.

SUMMARY

Thirteen companies have 36 pricing initiatives covering 19 types of cancer and 29 specified cancer products (ten medicines on the Model EML, and two vaccines). Roche and Novartis address pricing for more products on the Model EML than other companies (four medicines each). Roche has the most pricing initiatives (9), including the broadest initiative (addressing ten cancer types). Novartis has the pricing strategy with the widest geographic scope: applying in 80 (unspecified) countries.

MAIN FINDINGS

Patient assistance/support programmes account for highest proportion of pricing actions

Thirteen pharmaceutical companies are engaged in 36 access initiatives pertaining to pricing for cancer medicines. Many initiatives (17 out of 36) focus on tiered or differential pricing for a total of 30 medicines, 2 vaccines, and one monoclonal antibody* through PAPs, PSPs, early access, or other types of programmes on an intra-country level. Roche reports the most pricing initiatives (9), followed by Merck KGaA (with 5).

*Companies were asked to describe their pricing initiatives. Several companies included initiatives linked to specific products.

Ten cancer products on Model EML have pricing initiatives in place

Ten out of 30 medicines with pricing initiatives are on the Model EML. Roche accounts for the highest number. It has six pricing initiatives in place for four of its cancer medicines on the Model EML: Herceptin® (trastuzumab), MabThera®/ Rituxan® (rituximab), Avastin® (bevacizumab), and Pegasys® (pegylated interferon). Novartis also addresses the affordability of four products on the Model EML: Anastrozole, Tamoxifen, Glivec® (imatinib) and Exjade® (deferasirox).

Pricing initiatives are in place for wide range of cancer types

Companies' pricing initiatives together target 19 types of cancer. The largest proportion focuses on breast cancer (8 initiatives), followed by haematologic cancers (7), lung cancer (5), and then prostate, renal and colorectal cancers (4 each). Many initiatives relate to multiple medicines. Compared with other cancers, prostate cancer has the most medicines with pricing initiatives in place.

Most pricing initiatives are implemented in active emerging manufacturing markets such as India and China

A total of 36 pricing initiatives are implemented in a total of 45 LMCs, insofar as publicly reported by the companies. Most pricing initiatives are implemented in India (9), the Philippines (6) and China (5). On a global level, the highest density of pricing initiatives is present in East Asia & Pacific.

HOW ARE PHARMA COMPANIES ADDRESSING AFFORDABILITY OF CANCER PRODUCTS?

This section describes the 34 initiatives identified by this study that address the price of one or more cancer medicines in at least one country in scope.

Astellas

PRODUCTS

- Xtandi

 (enzalutamide)
- DISEASES
- Prostate cancer
- COUNTRIES
- Multiple countries

Pricing strategy for Xtandi® for prostate cancer

In the case of Xtandi® (enzalutamide), Astellas' country teams are offering a number of schemes to both payers and self-pay patients in Hong Kong, South Africa, Brazil, and other countries to bridge the gap between the products' commercial list price and customers' affordability thresholds in order to achieve reimbursement and/or patient access. The published commercial list prices for Xtandi® around the world range from EUR 2,300 to EUR 9,000 per pack of 112 equivalent 40mg oral capsules, before all discounts. Astellas' approach does not mandate list prices to affiliates. The approach offers flexibility for affiliates to orientate their list prices to national governments, considering their relative wealth and income, in order to bridge the gap between the global commercial pricing strategy and the country's ability to pay. In this way, lower-income countries may be able to benefit from list prices close to Astellas' list floor price.

AstraZeneca

AstraZeneca has oncology Patient Assistance Programmes (PAPs) running in several markets, including nine markets in scope. Access is stated to be reviewed for all launched brands to ensure that PAPs are available from the day the products are commercially available in that market. AstraZeneca also states their focus on how they can appropriately support Early Access through medically led initiatives even prior to registration where there is significant unmet need and a compassionate request from physicians.

PRODUCTS

- Arimidex® (anastrozole)
- Casodex® (bicalutamide)
- Nolvadex® (tamoxifen)Zoladex® (goserelin)

DISEASES

Breast cancer

Prostate cancer

COUNTRIES

South Africa

PRODUCTS

EGFR test

DISEASES
• Lung Cancer

COUNTRIES

Egypt

Hormonal treatments for breast and prostate cancer through Phakamisa Initiative Access initiative 'Phakamisa' is a programme developed by AstraZeneca in South Africa in

2010. Ensuring access to AstraZeneca's range of hormonal treatments such as Nolvadex®, raising breast cancer awareness, increasing early diagnosis, and improving access to support networks across South Africa are all part of the Phakamisa initiative. Following Phakamisa breast cancer, Phakamisa prostate has recently been launched. Through these programmes, AstraZeneca is also working to ensure that its range of hormonal treatments for breast and prostate cancer (Arimidex® (anastrozole), Zoladex® (goserelin), Casodex® (bicalutamide), and Nolvadex® (tamoxifen)) is made available to the health service, with the aim of doing so cost-effectively.

See page 60 for Phakamisa's capacity building activities.

PSP for EFGR test for lung cancer in Egypt

The oncology patient support programme in Egypt was implemented in 2015. 496 patients were included in the programme, which fully sponsors the EGFR test for Egyptian patients diagnosed with lung cancer.

Bayer*

PRODUCTS

- Nexavar® (sorafenib)
- Kidney cancer
- Hepatocellular carcinoma
 (liver cancer)
- COUNTRIES
- South Africa
- Asia

PAPs for Nexavar® in South Africa and Asia

Bayer provides additional access to patients who otherwise would not be able to afford treatment in oncology by the implementation of commercially sustainable PAPs. Patients in China, Philippines, Thailand, Indonesia, Pakistan and South Africa receive Nexavar® (sorafenib) for the treatment of renal cell carcinoma and unresectable hepatocellular carcinoma at a preferred price. In 2008, Bayer implemented a PAP in India, along with the market launch of Nexavar® in the Indian market. According to the Bayer website, the programme reduces the cost of the monthly treatment of the patented Bayer drug therapy for qualified patients enrolled, to about 10% of the regular pharmacy price for the complete duration of treatment.¹⁵

*Bayer also confirms a PAP for Stivarga® (regorafenib) in countries like Thailand and Hong Kong, but no further information is available.

Boehringer Ingelheim

PRODUCTS

- Giotrif® (afatinib)
- Vargatef® (nindetanib)
- DISEASES
- Lung cancer
- COUNTRIES
- Emerging markets

GSK

PRODUCTS

- Gardasil
 and Cervarix
 DISEASES
- Cervical cancer
 COUNTRIES
- Gavi eligible countries
- Multi-company

Eisai

PRODUCTS

- Halaven® (eribulin)
- DISEASES
- Breast cancer
 COUNTRIES
- Asia

Pricing of medicines for lung cancer in emerging markets

Boehringer Ingelheim provides Giotrif® (afatinib) and Vargatef® (nindetanib) for the treatment of lung cancer in developing countries at locally adapted prices. Boehringer Ingelheim offers prices whose aim, it says, is to ensure broad patient access at the specific local level in a sustainable and medically appropriate way, in all emerging markets. Boehringer Ingelheim also commits to future investments to develop medicines for patients with considerable unmet medical needs in specialty care, particularly for patients with cancer.

Access to Gardasil® and Cervarix® for the prevention of cervical cancer with Merck & Co., Inc. and Gavi Alliance

GSK and Merck & Co., Inc. have reduced the price of their respective HPV vaccines, Gardasil® and Cervarix®, to less than USD 5 per dose, in a partnership with the Gavi alliance. Gavi reports that it aims to reach more than 30 million girls in more than 40 countries with these vaccines by 2020. Merck & Co., Inc. commits to supplying around 2.4 million doses of Gardasil at USD 4.50 per dose to Gavi-eligible countries between 2013 to 2017. GSK has stated Cervarix would cost USD 4.60 per dose. The vaccines are priced at up to USD 100 in developed countries. In 2015, Merck & Co., Inc. committed to extend its 2015 Gavi prices for Gardasil® to Gavi-transitioned countries, in order to maintain their access to the vaccine for 10 years (2016–2025). Merck & Co., Inc. supplied over 4 million doses of Gardasil® to Gavi through UNICEF between 2012 and 2016.

This practice is also described under Merck & Co., Inc.

Hope to Her tiered pricing PAP for metastatic breast cancer

Eisai has a tiered-pricing strategy for Halaven® (eribulin), currently implemented as a Patient Assistance Program (PAP) and branded as "Hope To Her" Program. In 12 months (Apr 2016-March 2017), the company states more than 1000 metastatic breast cancer (MBC) patients having obtained access to Halaven® in Asian countries including India, the Philippines, Indonesia, Thailand, Myanmar, have done so through Hope to Her. Eisai is expanding its schemes so that more MBC patients can access to Halaven® (EML) treatment.

Johnson & Johnson

PRODUCTS

- Dacogen® (decitabine)
- Imbruvica® (imbrutinib)
- Sylvant® (siltuximab)
- Zytiga® (abiraterone acetate)
 DISEASES
- Haematologic cancers
- Myelodysplastic syndrome
- Prostate cancer
- COUNTRIES
- Asia
- Latin America

PRODUCTS

- Dacogen® (decitabine)
- Imbruvica® (imbrutinib)
- Velcade® (bortezomib)
- Zytiga® (abiraterone acetate)
- Haematologic cancers
- Multiple myeloma
- Myelodysplastic syndrome
- Prostate cancer
- COUNTRIES
- Multiple countries

PRODUCTS

- Oral oncology medicines DISEASES
- General or unspecified cancers
- Brazil

Merck & Co., Inc.

Merck & Co., Inc. is known as MSD outside the US and Canada.

PRODUCTS

- Gardasil®
- DISEASES
- Cervical cancer
- COUNTRIES
- Peru

CerviCusco Peru for access to Gardasil® for cervical cancer prevention

Merck & Co., Inc. is providing Gardasil® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] to CerviCusco, a Peruvian non-profit focused on cervical cancer, at no cost, along with technical support for the design and implementation of the programme. (See also capacity building section.)

Johnson & Johnson makes use of a variety of approaches to optimise access to medicines, such as tiered pricing and partnerships with public health organisations. Johnson & Johnson is also working with payers to explore approaches that tie reimbursement to health outcomes.

Early-access programmes for multiple cancers

Johnson & Johnson has launched early-access programmes for Zytiga® (abiraterone acetate) and Sylvant® (siltuximab), Imbruvica® (imbrutinib), and Dacogen® (decitabine) for the treatment of prostate cancer, haematologic cancers, and myelodysplastic syndrome, respectively, and provides these products at discounts or free of charge in low- and middle-income countries, depending on local regulations and patient affordability. Zytiga® is being offered at different price points across some markets in Asia and Latin America, including India, the Philippines and Mexico. Johnson & Johnson commits to launching Zytiga® in more markets in the future. The tiered pricing programme rollout for Imbruvica® is currently ongoing in various markets globally. Johnson & Johnson commits to utilising similar tiered pricing initiatives for all new oncology products, including recently approved Darzalex® (daratumumab) for the treatment of multiple myeloma.

PAPs for multple cancers

Johnson & Johnson had launched PAPs as a way of creating pricing solutions on an intra-country level. Zytiga® for prostate cancer, Imbruvica® for haematologic cancers, Velcade® (bortezomib) for the treatment of multipl myeloma, and Dacogen® for myelod-ysplastic syndrome have been offered via PAP in many low- and middle- income markets. In many cases, the medicine is provided to patients in need free of charge, as a donation.

Reducing post-approval coverage lag time for oral oncology medicines in Brazil

In Brazil, Johnson & Johnson has a policy and advocacy campaign to reduce the post-approval coverage lag time by private insurance companies of oral oncology medicines, with the goal of improving access for patients to oral oncology drugs that were not reimbursed by private insurance under the previous regulations.

- Gardasil
- DISEASES
- Cervical cancer
 COUNTRIES
- Courielisible
- Gavi eligible countries

PRODUCTS

- Gardasil
 and Cervarix
 DISEASES
- Cervical cancer
- COUNTRIES
- Gavi eligible countries
- Multi-company

HPV vaccine tender for Gardasil®

Merck & Co., Inc. participates in a UNICEF tender to supply Gardasil® to developing countries with Gavi support. Merck Co., Inc.'s partners with Gavi and other Alliance partners for access to these vaccines.

Access to Gardasil® and Cervarix® for the prevention of cervical cancer with GSK and Gavi Alliance

Merck & Co., Inc. and GSK have reduced the price of their respective HPV vaccines, Gardasil® and Cervarix®, to less than USD 5 per dose, in a partnership with the Gavi alliance. Gavi reports that it aims to reach more than 30 million girls in more than 40 countries with these vaccines by 2020. Merck & Co., Inc. commits to supplying around 2.4 million doses of Gardasil at USD 4.50 per dose to Gavi-eligible countries between 2013 to 2017. GSK has stated Cervarix would cost USD 4.60 per dose. The vaccines are priced at up to USD 100 in developed countries. In 2015, Merck & Co., Inc. committed to extend its 2015 Gavi prices for Gardasil® to Gavi-transitioned countries, in order to maintain their access to the vaccine for 10 years (2016–2025). Merck & Co., Inc. supplied over 4 million doses of Gardasil® to Gavi through UNICEF between 2012 and 2016.

This practice is also described under GSK.

Access and Affordability Initiative (AAI) pilots on differential pricing

Three companies are partners in pilot studies in Ghana and the Philippines (Novartis, Merck & Co., Inc, Pfizer). These pilot studies look at whether a coordinated approach to health systems strengthening, medicines supply management and intra-country differential pricing policies, contribute to access to medicines for NCDs, including some cancers. The pilot in Ghana, titled Ghana Access and Affordability Programme (GAAP), was launched in 2014. The pilots are part of the Access and Affordability Initiative (AAI), a global health collaboration between three pharmaceutical companies (Merck & Co., Inc., Novartis and Pfizer) and the Gates Foundation. Sources state that around 3,000 people enrolled in each pilot. *This practice is also described under Pfizer and Novartis.*

Strategy for access to Erbitux® for multiple cancers

In order to increase access to Erbitux® (cetuximab), Merck KGaA reports PAPs and PSPs in several low- and middle-income countries. PAPs for Erbitux® for the treatment of colorectal cancer (CRC) are run in China and in Asia Pacific countries, such as Indonesia, the Philippines, Thailand and Vietnam. PSPs for Erbitux® for the treatment of CRC and/or head and neck squamous cell cancer (HNSCC) have been implemented in Brazil, India and Peru. The various programmes are outlined below.

PAP for Erbitux® for CRC in China

The Erbitux® China PAP was launched in October 2012 in partnership with the Beijing Red Cross Foundation and the China Charity Federation, with the aim of making Erbitux® treatment available to patients through a variable amount of free stock to each eligible patient, based on their financial circumstances. Since its launch, Merck KGaA has set up registration centres at 312 hospitals with 729 doctors registered in 93 cities across China, and more than 7,928 CRC patients have been reported to receive Erbitux® (cetuximab) treatment for free till the end of March 2017. Merck KGaA has so far donated a total of 586,819 Erbitux® (cetuximab) with a total worth of RMB 2,757 million.

PRODUCTS

- Oncology medicines
 DISEASES
- General or unspecified cancers
 COUNTRIES
- Ghana and Phillippines
- Multi-company

Merck KGaA

PRODUCTS

- Erbitux® (cetuximab) DISEASES
- Colorectal cancer
- Head & neck cancer
 COUNTRIES
- · China and Asia Pacific

PRODUCTS

- Erbitux® (cetuximab)
- diseases
- Colorectal cancer
- COUNTRIES
- China

- Erbitux ® (cetuximab)
- RAS biomarker test
- Colorectal cancer
- Head & neck cancers
 COUNTRIES
- India

PRODUCTS

- Erbitux® (cetuximab)
- Colorectal cancer

COUNTRIES

Asia Pacific

PRODUCTS

• Erbitux® (cetuximab)

Head & neck cancer

COUNTRIES

• Latin America

PRODUCTS

- Monoclonal antibodies
- General or unspecified cancers
 COUNTRIES

India

Novartis

PRODUCTS

- Generic anastrozole
- Generic tamoxifen
- Femara® (letrozole)
- Breast cancer
- COUNTRIES
- Kenya, Ethiopia and Lebanon

PSP for Erbitux® for mCRC and HNSCC in India

In India, Merck KGaA has initiated the AADHAR Patient Support Programme for Erbitux® (cetuximab), which helps patients undergoing treatment with Erbitux® (cetuximab) for metastasised CRC and HNSCC. This programme provides access to medicines, while at the same time assisting patients in the management of the disease, treatment and side-effects. The programme also supports the RAS biomarker testing. 1,056 patients in India have been enrolled in AADHAR since 2014.

PAPs for Erbitux® for CRC in Asia Pacific

Merck KGaA runs PAPs for CRC in APAC Index Countries, such as the Philippines, Indonesia, Thailand and Vietnam, where Merck KGaA offers Erbitux® (cetuximab) at reduced prices. Through its PAP in Indonesia, Merck KGaA provides a scheme of 'buy 3 cycles, get 1 cycle free' for patients in private hospitals.

PSPs for Erbitux® for HNSCC in Latin America

Merck KGaA also provides PSPs for Erbitux® (cetuximab) for patients with HNSCC in all Latin American countries in scope. In Peru, Merck KGaA's stated focus is on improving accessibility to low-income patients with HNSCC and thereby also adherence to treatment.

Manufacturing partnership in India

Merck KGaA is engaged in a partnership with India-based Dr. Reddy's Laboratories to co-develop a portfolio of biosimilar products in oncology. The collaboration agreement covers co-development, manufacturing and commercialisation of the compounds globally, with the exception of certain select emerging markets, where Dr. Reddy's will retain the rights. This partnership aims to deliver high-quality, high-value monoclonal antibody products to patients at lower prices.

Novartis Access

Novartis Access offers a portfolio of 15 on- and off-patent Novartis medicines addressing key NCDs, including generic anastrozole, tamoxifen, and Femara® (letrozole) for breast cancer. The portfolio is offered as a basket to governments, NGOs and other public-sector stake-holders in low- and lower-middle-income counties (LMICs) at a price of USD 1 per treatment per month. Since the launch of Novartis Access in September 2015, Novartis reports 120 000 treatments, each providing a one-month supply of medicine, have been delivered to Kenya, Ethiopia and Lebanon (through the International Committee of the Red Cross). In November 2016, Novartis announced a Memorandum of Understanding with Rwanda to become the third country to launch with first deliveries planned in Q2 2017. Discussions are currently ongoing to introduce the programme in more than 10 countries across three continents. In the coming years, Novartis sates their aim to reach 30 LMICs with Novartis Access. Since launch, preparing the ground for future country roll-outs, 380 product submissions have been filed with health authorities for marketing authorisation in 21 countries. Novartis also reports partnering with organisations to ensure proper programme implementation and roll-out on the ground. *More details are included in the capacity building section.*

- Glivec® (imatinib)
- Tasgina® (nilotinib)
- Exjade® (deferasirox)
- Haematological cancers
- GIST
- COUNTRIES
- 80 countries

PRODUCTS

- Glivec® (imatinib)
- DISEASES
- Haematological cancers
- GIST
- COUNTRIES
- 75 countries

PRODUCTS

- Oncology medicines
 DISEASES
- General or unspecified cancers
 COUNTRIES
- Ghana and Phillippines
- Multi-company

Novartis Oncology Access (NOA): Access to medicines for CML, GIST and iron overload NOA is a solution through which Novartis shares the cost of its medicines with government healthcare systems, charities and other payers, or directly with patients without healthcare coverage who are unable to pay for the full cost of their medication. NOA reports an approach that encompasses different features to provide solutions based on local needs and structure/ environment. NOA is designed for countries with very limited healthcare reimbursement systems. Today, NOA offers assistance to emerging countries in Asia, the Middle East, Central and Eastern Europe, Africa and Latin America that have challenging healthcare environments. Novartis Oncology commits to bring innovative cancer medicines and improve access to treatment through its patient assistance and cancer resource programmes. NOA takes a partnership-based approach through three models:

- 1) Shared contribution, in which national or provincial governments and other entities share the cost of treatment with Novartis
- 2) Co-pay, in which the patient shares the cost of treatment with Novartis
- 3) Full donation of certain products

Today, NOA includes Novartis' haematology drugs Glivec® (imatinib) for chronic myeloid leukaemia (CML) or gastrointestinal stromal tumours (GIST), Tasgina® (nilotinib) for CML, and Exjade® (deferasirox) for iron overload associated with therapeutic transfusions in haematological malignancies. These programmes support access to therapy in approximately 80 countries and are reported to have reached more than 83,000 patients in 2016 (total cumulative patients, since 2001 in all programmes: over 130,000).

Glivec® International Patient Assistance Program (GIPAP) for CML and GIST

Through GIPAP (the donation programme within NOA) Novartis provides Glivec® at no cost to eligible patients with CML and GIST. Just as Glivec® was the first targeted therapy for CML, GIPAP was the first PAP for a targeted therapy. To date, 78,837 patients from 75 countries are reported by the company to be enrolled in GIPAP since the inception of the programme in late 2001, and more than a million 1-month supplies of treatment have been approved for donation. Currently, there are more than 33,000 active patients reported in GIPAP.

Access and Affordability Initiative (AAI) pilots on differential pricing

Three companies are partners in pilot studies in Ghana and the Philippines (Novartis, Merck & Co., Inc., Pfizer). These pilot studies look at whether a coordinated approach to health systems strengthening, medicines supply management and intra-country differential pricing policies, contribute to access to medicines for NCDs, including some cancers. The pilot in Ghana, entitled Ghana Access and Affordability Programme (GAAP), was launched in 2014. The pilots are part of the Access and Affordability Initiative (AAI), a global health collaboration between three pharmaceutical companies (Merck & Co., Inc., Novartis and Pfizer) and the Gates Foundation. Sources state that around 3,000 people enrolled in each pilot. *This practice is also described under Pfizer and Merck & Co., Inc.*

Pfizer

Pfizer uses a combination of strategies to address oncology access in low- and middle-income countries. Pfizer employs a tiered pricing approach across countries, stratifying markets by GNP per capita. Tiered pricing within countries is based on the individual's income; the lower the income level, the higher the subsidy from Pfizer. Pfizer deploys other payment models, as well as PAPs and donations of products. Pfizer evaluates the therapeutic value of each individual product when determining patenting strategy.

PAPs, including for Sutent®, for renal cell carcinoma and GIST, in Southeast Asia

In countries including India, Thailand and China, Pfizer runs PAPs through which the patients pay just for the first few medicine packs, after which they receive the rest for free for as long as required. In India, Pfizer runs a PAP for Sutent® (sunitinib malate) for treatment of renal cell carcinoma and gastrointestinal stromal tumour (GIST), in partnership with V Care, a Mumbai-based registered trust.

Access programme for Cancer Care in Low- and Middle-Income Countries

Pfizer is partnering with The Max Foundation on a programme for access to select products in their oncology portfolio, to help ensure that international prescription assistance requests are addressed consistently and objectively. The collaboration aims to reach uninsured or underinsured patients living in low- and middle-income countries, where the product is either not available commercially or significant hurdles to access exist, and where local market initiatives cannot address the request. The programme, originally designed for patients in need of Sutent® (sunitinib malate), has been expanded to include Xalkori® (crizotinib), Torisel® (temsirolimus), and Bosulif® (bosutinib) (see also section product-linked capacity building initiatives by company).

Pricing oncology products in Thailand

Pfizer reports that it has implemented a pricing strategy for oncology products in Thailand, with 5 tiers based on income levels. The strategy includes packaging adjustments and product donations, but the products and other details have not been disclosed.

Access and Affordability Initiative (AAI) pilots on differential pricing

Three companies are partners in pilot studies in Ghana and the Philippines (Novartis, Merck & Co., Inc, Pfizer). These pilot studies look at whether a coordinated approach to health systems strengthening, medicines supply management and intra-country differential pricing policies, contribute to access to medicines for NCDs, including some cancers. The pilot in Ghana, entitled Ghana Access and Affordability Programme (GAAP), was launched in 2014. The pilots are part of the Access and Affordability Initiative (AAI), a global health collaboration between three pharmaceutical companies (Merck & Co., Inc., Novartis and Pfizer) and the Gates Foundation. Sources state that around 3,000 people enrolled in each pilot. *This practice is also described under Novartis and Merck & Co., Inc.*

PRODUCTS

- Sutent® (sunitinib malate)
- Kidney cancer
- GIST
- COUNTRIES
- Multiple countries, incl. India, Southeast Asia

PRODUCTS

- Sutent® (sunitinib malate)
- Xalkori® (crizotinib)
- Torisel® (temsirolimus)
- Bosulif® (bosutinib)

DISEASES

- Kidney cancer
- Lung cancer
- Haematological cancers
- Primitive neuroectodermal tumour (PNET)
- GIST
- COUNTRIES
- Low- and middle-income
 Countries

PRODUCTS

• Oncology products
DISEASES

Thailand

PRODUCTS

Oncology medicines
 DISEASES

- General or unspecified cancers
 COUNTRIES
- Ghana and Phillippines
- Multi-company

Roche

PRODUCTS

- Her2 testing
- DISEASES
- General and breast cancer
 COUNTRIES
- Bangladesh
- Bangladesi

PRODUCTS

- Herceptin® (trastuzumab) DISEASES
- Breast cancer
- COUNTRIES
- China

PRODUCTS

- Herceptin® (trastuzumab)
- Her2 testing
- Breast cancer
- COUNTRIES
- The Philippines

PRODUCTS

- MabThera®/Rituxan® (rituximab)
- Avastin® (bevacizumab)
- Herceptin® (trastuzumab)
- Tarceva® (erlotinib)
- Colorectal cancer
- Breast cancer
- Haematological cancer
- Head & neck cancer
- Kidney cancer
- Lung cancer
- COUNTRIES
- China

Locally tailored reimbursement solutions in Bangladesh

Bangladesh is an exclusively out-of-pocket market which means that only those who can afford it receive cancer treatments. In partnerships with oncologists, hospital and private healthcare insurers, Roche is working on: Introducing the reimbursement of cancer medicines through value proposition, raising the awareness on socio-economic burden of cancer & cancer prioritization, encouraging stakeholders to introduce first ever Cancer Care Private Health Insurance and enhancing HER2 testing. Roche reports three public hospitals out of ten having introduced reimbursement schemes. Furthermore, Roche has also signed a Memorandum of Understanding with a private insurance and reports to be able to launch the first cancer care insurance in Q4 2017.

Reimbursement and PAPs for Herceptin® in China

Roche has committed to seeking reimbursement in 6 Chinese cities for Herceptin® (trastuzumab) for treating HER2 positive breast cancer and enabling patients to receive Herceptin® under PAPs. Over 60,000 patients are reported to have access to Herceptin through Roche's PAP in China.

PAP for Herceptin® (trastuzumab) for breast cancer in the Philippines

The Roche Patient Access Programme offers a discounted price for Herceptin® (trastuzumab) based on patients' financial status. In addition, Roche has established HER2 programmes to create awareness of the need for HER2 testing and to address testing accuracy. Roche has also partnered with Philam Life Insurance, Pru Life Insurance and five health management organisations to develop cancer insurance programmes. Roche states that over 30% of patients newly receive Herceptin® through the discount programme, and more patients are able to complete the full treatment duration.

Expanding private insurance coverage in China

Roche teamed up with four re-insurers and 16 local insurance companies, including the three largest, to facilitate the development of health insurance policies covering cancer treatment. This enables insurance companies to determine an appropriate pay-out for treatment and to launch cancer insurance policies that cover treatment, access to hospitals and doctors, and cancer education and support. Approximately 40 million policies have been sold in China. In 2015, Roche participated in a funding programme in Shenzen, reporting a reduction in patient co-payment under a private insurance scheme. Funding is covered through the Roche PAP and public reimbursement, and 10% through private insurance. This policy is aimed at ensuring MabThera®/Rituxan® (rituximab), (EML+) for follicular lymphoma, diffuse large B cell lymphoma, and chronic lymphatic leukaemia, Avastin® (bevacizumab), (EML+) for colon cancer, lung cancer, glioblastoma, and renal-cell carcinoma, Herceptin® (trastuzumab), (EML+) for breast cancer and Tarceva® (erlotinib), for metastatic NSCLC and pancreatic cancer to be reimbursed. Roche aims to also increase the patient access rate in China for Herceptin (trastuzumab) and MabThera®/Rituxan® (rituximab) over the next two years.

Oncology medicines

DISEASES

- Breast cancer
- COUNTRIES
- Morocco

PRODUCTS

- Oncology medicines
 DISEASES
- General or unspecified cancers
 COUNTRIES
- Peru

PRODUCTS

- Herceptin® (trastuzumab)
- Pegasys® (peginterferon alfa-2a)
- Breast cancer
- Dreast cancer
- Hepatocellular carcinoma
 (liver cancer)
 COUNTRIES
- Cote d'Ivoire

PRODUCTS

- Pegasys®
 (peginterferon alfa-2a)
 DISEASES
- Hepatocellular carcinoma
 (liver cancer)

COUNTRIES

Cameroon, Mauritania,
 Indonesia and Vietnam

PRODUCTS

- Oncology medicines including
- Herceptin ® (trastuzumab)
- General or unspecified cancers
 COUNTRIES
- Eastern Europe
- Middle East and Africa
- Latin America
- Asia Pacific

Reduced pricing for breast cancer medicine in Morocco

In Morocco, Roche is in partnership with the Lalla Salma Association Against Cancer (ALSC) to help indigent patients get access to oncology medicines for breast cancer. ALSC buys medicines from Roche at a reduced price, and Roche donates the money received to help strengthen the healthcare infrastructure in the country. Every year since its launch in 2009, 1,500 patients are reported to have received medicines under this scheme.

Plan Hope: public healthcare funding in Peru

In 2012, a new National Oncology Plan by the Peruvian government, known as Plan Esperanza or Plan Hope, was set up to address public healthcare funding for cancer treatment and provide access to treatment of most common cancers. In Peru, Roche has been supporting the plan with awareness campaigns and by diagnostic testing, as well as supporting the establishment of healthcare facilities. Before Plan Hope 5% of privately insured patients and 25% of patients supported by the Military and/or Social Security were covered. By 2016 these figures have reported to have grown to 11% of privately insured patients, 33% within the Military or Social Security system and 56% covered by the Public Health system.

Access to Herceptin® and Pegasys® in Cote d'Ivoire

In 2014, together with the Ministry of Health of Cote d'Ivoire, Roche launched a partnership to address access to its medicines for viral hepatitis and breast cancer over a five-year period. The programme is aimed at people with low incomes, who will pay a small portion of the drug cost, while Roche and the government cover the remainder. Roche aims to provide treatment over five years to around 3,000 hepatitis patients and 1,000 women with breast cancer.

Pricing or donation of Pegasys® (peginterferon alfa-2a) (EML+) for viral hepatitis in Cameroon, Mauritania, Indonesia and Vietnam

Roche has entered into agreements with national governments of Cameroon, Cote d'Ivoire (see above), Mauritania, Indonesia and Vietnam, for providing Pegasys® (peginterferon alfa-2a) either free of charge or at a discount.

Pricing initiatives for emerging markets and developing countries

International Differential Pricing (IDP) guidelines put in place by Roche align the prices public healthcare systems pay for Roche's medicines with the relative incomes of emerging markets and developing countries. Roche states that IDP is applied to all products, and permits price flexibility for the public market at the time of, or shortly after, launch. The model is based on GDP per capita, adjusted for Purchasing Power Parity (GDP-PPP per capita). The IDP is valid for all countries in Eastern Europe, the Middle East and Africa (EEMEA), Latin America (LATAM) and Asia Pacific (APAC) with a GDP per capita adjusted for Purchasing Power Parity of less than USD30,000. Roche reports that, for instance, the use of Herceptin® (trastuzumab) has almost tripled since Roche's introduction of IDP in emerging markets five years ago.

Takeda

PRODUCTS

- Adcetris® (brentuximab vedotin)
- Haematological cancers
 COUNTRIES
- Multiple countres

Product specific programmes: Adcetris® for Hodgkin's lymphoma

Takeda launched PAPs for Adcetris® (brentuximab vedotin), in several countries, such as the Philippines. Takeda is launching PAPs in the Ukraine, Kenya and Mexico for Adcetris®, a monoclonal antibody for treatment of Hodgkin's lymphoma and aggressive T-cell lymphoma, which is not on the EML. Takeda commits to extend the Adcetris Patient Assistance programme (PAP) to more countries, through a direct to institution model. The regional hub for the direct to institution model will be managed by a 3rd party. Hospitals throughout sub Saharan Africa, which form part of the Takeda PAP network, will be audited for capacities in product and patient safety. Only facilities that can ensure appropriate care and safety of the patient will form part of the network. Takeda also recently committed to provide free access to Adcetris®, in Kenya, when determined by a third party that a patient is unable to afford even one vial of treatment.

DISCUSSION

Where are pricing initiatives heading?

In conclusion, 13 pharmaceutical companies employ a total of 36 access initiatives pertaining to pricing. Many (17 out of 36) initiatives comprise tiered or differential pricing and discounts, achieved through PAPs, PSPs, early access, or other types of programmes on an intra-country level. From the data available, it is not possible to determine whether pricing initiatives truly address affordability or the impact on patient access.

The 36 pricing initiatives are being implemented in a total of 45 LMCs. More pricing initiatives are

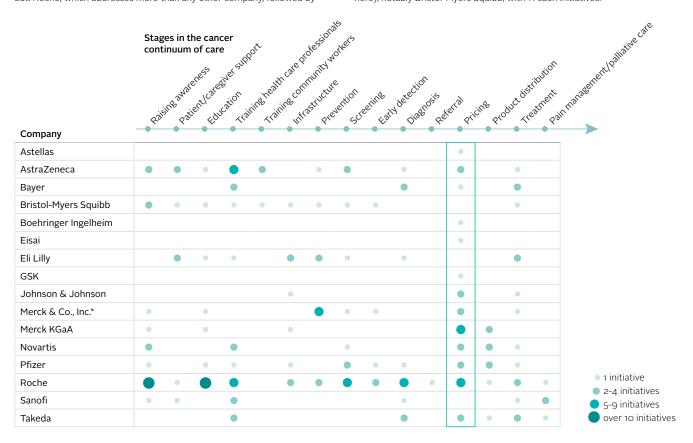
being implemented in India (9), the Philippines (6) and China (5) than in other countries in scope. On a regional level, more pricing initiatives are being implemented in East Asia & Pacific than elsewhere (22 initiatives and 1 commitment in 6 countries), followed by South Asia (8 initiatives, all in India), Latin America & Caribbean (9 initiatives in 18 countries), sub-Saharan Africa (7 initiatives in 6 countries), and Middle East & North Africa (2 initiatives in 2 countries). This distribution reflects the tendency of companies to engage in pricing initiatives where: the infrastructure and health services for cancer care is

more mature; where they have established relationships with governments, NGOs and hospitals; and/or where they view the country as a potential growth market for their oncology businesses.

Roche has the highest number of initiatives, with nine pricing initiatives, followed by Merck KGaA with five initiatives. Roche also has the broadest initiative: its initiative to expand private insurance coverage in China involves medicines for 10 different types of cancer.

Figure 11. Companies have 36 pricing initiatives for cancer products

Effective cancer management requires a sequence of health services, referred to as "the cancer continuum of care". While many companies address multiple stages of the cancer care continuum, six companies stand out: Roche, which addresses more than any other company, followed by AstraZeneca, Pfizer, Bristol-Myers Squibb, Eli Lilly, and Merck & Co., Inc. Several initiatives address multiple stages. No company addresses all stages. A few companies support capacity building through philanthropy (not shown here), notably Bristol-Myers Squibb, with 11 such initiatives.



Pricing initiatives were identified for 29 products: 24 cancer medicines (together addressing 16 types of cancer), for one medicine for a haematological cancer-related pathology (iron overload), one medicine for viral hepatitis, one biomarker test, and two preventive vaccines. Seven of the medicines subject to pricing initiatives are used to treat breast cancer, five for prostate cancer, and three for renal cell carcinoma and lung cancer, two each for CML and GIST. More pricing initiatives address affordability of breast cancer medicines (8 initiatives) than any other cancer type, followed by haematologic cancers (6), then renal, prostate, and colorectal cancer (4 initiatives each). There are 3 pricing initiatives for cervical cancer, two involving Gardasil® (by Merck & Co., Inc.) and one involving Gardasil® and Cervarix® (initiatives by Merck & Co., Inc. and GSK).

Affordability contributes to survival rate

It seems reasonable to assume that the number of pricing initiatives per cancer type correlates with the effectiveness of the medicines involved in their (curative) treatment. If a particular medicine is part of the primary, curative treatment for a particular type of cancer, then its affordability is directly related to survival. Therefore, it is likely to be the subject of more pricing initiatives, and when not affordable to certain communities, to spark further debate. Similarly, the reverse is likely to be true where the medicine in question does not have a primary role in treatment, raising the opportunity for pharmaceutical companies to play a role in fostering better knowledge-sharing and understanding of the quality-of-life issues and the role medicines can play.

Cervical cancer as a case study

However, to take cervical cancer as a case study, there are no products with a pricing initiative in place that are involved in the curative treatment of cervical cancer – even though this is currently the second most prevalent cancer, and leading cause of cancer mortality, in developing countries." This is also despite there being several chemotherapeutics from companies in scope for both the curative and palliative treatment of advanced stages of cervical cancer (such as Platinol® (cisplatin), Paraplatin® (carboplatin), and Taxol® (paclitaxel), manufactured by Bristol-Myers Squibb; Hycamtin® (topotecan) by GSK (now Novartis); Gemzar® (gemcitabine) by Eli Lilly). Avastin® (bevacizumab), manufactured by Roche, is also used, as targeted chemotherapy.

Furthermore, several of these products are on the Model EML (cisplatin, carboplatin, paclitaxel, gemcitabine and bevacizumab). Yet, there are no reports of pricing initiatives for these medicines in the treatment of cervical cancer in LMCs. Roche does have a pricing initiative for Avastin® (bevacizumab) when used to treat colon cancer, lung cancer, glioblastoma, and renal-cell carcinoma but not cervical cancer. Similarly, Eli Lilly states that it has an access programme in place for Gemzar®, but neither provides nor publishes its specific disease target, nor whether the initiative pertains to pricing.

It should be noted that the absence of pricing initiatives for cervical cancer medicines may be due to the fact that the hallmark of treatment for cervical cancer consists of surgery and/or radiotherapy. Chemotherapy is mainly used in a neoadjuvant setting, with the aim of shrinking tumour volume preceding surgery. The absence may also be due to the limited availability of proper healthcare services for cervical cancer treatment in LMCs. Nonetheless, for people living with cervical cancer in LMCs who are eligible for chemotherapy, ensuring access to affordable medicines is critical. Companies continue to have a critical role in providing access.

Furthermore, in recent years, a larger part of cervical cancer management has become focused on prevention through vaccination against the Human Papilloma Virus (HPV), which causes the cancer. Two companies (GSK, and Merck & Co., Inc.) have responded, by implementing pricing initiatives for their HPV vaccines (Gardasil® and Cervarix®): Merck & Co., Inc. provides Gardasil® at no cost in Peru, and both companies have reduced the prices of their respective vaccines in LMCs, to around 5% of the list price in developed countries. Nevertheless, discussions around the affordability of these vaccines still exist.¹⁶

Breast cancer

Breast cancer is the leading cancer type by incidence in both developing and developed countries. It also accounts for the highest number of access initiatives from the companies in scope. In the primary treatment of breast cancer, surgery, radiation therapy and pharmacological therapies are all used, depending on the breast cancer sub-type. This range of treatment options seems to be reflected by the number of breast cancer medicines covered by pricing initiatives: four companies (AstraZeneca, Eisai, Novartis and Roche) have pricing initiatives for a total of 7 medicines for breast cancer in LMCs. Roche has 3 initiatives for Herceptin® (trastuzumab); AstraZeneca has one for Arimidex® (anastrazole) and Nolvadex® (tamoxifen), which are both on the Model EML; Eisai has one initiative for Halaven® (eribulin mesylate); and Novartis has one that applies to Femara® (letrozole), generic anastrozole and tamoxifen (both generics are on the Model EML). For breast cancer, as well as several other cancers, access to proper diagnostics alongside treatment is essential for oncologists to offer their choice of treatment. Some companies with diagnostic businesses, such as Roche, offer tests for free or discounted prices. If tests are available but treatments are unavailable or unaffordable, access can be restricted.

Prostate cancer

Compared to other cancer types, prostate cancer has more medicines with pricing initiatives than any other cancer type. Three companies (Astellas, AstraZeneca, and Johnson & Johnson) have pricing initiatives for five medicines for prostate cancer: Astellas has one for Xtandi® (enzalutamide); AstraZeneca has one for Zoladex® (gserelin acetate) and another for Casodex® (bicalutamide), which is on the Model EML; and Johnson & Johnson has one for both Zytiga® (abiraterone acetate) and Sylvant® (siltuximab).

This does not seem to reflect current cancer demographics in developing countries: although prostate cancer has the highest incidence rate in developed countries, its incidence does not reach the top five in developing countries. Primary treatment modality does not seem to fully account for this over-representation either. Although responding relatively well to pharmacological treatment, prostate cancer can still in most stages be managed through active surveillance, surgery and/or radiation therapy. Hormonal therapy and chemotherapy are often reserved for when the disease has spread beyond the prostate.

Lung cancer

Compared with other cancers, lung cancer has the highest incidence rate and is the leading cause of cancer mortality in developing countries." However, only two pricing initiatives are linked to a total of three medicines for lung cancer: for Giotrif® (afatinib) from Boehringer Ingelheim, and an initiative by Roche covering Avastin® (bevacizumab) and Tarceva® (erlotinib).

This paucity of initiatives may be well explained by the fact that lung cancer is primarily treated with surgery and/ or radiotherapy, with chemotherapy being reserved for adjuvant treatment and more advanced-stage disease. Moreover, the ability to detect these cancers at a stage when treatment is still feasible plays a role in determiningwhich products are covered in access initiatives. Nevertheless, for those patients who need medicine, healthcare providers and pharmaceutical companies share a responsibility for ensuring it is available and affordable.

Reduced prices continue to attract criticism

As already mentioned, pricing initiatives can improve the affordability of medicines, but only if the reduced prices indeed reflect the ability to pay of the target populations. For example, Merck & Co., Inc. and GSK have reduced the prices of their respective HPV vaccines (Gardasil® and Cervarix®) in Gavi-eligible countries to around 5% of the list prices in developed countries down to approximately USD 5 per dose, rather than USD 100. In absolute terms, this is a significant price reduction. However, both vaccines require three doses to confer full protection - the full vaccination schedule costs approximately USD 14. Critics state that this still exceeds the financial means of the population.¹⁶ Since WHO recommends HPV vaccination, and countries are building up immunisation programmes, the challenge remains for companies to respond by bringing prices in line with other life-saving vaccines and ensuring that a continuous supply can be made available.

There has also been controversy over Bayer's pricing strategy for Nexavar® (sorafenib) in India. Bayer's Patient Access Programme for Nexavar currently requires patients to pay Rs. 30,000 (USD493) for the first three days of the month. After this point, the patient can receive the medicine from Bayer for free for the next 27 days. However, the per-month outof-pocket cost of Rs. 30,000 is still 4.5 times higher than the cost of the generic alternative.¹⁷ In March 2012, a compulsory licence was granted to Natco Pharma Limited, an India-based generic drug producer, to market a more affordable, generic version of Nexavar, which brought down its price from approximately USD 5,551 a month for Bayer's patented version, to approx. USD 177 a month for the generic version.^{17,18} With reports citing prices of branded cancer medicines often higher than generic equivalents, it is difficult to make a judgement on the impact of pricing initiatives without understanding the impact on the affordability on

the ground. As such, pharma pricing strategies are often treated with scepticism when it comes to the affordability of cancer medicines.

Pricing of medicines on the Model EML

Eleven out of 26 medicines (24 cancer medicines, one medicine for viral hepatitis and one iron-overload medicine) involved in pricing initiatives are on the Model EML. However, a total of 24 medicines on the Model EML that are produced by at least one pharmaceutical company in scope are not subject to pricing (or other access) initiatives.

Compared to its peers, Roche has more pricing initiatives for products on the Model EML: six initiatives for four medicines: Herceptin® (trastuzumab), MabThera®/Rituxan® (rituximab), Avastin® (bevacizumab), and Pegasys® (pegylated interferon). AstraZeneca has pricing initiatives for three medicines on the Model EML.

The findings and data presented here may support further socioeconomic analyses on cancer products and services, in order to ensure pricing initiatives for cancer medicines reflect the population's ability to pay. Such analyses could help guide governments, healthcare providers, pharmaceutical companies and the international community to prioritise access to cancer care, to determine specific treatments and population needs, and to indicate the best modes of action to reach those underserved by cancer treatment.

ACCESS TO PRODUCTS: INTELLECTUAL PROPERTY POLICIES

Twelve companies disclose current IP policies; two companies discussing licensing of oncology products

CONTEXT

How pharma companies manage their intellectual property (IP) can have a profound impact on competition from other manufacturers, and the affordability and supply of products. Companies can commit to abandoning IP rights, or to neither filing for nor enforcing patent rights in specific countries or for specific products. Or companies can choose to negotiate licensing terms for specific products, territories or technologies. To have a significant impact on access, licensing terms must be non-exclusive (i.e., not restricted to one manufacturer), transparent and access-oriented. Companies' IP rights for new products can last as long as a decade. Consequently, the licensing of newly registered products - or even ones still in development - can significantly accelerate the speed at which they can be made accessible and affordable in volume in LMCs.

SUMMARY

12 companies have pledged not to file for or enforce patents in either all or specific subsets of lower middle-income countries, and have made some details publically available. Two companies are in preliminary discussions about potential licensing terms for oncology medicines with the Medicines Patent Pool (NGO).

MAIN FINDINGS

Twelve pharmaceutical companies disclose current IP policies

Twelve companies disclose IP policies pertaining to low- and middle-income countries. One company (GSK) has also committed to considering licensing terms on a per product basis.

Two companies are discussing potential licensing terms for oncology products GSK and Merck KGaA report that they are in preliminary discussions about the possibility of including oncology medicines within the scope of the activities of the Medicines Patent Pool (MPP). Such terms, if agreed, would enable generic versions of oncology medicines to be made available in LMCs, regulatory approval permitting

INTELLECTUAL PROPERTY POLICIES PER COMPANY

This section describes the IP policies of the companies in scope toward patent rights in poor countries. The IP policies reported here are not specific to cancer products, but apply generally to all patents (unless mentioned otherwise). They are assumed to apply to companies' pipelines and marketed portfolios for the treatment of cancer. For this study, the companies submitted data on their IP policies toward either: Least Developed Countries (as defined by the United Nations); Low- and middle-income Countries (LMICs), Low-income countries (LICs) and/or Upper Middleincome countries (UMIC) as defined by the World Bank; and/ or the 107 countries in the scope of the study as defined by the 2016 Access to Medicine Index.

Astellas

Non-filing, non-enforcement policy

Astellas reports non-filing and non-enforcement of patents in selected low-income countries (LICs) and Least Developed Countries (LDCs).

AstraZeneca	Policy for non-filing in several countries AstraZeneca publicly commits not to file for patents in a range of LICs, LMICs and UMIC, that together comprise 70% of countries within the scope of the Index. Country exceptions to this policy include Angola, Ethiopia, Gambia, Ghana, Kenya and Nigeria and South Africa
Bayer	Policy of non-filing in LDCs (not published) Bayer has an internal (non-public) policy for non-filing in LDCs.
Eisai	Commitment to not enforcing patents in early-stage markets Eisai publicly states that it recognises that there are circumstances in which it is appropriate and right not to enforce patent rights, such as in LICs. This policy applies to oncology products as well.
Eli Lilly	Patent policy in Least Developed Countries Eli Lilly states that it does not seek, maintain, or enforce patents in LDCs.
GSK	Patent policy in Least Developed Countries or LICs GSK has a public policy of neither filing for nor enforcing patents in LDCs or LICs. In addi- tion, though the company will continue to file for patents in lower-middle-income countries (LMICS), it has pledged to consider licensing terms for supply to these countries for all of its patented products for (at least) 10 years.
Merck & Co., Inc.	Policy of not filing patents in LICs Merck & Co., Inc. has a general, publically available policy of not filing for patents in LICs.
Merck KGaA	Patent policy covering majority of countries in scope Merck KGaA has adopted a public policy of not filing for or enforcing patent applications in a large majority of the 107 countries in scope.
Novartis	Patent policy in least developed countries Novartis has a public policy of non-enforcement of patents in any LDCs, which includes most of the LICs, many of the LMICs, and some UMICs in scope. This policy and commitment applies to all Novartis' patents, including those covering oncology products. In addition, Novartis has a stated commitment that it "will grant non-exclusive licenses to qualified third parties to supply patented products exclusively to LDCs". This commitment applies to all products across all dis- ease areas, including all oncology products.
Roche	Patent policy in LDCs/LICs Roche publicly states it will not file or enforce patents in LDCs or LICs.
Sanofi	Policy of non-filing and non-enforcement in LDCs, LICs (not published) Sanofi has an internal (non-public) policy of non-filing, non-enforcement of patents in LDCs and LICs.
Takeda	Patent policy in sub-Saharan Africa Takeda has a policy (not yet public) of not filing for patents and of abandoning existing patents in sub-Saharan African countries (except for South Africa). Following this patent policy, Takeda is abandoning patents in LDCs in sub-Saharan African countries (except South Africa). Takeda does not enforce its patents in LDCs, LICs and LMICs. Takeda supports voluntary licensing and non-assert declarations. Takeda offers, under appropriate terms, royalty-free licenses to man- ufacturers that supply low-cost access to the company's medicines, on a selected basis.

DISCUSSION

Two companies are discussing possible licensing terms for oncology products

In summary, 12 companies report that they have IP policies that apply to oncology products in developing countries. Ten of these companies have published statements pertaining to the non-filing and/or non-enforcement of patents. One company (GSK) has also committed to considering licensing terms on a per product basis. Pfizer runs an access initiative specifically for its off-patent portfolio.

Of the 12 companies with patent policies, almost all companies focus on least-developed countries (LDCs) and low-income countries (LICs). The exceptions are Merck KGaA and Takeda, which focus on countries in the scope of the Access to Medicine Index and on sub-Saharan African countries (except South Africa), respectively. GSK has publically stated that it will consider licensing terms for supply to all LMICs for all patented products on a product-by-product basis.

While these policies are undeniably welcome, the question remains as to when and how they will have the desired impact on access to cancer medicines. Generic medicine manufacturers must also be willing or able to take advantage of patent waivers and/or licensing to engage in the production of these medicines and contribute to improved affordability and supply. There must be a sufficient market for these products to draw generic manufacturers in, and the manufacturers must be able to make the product safely and at an affordable price. The health system must have the capacity and the readiness to receive the product.

LDCs are usually not manufacturing countries, and thus it is unlikely there is a sufficient volume of manufacturers in these countries in the position to take advantage of patent waivers. Furthermore, the World Trade Organisation (WTO) has exempted LDCs from needing to recognise patent rights on pharmaceuticals until 2033, meaning that these countries are already able to independently choose whether or not to enforce patents.¹⁹

Companies can support their policies by publically stating whether they are willing to license cancer products to other manufacturers for supply. Novartis is the only company that has so far publically stated that it will grant non-exclusive licences to qualified third parties to supply certain/selected patented products, including for cancer, exclusively to LDCs. GSK has agreed to license their patented portfolio for supply to lower-middle-income countries (note however that GSK's current oncology portfolio remains in the pipeline).

Two companies, GSK and Merck KGaA, have reported that they are engaged in discussions with the Medicines Patent Pool (MPP) about potential licensing terms for cancer products.* Specifically, GSK states that it is considering the licensability of future cancer treatments to patent pools and will explore the concept with the MPP; MercK KGaA is exploring the possibility of joining the MPP. The MPP offers a public-health-driven business model that aims to lower the prices of medicines for HIV/AIDS, tuberculosis and hepatitis C, and to facilitate the development of better-adapted HIV/AIDS treatments through voluntary licensing and patent-pooling. The MPP may include oncology products in the future.²⁰ Expanding its approach to include oncology medicines would help enable generic versions of current and next-generation medicines, including those currently in clinical development, to be made available in LMCs, pending regulatory approval.

The appropriate management of IP for pharmaceuticals is often hotly debated. Policy changes and payer decisions can change the way IP is managed. When companies are judged to be too protective of their IP rights, governments may respond by issuing compulsory licences. Governments can grant compulsory licences to domestic firms to produce copies of drugs if the original is not available locally at a price it deems reasonable, regardless of whether they are under patent. For example, in March 2012, a compulsory license was granted to Natco Pharma Limited, an Indiabased generic medicine manufacturer, to market a generic version of Bayer's Nexavar® (sorafenib), used to treat primary kidney cancer, advanced primary liver cancer, and radioactive iodine-resistant advanced thyroid cancer. This brought down the price of sorafenib by 97% in India.17,18 Glivec® (imatinib) is a drug used to treat leukaemia and other cancers. After the failure of negotiations with Novartis to secure a lower price for Glivec®, Colombia's Ministry of Health enforced a Declaration of Public Interest (DPI), leading to a reduction in Glivec®s price of 44%.21

*The MPP is a United Nations-backed organisation dedicated to open-source, pro-access pharmaceutical licences. It was founded in July 2011 and is based in Geneva, Switzerland.

Companies engage in wide variety of capacity building initiatives

CONTEXT

Pharmaceutical companies can play a significant supporting role as the governments of LMCs strengthen their local health systems. In order to maximise their impact on access to medicine, companies' activities should be designed to respond directly to local needs, tailoring each approach to the health system, the portfolio of products and services needed and the ability to make impact. Capacity building initiatives should: 1) involve local partners; 2) have specific and measurable goals; 3) have clearly defined roles, responsibilities and accountability mechanisms for different partners; 4) have clear commitments and timeframes; and 5) have regular monitoring and evaluation and public sharing of approaches, progress and learnings.

Capacity building initiatives should offer long-term, sustainable solutions to countries' own, independently identified capacity building needs and priorities, in line with the national cancer control plans. Partnerships with companies – whether by governments, non-governmental or private sector organisations – can be mutually beneficial. Partners understand local contexts, and can engage effectively with the industry to drive shared goals, with management of actual and perceived conflicts of interest.

SUMMARY

Thirteen companies engage in a combined total of 71 initiatives relating to capacity building. These are very varied in nature. Most combine various elements of capacity building, such as awareness-raising (28 initiatives) and education/training (45). A sizeable group of initiatives aim to build capacity in either cancer diagnosis (16) screening (14) and/or early detection (5). A small core of capacity building initiatives (13) also include programmes designed to increase access to specific products, for example by addressing pricing (e.g., AstraZeneca, Novartis, Roche). The most comprehensive access initiatives either combine different access strategies, multiple types of capacity building activity per project, or address several forms of cancer. Four companies have each launched an initiative relating to mobile health and/or online training programmes on cancer care. Companies are also bringing their financial reserves to bear: the study found 17 cases of companies providing philanthropic financial support for capacity building activities.

MAIN FINDINGS

Capacity building accounts for more than 50% of company initiatives addressing access to cancer care

More than 50% of companies' access initiatives relating to cancer care (71 out of 129) involve capacity building in some shape or form. They range from initiatives that support health systems (e.g., through awareness-raising, stigma reduction, patient support, education, training of community members and healthcare personnel), to activities that support different stages of medical management (e.g., prevention, screening, early detection, diagnosis, treatment, palliative care (including pain management), and to practical and technical activities (e.g., investments in infrastructure, equipment, or improving administrative activities such as registries or medical records).

Companies are engaged in a wide variety of capacity building initiatives

Companies' capacity building programmes are very varied in nature; the most comprehensive ones are marked by multi-pronged approaches to access. Some combine multiple approaches for improving access or multiple types of capacity building activity. Others address multiple stages of the continuum of care and/or address several forms of cancer. Almost all of the capacity building initiatives identified in this study combine two or more different activities. Initiatives that are linked to specific products will often also focus on general capacity building. Most Patient Assistance/Access Programmes (or PAPs), for instance, combine pricing actions such as discounts or donations with activities such as awareness-raising, training or education.

Most capacity building initiatives are not linked to specific products

Out of 71 capacity building initiatives, only 13 (19%) are linked to specific products. These are being run by six companies: Merck & Co., Inc., Merck KGaA, Novartis, Pfizer, Roche and Takeda. Initiatives linked to specific cancer products are assumed to have a more direct impact on access than other, more general capacity building initiatives. As the products' manufacturers, pharmaceutical companies are particularly well positioned to establish such initiatives. Merck & Co., Inc. is running the most product-linked initiatives, with five initiatives linked to its HPV vaccine Gardasil®.

The level and scope of engagement varies widely between companies

Numerically, Roche does the most: it has the most initiatives for access to cancer care, all focusing on either capacity building or pricing. Roche has the most initiatives linked to medicines on the WHO Model Essential Medicines List (Model EML). Sanofi has the broadest initiative by number of countries served: it reports that its initiative on childhood cancer serves 28 individually named countries. Bristol-Myers Squibb reports the longest-standing initiatives and partnerships. One of its initiatives has been in place since 1999. Three companies, Roche, Sanofi and Takeda, have initiatives in place that address access to (or education for healthcare providers on) palliative care and/or pain management. GSK, Eli Lilly, Novartis and Takeda are the only companies active in R&D capacity building for oncology in an LMC in scope: GSK through its Africa NCD Open Labs and South Africa MRC partnerships, Eli Lilly through its initiative for gynaecology oncology having founded an oncology research institute in Kenya, Novartis through its Next Generation Scientist programme, and Takeda with multiple partners in sub-Saharan Africa for paediatric cancer care.

Two companies (Novartis and Roche) have linked capacity building initiatives to products on the Model EML

Novartis has a capacity building initiative for two products on the Model EML: generic anastrozole and tamoxifen, as part of their Novartis Access Portfolio, which entails a pricing strategy as well. Roche has a capacity building initiative for one product that is on the Model EML: an initiative for referral teams, test donations and product access linked to Pegasys® (pegylated interferon), used in the treatment of viral hepatitis, a key etiologic factor for hepatocellular carcinoma.

Many capacity building projects focus on female cancers

Capacity building initiatives linked to products target a diverse range of cancer types. Cervical cancer receives the most attention, with 5 initiatives, all focused on prevention. Colorectal cancer (CRC) comes second with three initiatives. General capacity building strategies without products focus on a wide range of 12 different types of cancer. Most initiatives without products are focused on breast cancer (20), cervical cancer comes second with 6 initiatives, haematologic cancers come third with 5 initiatives, followed by prostate and paediatric cancer with 4 initiatives each.

PRODUCT-LINKED CAPACITY BUILDING INITIATIVES BY COMPANY

This section outlines the access initiatives that pharma companies have linked to specific medicines and vaccines. Some activities are also mentioned in the section on pricing initiatives. Specific details on pricing strategies within capacity building initiatives when available are covered in the pricing section.

Merck & Co., Inc. Merck & Co., Inc. works with governments and non-governmental organisations on vaccination delivery programmes for cervical cancer across several countries.

In India, Merck & Co., Inc. is expanding access to Gardasil® via cervical cancer awareness and

PRODUCTS

• Gardasil®

- DISEASES
- Cervical cancer
- COUNTRIES
- India

PRODUCTS

- Gardasil®
- DISEASES
- Cervical cancer COUNTRIES
- Peru

PRODUCTS

- Gardasil
- DISEASES
- Cervical cancer COUNTRIES
- Bhutan

PRODUCTS

- Gardasil®
- DISEASES
- Cervical cancer
- COUNTRIES
- Rwanda

PRODUCTS

- Gardasil® DISEASES
- Cervical cancer Zambia

Awareness and expanding access to Gardasil® for cervical cancer in India

prevention through early detection and vaccination.

CerviCusco Peru for access to Gardasil® for cervical cancer prevention

Merck & Co., Inc. is engaging with CerviCusco, a Peruvian non-profit focused on cervical cancer, to bring Gardasil® to adolescents in the Cusco region with other cervical cancer control and prevention activities. The one-year programme began in early 2016, and aims to vaccinate around 20,000 girls. Merck & Co., Inc. states that it is providing Gardasil® to CerviCusco at no cost along with technical support for design and implementation of the programme.

Vaccination programme for Gardasil® for cervical cancer in Bhutan

In 2010, in partnership with the Government of Bhutan, and the Australian Cervical Cancer Foundation, Merck & Co., Inc. began providing Gardasil® to eligible girls in the country. Merck & Co., Inc. reports more than 90% of targeted girls vaccinated with three doses of the vaccine in the first year of the programme.

Cervical cancer prevention through providing Gardasil® and HPV testing in Rwanda

In 2011, in partnership with the Government of Rwanda, Merck & Co., Inc. began providing Gardasil® to eligible girls, as part of an approach to cervical cancer prevention that included both HPV vaccination and HPV DNA testing. Merck & Co., Inc. reports that more than 96% of targeted girls were vaccinated in 2011 and 2012. This programme has now fully transitioned to Gavi support.

Gardasil® vaccination demonstrations project in Zambia

Merck & Co., Inc. works with the Zambian Ministry of Health to conduct an HPV vaccine demonstration project across the province of Lusaka by providing 180,000 doses of Gardasil® to vaccinate 50,000 eligible girls over two years, and providing technical support for the programme. The Zambian government has been reported to be planning to transition to a national HPV vaccination programme with Gavi support.

Merck KGaA

PRODUCTS

- RAS test
- DISEASES
- Colorectal cancer
- COUNTRIES
- Philippines

PRODUCTS

- RAS test
- DISEASES
- Colorectal cancer
- COUNTRIES
- Thailand

PRODUCTS

- RAS test
- Colorectal cancer
- COUNTRIES
- China

Novartis

PRODUCTS

- Femara® (letrozole)
- Generic anastrozole
- Generic tamoxifen

DISEASES

- Breast cancer
- COUNTRIES
- Multiple countries, incl. Kenya

Free RAS testing for metastatic colorectal cancer through iCare in Philippines

In the Philippines, Merck KGaA provides free testing for RAS (an oncogene used as a biomarker for mCRC) through its iCare programme in partnership with a leading tertiary hospital called Medical City. In order to enhance patients' access to RAS testing, Merck KGaA leases the testing machine and kits for free and covers the cost of testing (reagents and other fees).

Setting up biomarker testing for CRC laboratories in Thailand

In Thailand, Merck KGaA has partnered with pathologists to facilitate the setup of RAS testing labs in key centres across the country in order to enhance access to RAS testing.

Biomarker tests for mCRC in China

In China, Merck KGaA reports that it collaborates with central labs to provide free RAS tests to patients where needed. Since the launch of the programme in 2014, more than 23,000 patients have been reported by Merck KGaA to have received the tests until 2016. From 2017 onwards, Merck KGaA China plans to continue supporting hospitals to set up test capability and enhance patient access to RAS testing.

Novartis Access: focus on cancer medicine in multiple countries

The Novartis Access portfolio (see pricing strategy outlined in the pricing section) focuses on affordability and availability of 15 on- and off-patent Novartis medicines addressing key NCDs, including breast cancer. Novartis Access includes the strengthening of healthcare capabilities in the countries where it is rolled out. The company collaborates with partners on the ground to train medical professionals and healthcare workers on screening, diagnosis and treatment, and to raise awareness and educate local communities about non-communicable diseases. Novartis also focuses on distribution chain integrity to ensure products are delivered through designated channels, refills are available in rural areas with sufficient shelf life and no excessive markups are charged to patients.

In Kenya, for instance, the first country to implement Novartis Access in 2015, the company joined forces with the Christian Health Association of Kenya (CHAK), the Kenyan Conference of Catholic Bishops (KCCB) and the Kenyan Red Cross Society (KRCS) to address screening, diagnosis and management of chronic diseases in local facilities across the country.

Pfizer

PRODUCTS

- Bosulif® (bosutinib)
- Sutent® (sunitinib malate)
- Torisel® (temsirolimus)
- Xalkori® (crizotinib)

DISEASES

- Haematological cancer
- Lung cancer
- Kidney cancer
- GIST
- PNET
- COUNTRIES
- LMCs

PRODUCTS

- Oncology products
 DISEASES
- General or unspecified cancers Kenya

Roche

PRODUCTS

- Pegasys®
- (peginterferon alfa-2a) • HBV tests
- HCV tests
- DISEASES
- Hepatocellular carcinoma
 (liver cancer)
- COUNTRIES

Access programme for Cancer Care in Low- and Middle-Income Countries

Pfizer is partnering with The Max Foundation on a programme for access to selected products in its oncology portfolio, to help ensure that international prescription assistance requests are addressed consistently and objectively. The collaboration aims to reach uninsured or under-insured patients living in low- and middle-income countries, where the product is either not available commercially or significant hurdles to access exist, and where local market initia-tives cannot address the request. The programme, originally designed for patients in need of Sutent® (sunitinib malate), has been expanded to include Xalkori® (crizotinib), Torisel® (temsirolimus), and Bosulif® (bosutinib) (see also section pricing initiatives by company).

Pfizer access programme for off-patent oncology products in Kenya

Pfizer has engaged with the Kenya umbrella Cancer Patient Association on an Access Program that will include Pfizer off-patent oncology products and eventually on-patent molecules. The project also considers a partnership with the National Health Insurance Fund. Products are not specified here but could include several EML products.

Referral teams, test donations and Pegasys® in China

Roche works to address HBV and HCV infections as the main cause of liver cancer. Roche has taken several steps to strengthen the availability of tests and treatment, including the donation of HBV and HCV diagnostic tests, building up a HCV referral team and collaborating with Chinese authorities to provide training programmes on treatment regimes for healthcare professionals. Roche reports that, over the past two years, the HCV referral team was in 110 key hospitals to issue hospital regulations to ensure that HCV-positive patients receive the appropriate diagnostic test. In over 200 hospitals, Roche reports that the HCV referral team has enrolled more than 6,000 patients. In 2014, around 16,600 HBV patients and 21,000 HCV patients were reported to have been treated with Pegasys® (peginterferon alfa-2a). This is a 23% and 14% increase respectively in patients treated, since the programme started in 2011.

GENERAL CAPACITY BUILDING INITIATIVES BY COMPANY

This section looks at access initiatives that aim to address capacity building: specific products are not reported to be included in these initiatives. These projects and programmes take a combination of measured to increase access to cancer care.

AstraZeneca

DISEASES

- Breast cancer
- COUNTRIES
- South Africa

DISEASES

- Prostate cancer
- COUNTRIES
- South Africa

DISEASES

- Breast cancer
- COUNTRIES
- Kenya

DISEASES

- Breast cancer
- Prostate cancer
- COUNTRIES
- Ghana

Phakamisa: Tackling breast cancer in South Africa

Through Phakamisa, in collaboration with South Africa's Foundation for Professional Development, AstraZeneca reports that it is providing accredited courses in cancer diagnosis, treatment and care to doctors, nurses and other healthcare professionals. In partnership with the Cancer Association of South Africa and the Breast Health Foundation, AstraZeneca is training volunteers and counsellors to go out into the community, raise awareness and support patients, as Phakamisa 'Navigators'. Since the launch of Phakamisa in 2011, AstraZeneca reports that more than 600 healthcare professionals and 400 volunteers have been trained as Navigators. In its sixth year of operation, AstraZeneca reports that 1,606,978 women have been reached by Phakamisa Navigators across the country, 52,706 public meetings have been organised, and 4,046 malignant lumps have been identified and referred for treatment. A monthly average of 2,501 patients are reported to have been supported by Phakamisa Navigators in the public health sector. AstraZeneca reports that a total of 25,259 patients have been navigated.

Phakamisa prostate: Addressing prostate cancer in South Africa

In 2016, Phakamisa Prostate was implemented, modelled after the existing initiative for breast cancer, and offering the same service. The programme is currently being rolled out in three of South Africa's nine provinces, with implementation in the rest of the country planned for 2017.

Breast Health Initiative in Kenya

Since the Phakamisa initiative in South Africa, in 2012 AstraZeneca set up a Breast Health Initiative in Kenya. 150 healthcare practitioners and 60 volunteers have been trained through workshops in four major Kenyan cities.

Breast and prostate cancer education initiative in Ghana

In 2013, AstraZeneca launched Enidaso, a Breast Cancer Awareness & Disease education programme to boost breast cancer and prostate cancer care, with activities ranging from awareness creation and training of healthcare personnel, and addressing access to medicines. In 2016, AstraZeneca committed to supporting prostate cancer patients through the abovementioned projects in Kenya and Ghana. The company also committed to extending the programme to more countries in sub-Saharan Africa, such as Nigeria, Angola, and Ethiopia.

DISEASES

- General or unspecified cancers
 COUNTRIES
- 20+ countries

DISEASES

- Breast cancer
- COUNTRIES
- Cambodia

Young Health Programme

The Young Health Programme (YHP) focuses on young people and prevention of the most common NCDs including cancer. YHP targets five primary modifiable risk factors that lead to NCDs, including cancer. According to AstraZeneca, YHP have now reached over 1.6 million young people in more than 20 countries. Kenya was the latest addition in 2015. AstraZeneca states that over 40,000 young people and over 12,600 health providers have received health education training.

Cambodia Breast Cancer Initiative

The Cambodia Breast Cancer Initiative is an ongoing partnership between AstraZeneca, AmeriCares and Sihanouk Center of Hope (SHCH) Hospital in Phnom Pen, Cambodia, that aims to educate patients and healthcare providers while strengthening existing treatment services. Through the partnership AstraZeneca provides free medicine to postmenopausal breast cancer patients in the Center of Hope's treatment cohort and supports the education of Cambodian women about the importance of early detection and prompt care-seeking.

At latest count, which includes programme activities through September 2016, the company reports:

- 1,200 breast cancer education brochures distributed within the provinces and used during community education sessions
- 3,450 women educated about women's cancer through the nurse education programme at the SHCH-affiliated Community Medical Center (running 2 days/week)
- 250 additional women received education onsite at SHCH through a new nurse educator programme in Year 9
- 250 people participated in a 'Zumbathon' fundraising event organised by the Advance Learning Academy that raised both funds and awareness
- 410 women evaluated and screened for breast cancer. These evaluations included mammograms, ultrasounds and pathology tests which helped in the identification of the need for biopsies, mastectomies and treatment in some patients.
- 64 biopsies conducted
- 48 mastectomies preformed
- 44 pathology tests performed in the SHCH lab
- 18 women received mammography tests
- 156 women had ultrasound screenings
- 376 existing breast cancer patients continued to receive follow up treatment
- 219 patients received anti-hormonal treatment (85 continuing with Arimidex, 63 on Tamoxifen)

Bayer

DISEASES

- General or unspecified cancers
- COUNTRIES
- China

Go West Training Programme

In cooperation with China's National Health and Family Planning Commission, Bayer provides professional trainings for local physicians and hospital executives in rural hospitals in China, with the aim of improving access to diagnosis techniques and therapies for a range of NCDs, including cancer. Since its launch in 2007, the Go West programme has expanded to 23 provinces/regions, providing 143 training courses and provided professional training modules to over 16,000 doctors and hospital executives by the end of March 2014. An additional USD3.09 million (20 million yuan) has been provided for the 2012 to 2017 extension of the programme.

Bristol-Myers Squibb

DISEASES

- Breast cancer
- Cervical cancer
- Americas
- Multi-company

DISEASES

- Breast cancer
- Cervical cancers

COUNTRIES

Sub-Saharan Africa

Women's Cancer Initiative to improve national programmes, registries and education for breast and cervical cancer in the Americas

Two companies, Bristol-Myers Squibb and Pfizer, engage in a Women's Cancer Initiative in the Americas* with support from the IFPMA and its members. The programme aims to works to improve the quality and effectiveness of national breast and cervical cancer programmes and national cancer registries in Latin America and the Caribbean.**

The first year of the partnership had reported progress along three work streams:

- 1. Raising awareness of breast and cervical cancer to promote participation in screening and early detection services, by producing and distributing educational materials on breast and cervical cancer prevention, detection and treatment.
- A pilot project is being carried out with the Ministry of Health in Chile to strengthen national cervical cancer screening programmes and policy workshops with government officials and health experts.
- 3. Cancer registry training with relevant officials in 11 countries, in collaboration with the International Agency for Research on Cancer (IARC) was hosted by the National Cancer Institute of Argentina.

This practice is also described under Pfizer.

*Founded in 2014 by the Pan American Health Organisation (PAHO) Foundation. **Argentina, Bolivia, Brazil, Chile, Costa Rica, Cuba, Ecuador, Jamaica, Mexico, Panama, Paraguay, Peru, Venezuela.

Secure the Future: Raising awareness and support of programmes in sub-Saharan Africa

In 1999, Bristol-Myers Squibb Foundation launched a programme called Secure the Future® (STF), focused on developing and testing an innovative and sustainable model of care for HIV prevention, treatment, care and support for communities affected by HIV/AIDS in sub-Saharan Africa. STF currently also raises awareness of breast and cervical cancer and is helping to support a number of related programmes throughout sub-Saharan Africa. STF has partnered with Pink Ribbon Red Ribbon (PRRR) to expand the availability of cervical screening and treatment and breast cancer care education. STF is active in Botswana, Ethiopia, Lesotho, Malawi South Africa, Swaziland, Tanzania and Uganda.

Programme of Action for Cancer Therapy (PACT)

Bristol-Myers Squibb works on the Programme of Action for Cancer Therapy (PACT), a joint collaboration between IFPMA and its members and the International Atomic Energy Agency (IAEA), which is involved in raising awareness, resource mobilisation, and capacity building for cancer control. During the pilot phase of PACT, 500 African health professionals were reported to have been trained in Ghana, Uganda, Tanzania and Zambia, and the training is now expected to extend to 33 sub-Saharan African countries.

Global HOPE: Paediatric haematology-oncology initiative in Botswana, Malawi, Uganda Bristol-Myers Squibb Foundation has entered into a partnership in March 2017 aimed at treating paediatric cancer and blood disorders. The USD 100 million initiative aims to create a paediatric haematology-oncology treatment network and care infrastructure in southern and east Africa, supported by USD 50 million in donation from the Bristol-Myers Squibb Foundation and matched by USD 50 million in additional philanthropy. The Partnership also includes Texas Children's Cancer and Haematology Centers, Baylor College of Medicine International Paediatric AIDS Initiative at Texas Children's Hospital and the Governments of Botswana, Uganda and Malawi. Global HOPE (Haematology-Oncology Paediatric Excellence) will build long-term capacity to treat and improve the prognosis of thousands of children with cancer and blood disorders.

DISEASES

- General or unspecified cancers
 COUNTRIES
- Sub-Saharan Countries

DISEASES

- General or unspecified cancers
- Botswana, Malawi, Uganda

Eli Lilly

DISEASES

- General or unspecified cancers
 COUNTRIES
- Global

DISEASES

- General or unspecified cancers
 COUNTRIES
- Kenya

Patient access to cancer care excellence

Patient Access to Cancer Care Excellence (PACE) is a global Eli Lilly Oncology initiative, that aims to encourage public policies and healthcare decisions that speed the development of new medicines, promote learning from patients, and provide access to cancer treatment and care.

AMPATH Program: oncology institute in Kenya with gynaecological and medical oncology focus

Eli Lilly partners with AMPATH (Academic Model Providing Access to Healthcare). Eli Lilly reports that, since 2002, it has donated over USD 60 million in medicine and over USD 80 million in products to AMPATH for cancer, diabetes and mental illness. Eli Lilly committed USD 1 million, to be paid out from 2015 to 2018, to the AMPATH Oncology Institute, which launched in 2009 as one of only two cancer centres in Kenya. The aim is to equip the oncology outpatient centre, hire additional staff, train local healthcare professionals, and create a research and training institute focused on cancer prevention, screening, treatment and supportive care. A curriculum will be developed for gynaecological and medical oncology. In 2016, Eli Lilly also committed human capital by deploying 13 employees to AMPATH: ten employees became part of the skills-based Connecting Hearts Abroad program; while three employees are examining long-term employee engagement partnerships for 2017 and beyond.

Additional Oncology Programmes: Global Connecting Hearts Abroad for cancer patient and caregiver support

Since 2016, Eli Lilly added two programmes to Global Connecting Hearts Abroad. The first includes support for people affected by cancer or their immediate caregivers. Since 2016, Eli Lilly has been sponsoring "A Fresh Chapter Peru Odyssee" in Lima, Peru, through Connecting Hearts Abroad. A Fresh Chapter (Alliance Foundation) is a non-profit organisation that combines domestic and international volunteering with support programmes. Global Connecting Hearts Abroad is a company-sponsored volunteer programme, launched by Eli Lilly in 2011.

Incubator grant for project HOPE for prevention, diagnosis and management of cancer

Eli Lilly funded a three-year innovation incubator grant for Project HOPE, a global health education and humanitarian assistance organisation, working to increase the capacity of health professionals, healthcare workers, peers, and individuals to prevent, diagnose, and more effectively manage various chronic diseases, including cancer. This central grant funds innovative ideas on delivering essential medicines and healthcare expertise around the world.

DISEASES

General or unspecified cancers
COUNTRIES
 Global

- DISEASES
- General or unspecified cancers
 COUNTRIES
- Global

GSK

DISEASES

- General or unspecified cancers
- COUNTRIES
 Africa

Africa NCD Open Labs and South African MRC partnership

Related to capacity building, GSK Africa NCD Open Labs works in partnership with researchers and funders to share expertise and resources to increase understanding of NCDs in African patients, and also invests in a partnership with South African MRC and MRC UK at the university of Cape Town. More details are not available.

Johnson & Johnson

DISEASES • Lung cancer COUNTRIES • China DISEASES • Prostate cancer COUNTRIES

• China

Merck & Co., Inc.

Merck & Co., Inc. is known as MSD outside the US and Canada.

DISEASES

- Breast cancer
- Cervical cancer
 COUNTRIES
- Sub-Saharan Africa

Lung Cancer Center in China

Johnson & Johnson founded the Lung Cancer Center, with headquarters in China, where the stated goal is to transform lung cancer in markets with high prevalence of the disease into a preventable and curable disease.

Accessibility of prostate cancer guidelines in China

Johnson & Johnson sponsors the translation of current National Comprehensive Cancer Network (NCCN) Treatment Guidelines for Prostate Cancer into Mandarin to address access to new treatments for patients in China.

PRRR: Breast and cervical cancer care in sub-Saharan Africa

In September 2011, Merck & Co., Inc. committed to contributing USD 3 million over three years to the PRRR initiative for both cervical and breast cancer in sub-Saharan African nations by supporting disease education, screening and treatment and access to cervical cancer vaccination. Through this partnership, Merck & Co., Inc. states that it raises awareness in Zambia and Tanzania of breast and cervical cancer, mobilises additional programme partners and donors, advocates for increased access to screening, treatment and cervical cancer vaccination, and promotes follow-up care among women in sub-Saharan Africa. Merck & Co., Inc. has also reported that it has provided in-kind donations and technical support to the national cervical cancer vaccination programmes in both Zambia and Botswana.

Merck KGaA

DISEASES

- General or unspecified cancers
- Africa

Merck Cancer Control Program for cancer awareness

In partnership with the MOH of Uganda, Merck Cancer Control Program in Uganda was launched in 2015, as a combined diabetes and cancer awareness campaign. The programme is designed to create awareness about diabetes and cancer, promote early detection, and prevention of these diseases, improve treatment options and illustrate ways to prevent these diseases. Merck KGaA commits to providing more than 2,000 people with free cancer education. The Merck Cancer Control Program aims to partner with top global experts, to roll out in other African countries, and to focus on community awareness and strong educational programmes for medical students across Africa.

Merck Cancer Access Program (MCAP)

General or unspecified cancers
COUNTRIES

Africa

DISEASES

This programme aims to increase the limited number of medical oncologists and hence improve access to cancer care in Africa by supporting a fellowship programme for medical oncology for medical doctors across Africa. The programme is starting in Kenya.

DISEASES

- General or unspecified cancers
- COUNTRIES
- Tanzania

Novartis

DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIES
- LMCs

DISEASES

- Breast cancer
- Cervical cancer
 COUNTRIES
- Kenya

DISEASES

- General or unspecified cancers (children)
- COUNTRIES
- Philippines

Biomarker tests for mCRC in China

Merck KGaA holds a collaboration in Tanzania with the Foundation for Cancer Care in Tanzania (FCCT). The FCCT is a charity, based in the US, which works with regional and international partners to build a comprehensive, sustainable cancer care system to serve cancer patients across the Tanzanian Northern Healthcare Zone with the aim of reducing cancer morbidity and mortality. Partners involved include the Ministry of Health and Social Welfare (government), Duke University (academia) as well as local medical centers such as the Arusha Lutheran Medical Center and the Kilimanjaro Christian Medical Center. Opportunities identified include piloting a chemotherapy program; teaching labs and cancer research agreements; use "big data" research to develop cancer registries; local education as well as community awareness and support; and educational exchange and experiences such as preceptorships.

Next Generation Scientist programme

The Next Generation Scientist (NGS) Programme by Novartis and University of Basel is an intensive internship programme for talented scientists from low- and middle-income countries. One hundred and twenty scientists are reported to have participated since the programme started in 2011, with approximately 16% of them working on oncology-related projects.

These precompetitive NGS projects cover the full value chain for research and development in oncology ranging:

• from explorations of cancer biology for targets of disease (e.g. exploration of adaptive resistance mechanisms to JAK2 inhibition)

• to identification of chemical modulators (e.g. identification of compounds that preferentially target tumour-initiating triple negative breast cancer cells)

• to clinical for oncology translational medicine studies.

Healthy Family programme

In Kenya, Healthy Family (Familia Nawiri) works with locals, NGOs and outreach workers to address access and availability of medicines and doctors across 9 counties. The programme also teams up with Novartis Access on capacity building activities to raise disease awareness and diagnose chronic diseases, including conducting health camps to offer cervical and breast cancer screenings. Since the start of the programme in 2012, more than 12,000 patients have been diagnosed and treated in 125 health camps.

World Child Cancer Initiative

Through Sandoz, Novartis recently launched a new programme with World Child Cancer in the Philippines to increase access to medical capacity building and education of HCPs treating children with cancer. The programme will be expanded in 2017 to projects in Ghana, Myanmar and Mexico in addition to continuing the company's existing work in the Philippines.

Pfizer

DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIES
- Latin America

DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIES
- Americas
- Multi-company

NCD outreach programme for cervical and breast cancer in Latin America

Pfizer is partnered with ProMujer in Latin America (Mexico, Argentina, Peru, Bolivia and Nicaragua) to implement an NCD outreach programme that includes cervical and breast cancer screening, implementing electronic medical records in health clinics to improve care and long-term patient outcomes and piloting an insurance and savings programme for cancer care for low income women. The programme started in 2016 and Pfizer reports a commitment of USD 600,000.

In 2016, the Pfizer Foundation supported projects to improve breast cancer care in four emerging markets: Peru, Brazil, Rwanda and Kenya. Together, these programs explore opportunities to integrate breast cancer outreach, early screening and diagnosis into existing primary care systems with a link to oncology treatment facilities, thereby expanding access to quality oncology care service to patients in LMCs.

Women's Cancer Initiative to address national programmes, registries and education for breast and cervical cancer in the Americas

Two companies, Bristol-Myers Squibb and Pfizer, engage in a Women's Cancer Initiative in the Americas* with support from the IFPMA and its members. The programme aims to works to improve the quality and effectiveness of national breast and cervical cancer programmes and national cancer registries in Latin America and the Caribbean.**

The first year of the partnership had reported progress along three work streams: 1. Raising awareness of breast and cervical cancer to promote participation in screening and early detection services, by producing and distributing educational materials on breast and cervical cancer prevention, detection and treatment.

2. A pilot project is being carried out with the Ministry of Health in Chile to strengthen national cervical cancer screening programmes and policy workshops with government officials and health experts.

3. Cancer registry training with relevant officials in 11 countries, in collaboration with the International Agency for Research on Cancer (IARC) was hosted by the National Cancer Institute of Argentina.

This practice is also described under Bristol-Myers Squibb

*Founded in 2014 by the Pan American Health Organisation (PAHO) Foundation.

**Argentina, Bolivia, Brazil, Chile, Costa Rica, Cuba, Ecuador, Jamaica, Mexico, Panama, Paraguay, Peru, Venezuela

Roche

Roche aims to structure its Access to Healthcare approach around four key factors that need to be in place for patients to access the right treatment: 1. Increasing disease awareness

- 2. Improving diagnosis
- 3. Building healthcare capacity
- 4. Providing tailored funding solutions to address affordability

The following examples of Roche Access to Healthcare initiatives are clustered around the first three factors described above, examples of initiatives clustered around the fourth factor are described in the pricing section.

► INCREASING DISEASE AWARENESS

"We care for her" awareness programme for breast cancer in Vietnam

Between 2013 and 2015, Roche worked with the Ministry of Health in Vietnam and has implemented a wide-reaching awareness programme aiming at increasing the understanding, prevention and diagnosis of breast cancer. This was coupled with screening for women over 40 and includes social events in which people could share views, as well as listen to physicians and cancer patients tell their respective stories and share experiences. The programme received the full endorsement and support from the Ministry of Health and over 1 million people have received information on this. 16,000 women have been screened and over 600 healthcare professionals have received training on breast cancer. In that period 5 patient clubs and 2 patient forums were also created.

Raising awareness, education and training for HCV to reduce hepatocellular carcinoma in Indonesia

Roche in Indonesia is working to provide information, encourage voluntary testing, and promote referral and HCV treatment. Campaign partners are the Indonesian Red Cross, the Indonesian Association for The Study of The Liver (PPHI), and the Indonesian MOH. Roche reports that in 2015, public awareness seminars were attended by more than 200 people, hepatitis workshops were attended by more than 700 doctors, and over 750 people participated in a public awareness selfie competition.

Education about multiple cancers in Indonesia

Roche launched a national-level public education umbrella campaign "Let's Defeat Cancer Together", including cancer awareness and educational activities for breast, colorectal, ovarian, lymphoma, cervical and paediatric cancer. Roche collaborated with the Indonesian MOH and the National Cancer Control Committee to create an online information resource (www. KalahkanKanker.com). The campaign was attended by around 200 participants (partners and healthcare professional, community- and patient organisations). Educational materials were developed, including videos, (viewed more than 10,000 times), and almost 70,000 pamphlets (reaching approximately 2 million Indonesians). The website garnered over 10,338 views and registered 3,163 users after its launch in 2015.

SADARI: Breast cancer awareness and education in Indonesia

In partnership with the Indonesian Ministry of Health, Roche conducted an early detection campaign about breast self-examination (called 'SADARI' in Indonesian). Partnerships with medical oncologists were extended to include midwives and general practitioners. Roche reports that the campaign disseminated various educational materials, including more than 10,000 booklets and 20,000 leaflets. An educational video was watched by more than 6,600 online viewers and more than 10,000 people in the first three months. More than fifteen events were supported by the campaign, resulting in a reach of more than 20,000 people nationwide in the first three months.

DISEASES

Breast cancer
COUNTRIES

• Vietnam

DISEASES

- Hepatocellular carcinoma
 COUNTRIES
- Indonesia

DISEASES

- Breast cancer
- Colorectal cancer
- Ovarian cancer
- Lymphoma
- Cervical cancer

Paediatric cancer
COUNTRIES

Indonesia

DISEASES

- Breast cancer
- COUNTRIES
- Indonesia

DISEASES

- Colorectal cancer
- COUNTRIES
- Indonesia

DISEASES

- Ovarian cancer
- COUNTRIES
- Indonesia

DISEASES

- Breast cancer
- COUNTRIES
- China

DISEASES

- Colon cancer
- Kidney cancer
- Ovarian cancer
- Skin cancer
- COUNTRIES
- Colombia

DISEASES

- Breast cancer
- COUNTRIES
- Colombia

DISEASES

- General or unspecified cancers
 COUNTRIES
- Colombia

Education on CRC in Indonesia

Roche launched a national-level public education and awareness campaign for CRC in partnership with the Indonesian Ministry of Health. The aim was to increase public awareness and early detection of CRC. 10,000 posters, stickers and leaflets were disseminated in all government-mandated community health facilities located across Indonesia, with each receiving approximately 150 visitors daily. A media health forum was also conducted.

OvaCheck: Ovarian cancer awareness in Indonesia

Roche launched the "OvaCheck" – Kenali Kanker Ovarium (OvaCheck – Getting to Know Ovarian Cancer) campaign, which aims to raise awareness of ovarian cancer symptoms and to encourage women to seek medical consultation. Roche reports that its ovarian cancer awareness seminars were attended by more than 150 people, and more than 1,000 people received education materials, distributed through 100 clinics and hospitals nationwide.

'Run for Her' Programme: awareness, testing and treatment of breast cancer in China

In May 2016, Roche launched an awareness campaign called "Run for Her" in partnership with the China Cancer Rehabilitation Society, with the aim to raise public awareness on breast cancer, especially around the importance and value of pre-screening. Following the kick-off ceremony on the Great Wall of China, a series of activities were held in 48 cities across China involving over 50,000 participants, including cancer survivors, physicians, volunteers as well as media representatives. Roche also initiated a round of social media campaigns around the theme 'Touch for good'. The company reports that the project has generated more than 400 media reports and reached an audience of over 297 million readers. Roche states that the campaign delivered key messages on screening for breast cancer on a regular basis, early diagnosis and standardized treatment.

Driving awareness and education around public campaigns for multiple cancers in Colombia

In 2014 and 2015, Roche drove awareness initiatives around World Cancer Day, Colon Cancer Awareness Month, World Kidney Day, Word Ovarian Cancer Day and Skin Cancer Awareness Day. These campaigns were reported to have reached more than 1,200 people and assisted more than 9,400 patients in Colombia in 2015.

Health awareness in jails for breast cancer in Colombia

Roche promotes breast cancer awareness and prevention in Colombian jails, which house approximately 6,500 women. The project started in 2013 in the Buen Pastor jail in Bogotá in collaboration with the National Prison and Penitentiary Institute (INPEC).

Time to Live: PSP for cancer in Colombia

Roche established the "Time to Live" programme to provide support for cancer patients, their families and caregivers. The programme offers education on disease management, treatment compliance and non-pharmacological management of adverse events. Roche also provides supporting materials with nutritional and lifestyle information, workshops, support groups and educational home visits by nurses.

▶ IMPROVING DIAGNOSIS

Addressing cancer diagnostics through digital pathology solutions in Kenya, India and Haiti

DISEASES

- · General or unspecified cancers COUNTRIES
- Haiti, India, Kenya

DISEASES

- Hepatocellular carcinoma (liver cancer)
- COUNTRIES Vietnam

DISEASES

- Breast cancer
- Gastric cancer
- COUNTRIES
- Asia-Pacific

DISEASES

- Breast cancer
- COUNTRIES
- Northern Africa

Ventana, a member of the Roche Group, is a provider of digital pathology solutions. This

includes the digitalisation of pathology slides that enables pathologists in developing countries to view, analyse and share information with others, e.g., sending digital slides to international experts to aid in diagnosis. This telepathology platform has enabled experts at the University of Nebraska to connect with the people of Mumbai, patients in Kenya with pathology experts in Canada, and patients in Haiti with pathologists at the University of Miami.

Hepatitis C awareness, prevention and screening to reduce hepatocellular carcinoma in Vietnam

In 2013, Roche in Vietnam initiated support for organising public events around World Hepatitis Day, aimed at raising awareness, encouraging voluntary hepatitis C testing, and education. In 2014, Roche launched several initiatives around World Hepatitis Day with WHO support. The day focused on a call to action for the community to get tested. Roche reports that around 2,000 Hepatitis C Virus (HCV) blood tests were processed, and that extensive nationwide media coverage included including 8.1 million print publications, online content attracting 38 million page views, and more than 50 TV and radio airings. In 2015, over 3,000 people registered for free HCV tests at the four participating hospitals.

SPHERE programme: addressing breast and gastric cancer diagnosis in Asia-Pacific In 2010 Roche launched the SPHERE programme (Scientific Partnership for HER2 Testing Excellence) in Asia-Pacific, with the aim of integrating HER2 testing of breast and gastric cancer patients at the point of disease diagnosis. Roche states that it aims to increase the reliability and reproducibility of HER2 testing by training surgeons on taking and handling tissue biopsies, establishing training and quality control procedures for lab technicians, assisting pathologists in scoring and interpreting results, educating oncologists on HER2 testing and making the link to treatment decisions. In addition, the programme aims to educate, share best practice and facilitate communication on HER2 testing between pathologists and technicians across Asia-Pacific. SPHERE is reported to be operational in13 countries in Asia-Pacific: Bangladesh, China, Hong Kong, India, Indonesia, Korea, Malaysia, Myanmar, the Philippines, Taiwan, Singapore, Thailand and Vietnam. In 2015, close to 8,820 pathologists, surgeons and technicians participated in the training programme. Over 168,600 women with breast cancer and nearly 74,000 gastric cancer patients have been tested in the SPHERE programme.

Mobile breast cancer screening facility in Northern Africa

In 2013, a joint partnership between Roche, the Algerian government, patient advocacy group El Amel (Hope), and mobile phone operator Mobilis, launched the first mobile breast cancer screening facility. This 'mammobile' consists of a fully equipped truck, which brings trained nurses, radiologists, other healthcare staff and facilities to remote regions within Algeria. The goal is to combine cancer awareness campaigns with screening facilities in order to improve breast cancer detection and treatment. Roche supports the training of local radiologists, nurses and other professionals, and equips the mammobile with the software for performing mammograms. Through mobile mammography units in Algeria, Morocco and Tunisia, over 350,000 women have been screened since the initiative began in the first country in 2010. In 2013 alone, over 100,000 women were screened.

▶ BUILDING HEALTHCARE CAPACITY

DISEASES

- General or unspecified cancers
- COUNTRIES
- India

Blue Tree programme: A single platform for supporting cancer patients in India In March 2015, Roche India launched the "Blue Tree" patient support initiative, designed to take care of the multiple hurdles that a patient has to go through during the course of receiving treatment.

The programme helps patients understand treatment funding sources and provides guidance around the documentation needed to claim reimbursement, minimising the administrational demands of treatment. Tele-coordinators stay in close contact with patients, helping them navigate through the different service offerings of the programme. After treatment, the programme also offers support in finding suitable employment for those patients who are well enough and who wish to rejoin the workforce.

These materials are presently available in nine regional languages and will be made available to doctors and patients.

Roche India has partnered with multiple organisations to make this programme a reality, including Saarathi Healthcare, a leading patient engagement programme administrator in India, and Monster India Limited to provide specialised services such as job search assistance. The programme has received strong support from physicians. In 2015, more than 750 doctors supported the programme, resulting in over 1,200 patients enrolling. According to Roche, patients who enrolled showed a 40% increase in therapy adherence rates. Programme statistics indicate that in 2015, 50% of patients who enquired about the programme enrolled and benefited from its services. This percentage has increased to 76% in Q1 2016 alone.

Since March 2015, The Blue Tree has addressed 2600 patients and aims to add more services like home infusion to make treatment easier for patients. An additional stated benefit is the increasing trust and value established with physicians and the doubling of patient enrolments per month over the last 6 months.

Women Consulting Rooms for the awareness, diagnosis and early detection of breast cancer in Colombia

In 2012, Roche introduced a country-wide initiative called "Women Consulting Rooms" where healthcare professionals raise awareness and promote diagnostic testing. This initiative aims to enable the early detection of diseases, particularly breast cancer. The first room opened in the San Juan de Dios Hospital in Cali, Colombia's third-largest city. By 2015, 128 Women Consulting Rooms had been set up in 63 cities throughout Colombia. Roche reports that nearly 800 patients were diagnosed and treated for breast cancer. A total of 132,192 women are reported to have visited the Consulting Rooms.

Reducing access barriers for (breast) cancer patients in Kenya

In August 2016, First Lady Margaret Kenyatta, the Kenyan Ministry of Health and Roche launched a public-private partnership to strengthen initiatives to combat cancer in Kenya. This is the first of two memorandums of understandings Roche has signed in Kenya. The second, with the newly Beth Mugo Cancer Foundation, was signed in October 2016.

Access to medicine will be made available to patients seeking treatment at public institutions with the government of Kenya and Roche jointly covering the costs. The aim is to ensure breast cancer patients have access to timely diagnostic services and tailored cancer treatment to make cancer therapy much more effective. Planned activities for the public-private partnership with the Ministry of Health include breast cancer awareness programs, strengthening screening and diagnostics, training new oncologists and oncology nurses, supporting development of best practice national treatment guidelines and increasing the number of cancer treatment centers in Kenya.

DISEASES

- Breast cancer
- COUNTRIES
- Colombia

DISEASES

- Breast cancer
- COUNTRIES
- Kenya

DISEASES

- Breast cancer
- COUNTRIES
- Morocco

First national cancer plan in Morocco

In Morocco, Roche has partnered with the Lalla Salma Association Against Cancer (ALSC) on access to oncology treatment and raising awareness. The partnership has led to the launch of the first national cancer plan. The plan also includes:

- Infrastructure: Roche worked with ALSC to modernise and equip the National Oncology Centre in Rabat.

- Cancer registry: Roche worked with ALSC to establish cancer registries in the main public oncology hospitals. Casablanca and Fes registries are reported to be in an advanced phase.
- Education: Roche supports the African School of Oncology, and is aiming to help train oncology healthcare professionals. In 2013, the African school started a series of workshops, training local scientific writers in order to enhance scientific publication in oncology.

- Mobile diagnostic units: Roche sponsored the ALSC project with the aim of buying mobile trucks equipped for (breast) cancer diagnostic in remote areas.

- Roche helped the ALSC in a project aiming to visit patients at home and provide them with support and palliative care.

- Awareness: Roche aims to extend the early detection of cancer among the population and reduce prejudice. In 2013 the ALSC launched a large media awareness campaign co-sponsored by Roche in major Moroccan media channels.

Since 2009, Roche has assisted the ALSC in providing access to oncology medicines and helping to strengthen the healthcare infrastructure in the country.

Focus on HCV-induced liver cancer in Cameroon

Roche and the Republic of Cameroon signed a partnership agreement focused on the diagnosis and treatment of patients with the aim of reducing complications including HCV-induced liver cancer. The programme includes awareness/ screening campaigns to increase the population tested (target 10,000 per year). Roche is also working with professional bodies to set up a patient registry to monitor disease incidence and help set up future action plans.

DISEASES

- Hepatocellular carcinoma
 (liver cancer)
- COUNTRIES

 Cameroon

Sanofi

DISEASES

General or unspecified cancers
 COUNTRIES

• Low-resource countries

My Child Matters: targeting childhood cancer survival rates in low-resource countries The My Child Matters programme was set up in 2006 by the Sanofi in partnership with the International Union against Cancer (UICC), the St. Jude Children's Research Hospital and the International Society of Paediatric Oncology (SIOP), the French-African Paediatric Oncology Group (GFAOP) and the Children Cancer Institute (CCI). It was set up to give children the same chance at access to care, regardless of where they live. It provides financial support, cancer expertise of international specialists and effective networking to address the healthcare chain: information and awareness campaigns; health staff training; early diagnosis; access to care, including pain management and palliative care; and psychological support for children, families and care providers. The programme contributes to building capacity at the local level in different ways, among others: training healthcare professionals; creating and disseminating relevant information about childhood cancer (including cancer registries and epidemiologic data); encouraging earlier detection; and improving access to treatment and care. The programme is active in Algeria, Burkina Faso, Cameroon, Central African Republic, Colombia, Honduras, Ivory Coast, Madagascar, Mauritania, Morocco, Mali, Nicaragua, Niger, the Democratic Republic of Congo, Pakistan, Paraguay the Philippines, Senegal, Thailand, Togo and Tunisia. The action plans are organised around three main priorities: stronger support and evaluation for ongoing projects, support for inter-regional networks, and advocacy campaigns to prioritise child cancers. Since the programme was set up, Sanofi states that it has contributed to train 15,000 healthcare professionals and treat 50,000 children.

DISEASES

- General or unspecified cancers
- COUNTRIES
- India

Takeda

DISEASES

- General or unspecified cancers
- Emerging markets

Bringing NCD training to remote areas of Maharashtra (India)

Sanofi and Project Hope are supporting the Maharashtra State Government in India in training the counsellors and nurses in 35 districts. The programme will help upgrade the knowledge of healthcare professionals on the management of patients with NCDs, including cancer. In 2016, 199 healthcare professionals were trained. Moreover, approximately 22 million people were reached through the 1,211 awareness hoardings and posters put across 255 state run hospitals and community health centers in 17 districts.

Commitments to sustainable strategies for Hodgkin's lymphoma in emerging markets Takeda is piloting access-to-medicine approaches in Brazil, Ukraine and the Philippines, focused on the diagnosis and treatment of Hodgkin's lymphoma. Analysis in the Philippines identified 2 key reasons or barriers: (1) The cost of the CD30 test, used to diagnose Hodgkin's lymphoma, is underused in the Philippines due to its cost; (2) PET scans, important for disease monitoring and treatment and compliance are also underutilised in the Philippines due to their high cost. Takeda has developed a partnership programme to engage with local hospitals and medical societies to support better diagnostic testing for Hodgkin's lymphoma, whereby patients will be able to apply to undergo subsidised diagnostic tests, funded by Takeda. Takeda also states a commitment to deploying a transport programme for CD30 testing samples from remote areas to laboratories. Takeda is committed to making a considerable investment in these programmes during fiscal year 2016.

Commitment to Oncology Centre of Excellence for sub-Saharan Africa

In 2016, Takeda committed to developing Nairobi into a Centre of Excellence (CoE) for oncology / haematology, as the first step in a non-profit strategy to increase access to its medicines in sub-Saharan Africa. The new centre will focus on providing access to Takeda's oncology medicines, and will be the location where patients receive vital diagnosis, treatment and healthcare. As part of this, Takeda has committed to donating a cyclotron to Kenya to assist in the diagnosis and treatment of cancer patients in sub-Saharan Africa. Takeda also aims to launch a fellowship programme designed to train medical professionals in the region.

Cancer alliance in Kenya

Takeda facilitated the development of the Cancer Alliance ("Alliance") – with the aim to improve cancer services, by bringing together a group of established and functioning organisations and government agencies in Kenya, with the view to address the increasing incidence of cancers in Kenya and Sub-Saharan Africa. Takeda is working closely with the Cancer Alliance and an insurer to develop a low cost micro insurance, known as OncoCare, which will assist in supporting Bottom Of the Pyramid (BOP) patients in receiving access to diagnosis and treatment.

Training Primary Healthcare Providers in Kenya

Takeda has supported through the Elewa Foundation, and in association with the Kenyan Ministry of Health, the training of 75 Primary healthcare Providers in three (3) counties of Kenya, providing practical and specific knowledge for improving basic understanding of cancer care in the most common types of cancers (including breast, cervical, colorectal) as well as pain / palliative care.

DISEASES

- General or unspecified cancers
 COUNTRIES
- Sub-Saharan Africa
- General or unspecified cancer
 COUNTRIES
- Kenya
- General or unspecified cancer
 COUNTRIES
- Kenya

- General or unspecified cancers
- Sub-Saharan Africa

Increasing the number and skills of healthcare workers in Sub Saharan Africa

Takeda is funding the training of ten physicians from across SSA to become specialised in oncology through the University of Nairobi's two oncology year program. Takeda is exclusively supporting Access to Innovative Care Foundation (AICF) in Kenya, Ethiopia, Nigeria and Ghana with the purpose of enhancing oncology nursing care in these countries. This project aims to enhance the skills of nurses to provide quality oncology care through improved knowledge, confidence and nursing practice in line with global standards. Takeda is working together with German Hodgkin Study Group (GHSG) and the Clinica Universidad de Navarra, Takeda supported qualified oncologists and pathologists from Kenya to attend tutorials in Germany and Spain in 2016.

R&D fellowship programme access to pediatric cancer care in sub-Saharan Africa

Takeda is partnering with AMPATH, Foundation for Cancer Care Tanzania (FCCT), American International Health Allliance (AIHA) and Children's Pace international (CPI). Capacity building related to clinical care, education training and research in cancer treatment are stated to be supported here.

Supporting Diagnosis of Hodgkin's lymphoma in Emerging Markets

Takeda has commenced a year-long pilot in the Ukraine, focused on the diagnosis of Hodgkin's lymphoma. Takeda has developed a partnership programme to engage with local hospitals and medical societies in the Ukraine, to support better diagnostic testing for Hodgkin's lymphoma, whereby patients will be able to apply to undergo subsidised diagnostic tests, which Takeda will fund.

- General or unspecified cancers
 COUNTRIES
- Sub-Saharan Africa

Hodgkin's lymphoma

- COUNTRIES
- Emerging markets

CAPACITY BUILDING: mHEALTH / eHEALTH

In recent years, capacity building has also started to focus on the use of mobile devices and communication technology (ICT), such as computers, communications satellite,sand patient monitors for health services and information. This has many advantages in closed communities and rural areas where access to medicine is limited due to logistic issues. Four companies have each launched an initiative pertaining to mobile health and/or online training programmes that may be used interactively by healthcare professionals or patient advocates in order to gain information about cancer medicine.

Eli Lilly

DISEASES

- General or unspecified cancers
 COUNTRIES
- Multiple countries, incl. China

Medicine Evaluation Educational Training (eMEET)

eMEET (Medicine Evaluation Educational Training) is an online interactive training programme designed to help patient advocates navigate through the complex world of medicine development, evaluation and assessment of new drugs/indications. eMEET uses a variety of tools to educate people about the drug discovery and health technology assessment (HTA) processes. It also shows how valuable patients' experiences are to these complex processes, and how patients and advocates can participate in the decisions made. This training is reported to be available in multiple countries, including China.

Merck KGaA

DISEASES

- General or unspecified cancers
- COUNTRIES
- Kenya

Roche

DISEASES

- General or unspecified cancers
 COUNTRIES
- Sub-Saharan Africa

Telemedicine in rural Kenya

Merck KGaA reports a collaboration with the Kenyan Ministry of Health to address access to cancer therapies in rural regions through the use of telemedicine.

Online training for breast and other cancers in sub-Saharan Africa

The International Atomic Energy Agency (IAEA) and Roche initiated a strategic partnership (EDUCARE) to build human resource capacity in cancer control in sub-Saharan Africa by offering online training (a 'virtual university') for health professionals. Pilot countries are Ghana, Uganda, Tanzania and Zambia and mentor countries are Egypt and South Africa. The IAEA plays the lead role in project coordination, the development of a curriculum within the radiation medicine domain and coordinating an integrated approach across the spectrum of Cancer Control. Key implementation partners to the initiative are the African Radiation Oncology Group, the American Society of Clinical Oncology, the African Organisation for Research and training in Cancer, the Breast Health Global Initiative, the International Agency for Research on Cancer, the International Network for Cancer Treatment and Research, the National Cancer Institute (US), the Union for International Cancer Control and the World Health Organisation.

Pfizer

DISEASES

• General or unspecified cancers

• Mexico

Civil Society Capability Building in Mexico

Construyendo Lazos is a forum supported by the Pfizer Mexico Foundation and conducted as a joint effort with the Mexican Ministry of Health of Mexico and its National Volunteer Service. This initiative serves as a networking opportunity and education session. It seeks to enhance the management skills and operational capabilities of over 400 civil society organisations and patient groups throughout the country. Organisations participating receive training to enhance their skills in areas such as social media, fundraising and government support programmes.

CAPACITY BUILDING: FUNDING

Many companies build capacity through funding cancer initiative through (product) donations and grants. Seventeen initiatives that have been awarded with grants and funding are listed below.

Bristol-Myers Squibb

DISEASES

- Breast cancer
- Cervical cancer

COUNTRIES

• Sub-Saharan Africa

Secure the Future: strengthening services for breast and cervical cancer in aging and teen populations in sub-Saharan Africa

In 2014, through its Secure the Future initiative, the Bristol-Myers Squibb Foundation has awarded 12 grants that focus on strengthening community-based services in sub-Saharan Africa for adolescents and the elderly with HIV/AIDS, three of which focus on comorbid female cancers. The community-based services receiving grants are listed below:

1. Swaziland Breast and Cervical Cancer Network for awareness and clinical programmes for breast and cervical cancer

Bristol-Myers Squibb Foundation awarded a grant of USD 502,096, spread over three years to Swaziland Breast & Cervical Cancer Network – which launched cervical cancer screening services in a rural community in 2013 through funding from the Bristol-Myers Squibb Foundation – to expand national services for breast and cervical cancer through awareness and clinical programmes, in collaboration with Swaziland Baylor Children's Centre of Excellence and the Ministry of Health of Swaziland. A Rural Health Motivator training guide will be created to ensure that ongoing best practices are implemented throughout communities.

2. Right to Care Project for cervical and breast cancer screening

Bristol-Myers Squibb Foundation commits to awarding a grant of USD 90,383 to the Right to Care Project, which funds a programme focused on training physicians and nurses in Ethiopia, Swaziland and South Africa on current alternative methods and on improving capacity for cervical and breast cancer screening in HIV-positive patients. The project will expand the cancer screening services currently provided in these three countries

Medical Women Association of Tanzania for access to screening, prevention, and awareness of cervical and breast cancer

The Medical Women Association of Tanzania (MEWATA), Tanzania Marketing and Communications, Tanzania Youth Alliance and Mbeya HIV/AIDS Network-Tanzania have received funding (USD 191,637 over 18 months) and technical support from the Bristol-Myers Squibb. The purpose is to work with community and faith-based organisations to raise awareness on cervical and breast cancer and address access to screening and prevention in the Mbeya, Mwanza and Iringa regions, as well as to mobilise resources for cervical and breast cancer services among policy makers.

National expansion of breast and cervical cancer screening in Swaziland

The Swaziland Breast and Cervical Cancer Network (SBCCN) received a grant from Bristol-Myers Squibb to train teams of community members called Rural Health Motivators to raise awareness and promote early detection of HIV, breast and cervical cancer in communities across the country. The organisation, in collaboration with the Ministry of Health, operates three breast cancer clinics and four cervical cancer screening points throughout the country. The estimated overall value of the partnership is approximately EUR 1 million in equipment and training. The estimated number of people affected is around 16,000 additional women screened in 2015-2016.

DISEASES

- Breast cancer
- Cervical cancer
- Tanzania

DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIES
- Swaziland

DISEASES

- Cervical cancer
- COUNTRIES
- Zimbabwe

DISEASES

- Breast cancer
- Cervical cancer
 COUNTRIES
- Ethiopia

DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIESEthiopia

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DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIES
- Ethiopia

DISEASES

- Cervical cancer
- COUNTRIES
- Tanzania

DISEASES

- Cervical cancer
- COUNTRIES
- Tanzania

DISEASES

- Cervical cancer
- Tanzania

Cancer Association of Zimbabwe for cervical cancer screening and education

The Cancer Association of Zimbabwe will receive USD 119,871 to initiate an integrated HIV and cervical cancer screening and education programme in Zimbabwe. The grant will fund interventions that will help dispel myths and misconceptions in rural communities about cancer and HIV and AIDS, offer free cervical and breast cancer screening services and build capacity in rural communities for early detection, prevention and management of cervical cancer among patients with HIV/AIDS.

CORDAID-Ethiopia for awareness and strengthening of screening and treatment methods

The Catholic Organisation for Relief and Development Aid (CORDAID) received USD 99,770 to support the mapping and planning phases of its project to establish and develop the Ethiopia Female Cancer Initiative for prevention of female cancers. Together with Ethiopian partners, CORDAID will receive USD 200,000 to increase breast and cervical cancer awareness, strengthen cost-effective screening and treatment methods, help set policy and to provide comprehensive care and support in selected areas of Ethiopia. The CORDAID-led Ethiopian Female Cancer Initiative is reported to be working on the project with the Ethiopian government and other Pink Ribbon Red Ribbon Alliance members.

CUAMM (PRRR Alliance) for technical support to breast and cervical cancer services

The Italian organisation Collegio Universitario Aspiranti Medici Missionari (CUAMM), part of the PRRR alliance, will receive USD 400,225 over three years to provide technical support to health facilities in four districts in the Oromia region of Ethiopia for cervical and breast cancer services.

Mathiwos Wondu for education on breast and cervical cancer

Mathiwos Wondu - YeEthiopia Cancer Society will receive USD 99,363 to build capacity that will enable the organisation to expand and extend its reach to educate Ethiopian communities about breast and cervical cancers in an effort to reduce the incidence of and mortality from the diseases.

Mbeya HIV/AIDS Network for cervical cancer education, screening and prevention In Tanzania, the Mbeya HIV/AIDS Network – Tanzania received USD 115,314 over 18 months to leverage its HIV/AIDS community services to increase cervical cancer education and to improve access to screening and prevention in communities in Mbeya.

Tanzania Marketing and Communications for education and empowerment

Tanzania Marketing and Communications received USD 162,946 over 18 months to help reduce the incidence, morbidity and mortality of cervical cancer in Iringa, Tanzania, through community education and empowerment.

Tanzania Youth Alliance for awareness of cervical cancer

The Tanzania Youth Alliance received USD 99,000 over 18 months to increase awareness of cervical cancer by using technology to disseminate essential information about the disease and promote screening with the help of community leaders. TAYAO will collaborate with the Medical Women Association of Tanzania to address the barriers to early diagnosis and treatment through a combination of services, including a helpline, public information and financial support for transportation.

DISEASES

- Sprycel®(dasatanib)
- Chronic myeloid leukemia
 COUNTRIES
- Low-income countries

DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIES
- Africa
- Multi-company

Funding of a donation programme for Sprycel® for people with CML in specified low-income countries

Bristol-Myers Squibb has made a donation to The Max Foundation to increase access to Sprycel® for people living with chronic myeloid leukemia (CML) in specified low-income countries.

Funding for AMREF Health Africa for the prevention of breast and cervical cancer

Three companies support AMREF Health Africa for the prevention of breast and cervical cancer in Africa. Bristol-Myers Squibb has committed to awarding AMREF Health Africa with USD 550,000 over three years for Ask4Cancer, a project that will help reduce the incidence and mortality of breast and cervical cancers in remote communities in Ethiopia by integrating breast and cervical cancer prevention measures into already existing services. GSK also has a longstanding relationship with AMREF Health Africa, and has funded a number of cervical cancer projects. Takeda is supporting Amref Health Africa to perform a gap assessment of the entire Cancer Eco-System in Ethiopia, Nigeria, Ghana and Senegal, with the objective for both parties to gain a better understanding of the needs and capacity of health facilities – hospitals and health centres - in cancer diagnosis and treatment and determine the gaps in early and overall detection, diagnosis and comprehensive care of cancer. *This initiative is also described under GSK and Takeda*.

GSK

DISEASES

Breast cancerCervical cancer

- COUNTRIES
- Africa
- Multi-company

Funding for AMREF Health Africa for the prevention of breast and cervical cancer

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Pfizer

DISEASES

- Breast cancer
- COUNTRIES
- Peru

Supporting PATH for breast cancer in Peru

Since 2011, the international non-profit PATH has collaborated with Peruvian partners to implement a community-based breast cancer programme in the northern region of La Libertad. The programme has established a feasible, evidence-based approach to early detection at the community level, and linked it to triage and diagnostic services at the network level.

With the Pfizer Foundation's support, PATH is scaling up this programme to reach 115,000 additional women and demonstrate that the model is replicable and sustainable. Specifically, the Foundation's grant will help support the building of healthcare worker capacity, and the training of doctors and midwives in quality clinical breast exams, including in using ultrasound and fine-needle aspiration biopsy and training volunteers as patient navigators.

DISEASES

- Breast cancer
- COUNTRIES
- Brazil

Supporting Breast cancer care in Brazil

With the Pfizer Foundation's support, Susan G. Komen is implementing a programme to address breast cancer care in Brazil by integrating patient support, early detection and timely diagnosis into existing primary care services. More specifically, the programme aims to reduce time between screening, diagnosis and start of treatment by implementing the One-Day Clinic approach that has been effective in other Brazilian states; improving the quality of screening exams with specialized training for radiologists, physicists and medical technologists on quality of mammography; and providing patient support in navigating the system and understanding patient rights, including access to a help line. The Pfizer Foundation's grant will also help support a multi-phase programme that seeks to align Brazil's national cancer control policies at the city and state levels and help facilitate a more-efficient path for women as they seek and receive care.

Support for breast cancer with Partners in Health in Rwanda

Butaro Cancer Center of Excellence (BCCOE) is one of the few facilities in the country where women with breast cancer can be diagnosed and treated. With this in mind, Partners in Health is working with the Rwandan Ministry of Health (MoH) toward the goal of improving accessibility of treatment for breast cancer patients, while also documenting and disseminating lessons learned to inform future efforts to decentralize breast cancer diagnosis and treatment, accelerating the number of women who receive proper cancer care. A Pfizer Foundation grant will help Partners In Health to implement new, national clinical protocols for breast cancer diagnosis and treatment, including a comprehensive social support package. It will also help Partners In Health launch a government-certified, longitudinal oncology nurse training, which includes nurses from referral hospitals completing a three month curriculum. Together with the Rwandan MoH, Partners In Health will produce a report analysing the impact of providing comprehensive care based on breast cancer patient outcomes data.

Kenya (AMPATH) for breast and cervical cancer

A Pfizer Foundation grant will help support a two-year programme by the AMPATH Oncology Institute to build capacity and enable quicker identification, triage and care of patients through a variety of approaches. The programme aims to create tele-medicine and tele-pathology centers, develop a certificate-training curriculum for healthcare providers in oncology and expand a mobile screening unit to include breast screening. AMPATH also plans to train community health workers in clinical breast exam techniques and referral protocols, and improve data collection and sharing by establishing a cancer registry.

DISEASESBreast cancer

- COUNTRIES
- Rwanda

DISEASES

Breast cancer

Cervical cancer

COUNTRIES

• Kenya

Takeda

DISEASES

- Breast cancer
- Cervical cancer
- COUNTRIES
- Africa
- Multi-company

Funding for AMREF Health Africa for the prevention of breast and cervical cancer

Three companies support AMREF Health Africa for the prevention of breast and cervical cancer in Africa. Takeda is supporting Amref Health Africa to perform a gap assessment of the entire Cancer Eco-System in Ethiopia, Nigeria, Ghana and Senegal, with the objective for both parties to gain a better understanding of the needs and capacity of health facilities – hospitals and health centres – in cancer diagnosis and treatment and determine the gaps in early and overall detection, diagnosis and comprehensive care of cancer. Bristol-Myers Squibb has committed to awarding AMREF Health Africa with USD550,000 over three years for Ask4Cancer, a project that will help reduce the incidence and mortality of breast and cervical cancers in remote communities in Ethiopia by integrating breast and cervical cancer prevention measures into already existing services. GSK also has a longstanding relationship with AMREF Health Africa, and has funded a number of cervical cancer projects.

DISCUSSION

Capacity building initiatives are diverse; most relate to health system strengthening

Thirteen companies are currently engaged in a total of 71 capacity building initiatives, (three of which are combination initiatives with both a capacity building and a pricing component).

Half of initiatives are capacity building

Over 50% of companies' access initiatives relating to cancer care (71 out of 129) involve capacity building in some shape or form. Companies' capacity building programmes are very varied in nature, the most comprehensive ones being marked by multi-pronged approaches to access: some combine multiple approaches for improving access or multiple types of capacity building activity. Others address multiple stages of the continuum of care and/or address several forms of cancer. Almost all of the capacity building initiatives identified in this study combine two or more different activities. Initiatives that are linked to specific products will often also focus on general capacity building.

Six companies (Merck & Co., Inc., Merck KGaA, Novartis, Pfizer, Roche and Takeda) are engaged in capacity building initiatives that are linked to specific products (13 initiatives in total, two of which are combination initiatives that have a pricing component as well). Merck & Co., Inc. accounts for the highest number, with five initiatives linked to its HPV vaccine Gardasil®. Merck KGaA has three product-specific initiatives, Pfizer has two, while Novartis, Roche and Takeda each have one. As Gardasil® is a preventive vaccine, related initiatives have the potential to reach a larger volume of healthy people globally (compared to initiatives linked to curative medicines). This cancer prevention by Merck & Co., Inc. signals a global approach for increasing access to cancer medicine. Merck & Co., Inc. also covers more (5) countries than other companies with its product-specific capacity building activities: namely, Bhutan, India, Peru, Rwanda and Zambia. Merck KGaA comes second in this regard, with three biomarker-linked initiatives for CRC together covering four countries: China, the Philippines and Thailand.

Novartis and Roche have capacity building initiatives linked to products on the Model EML: Novartis is building capacity in relation to generic anastrozole and tamoxifen as part of its Novartis Access portfolio of 15 on- and off-patent medicines addressing NCDs, including breast cancer, while Roche is building capacity in relation to Pegasys® (pegylated interferon), used in the treatment of viral hepatitis, a key etiologic factor for hepatocellular carcinoma.

Impact and reach per initiative

Merck & Co., Inc. has the largest volumetric coverage per initiative in terms of patients reached: its projects for Gardasil® in Peru and Zambia are reported to have served 70,000 patients, while its projects in Bhutan and Rwanda have served 90% and 96% of all individuals targeted, respectively. Roche comes second, having reached 16,600 people infected with hepatitis B and 21,000 people with hepatitis C through one initiative linked to Pegasys® (pegylated interferon). These high numbers could reflect the fact that infection-related cancers are more widespread in developing countries, meaning higher numbers of people are eligible for such access initiatives.

Merck KGaA has linked a capacity building initiative with a biomarker test (the RAS test for CRC). Most products linked to capacity building initiatives are either medicines or vaccines.

Of the total of 13 product-linked initiatives, several address multiple cancer types: five address the prevention of cervical cancer, three target CRC, one targets breast cancer, one the prevention of hepatocellular cancer, one Hodgkin's lymphoma, one GIST, PNET, lung, renal cancer and CML, and one has no stated oncology focus.

Initiatives where product access and capacity building initiatives go together may also include pricing strategies. Such initiatives illustrate the growing trend of companies contributing to capacity building to expand global access to key products and help build health systems for cancer awareness, education care and control. In turn, this helps ensure markets can bear such products. For companies, there is an inherent business benefit to combining capacity building and pricing actions: improved health-seeking behaviour, better guidelines and greater knowledge among healthcare providers (of

disease and treatment options) can help drive sales, while also improving access to medicine – providing affordability is also addressed. There is an inherent risk that conflicts of interest will arise. Identifying and preventing such conflicts is critical – an area that needs further evaluation. Companies are expected to ensure that cancer products are made available to people, and to contribute to the development of health systems, but not to create a dependence or to monopolise a market with a single proprietary product.

General capacity building without products

Twelve companies (AstraZeneca, Bayer, Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis, Pfizer, Roche, Sanofi and Takeda) are active in general capacity building (i.e., initiatives not linked to specific products). These companies are involved in a total of 58 projects, including one combination initiative that has a pricing component as well.

Many of these 58 projects include multiple types of capacity building: 28 include awareness-raising, 45 include education/training, 16 on diagnosis, 14 on screening, 12 on prevention, five on early detection, nine on infrastructure, four on R&D capacity building, three on palliative care and pain management, one on administration (implementing medical records), and one on strengthening cancer registries. This distribution indicates the focus of pharma companies, thereby signalling that improving knowledge of cancers and health-seeking behaviour are seen as important to their businesses. The potential for conflicts of interest here challenges the notion that these initiatives are altruistic. It has been stated in literature that the gap of trust between patients and manufacturers can be bridged by disease awareness.²²

The 58 capacity building initiatives that are not linked to products focus on 13 different types of cancer. The highest proportion (20) address breast cancer. Cervical cancer comes second with six initiatives, haematologic cancers come third with five initiatives, prostate and paediatric cancer come joint fourth with four initiatives each, followed by CRC and ovarian cancer with three each. NB: as many as 18 initiatives merely list "cancer" or "NCDs including cancer" as their targets.

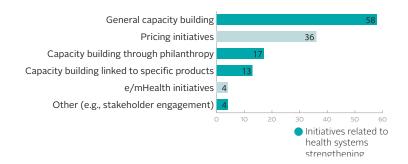
Roche is engaged in many of these general capacity building initiatives, with 21 projects, followed by Takeda with seven. Roche also reports the broadest reach among community members and healthcare professionals: its awareness and educational initiative on breast, colorectal, ovarian, lymphoma, cervical and paediatric cancer is reported to have reached 2 million people in Indonesia; its project for diagnosis, training and education on breast and gastric cancer is reported to have reached 8,820 healthcare professionals in 13 countries. Furthermore, Roche covers the highest number of cancer types: 11 different types of cancer through 19 capacity building projects. Roche is the only company with an initiative focused on ovarian and skin cancers.

Sanofi has the broadest initiative in terms of countries served: its initiative on childhood cancer reaches 28 countries. Bristol-Myers Squibb comes second in this regard, reaching 14 countries through its Secure the Future initiative, which focuses on awareness-raising and support for programmes on breast and cervical cancer in sub-Saharan Africa. Established in 1999, Secure the Future is also the longest-running initiative in this study. Sanofi and Roche have capacity building initiatives that address palliative care and pain management directly, while Takeda's initiative on Training Primary Healthcare Providers in Kenya also includes the subject of pain and palliative management in its training programs. Nonetheless, access to palliative care and pain management remain underserved by pharmaceutical companies and partners.

Eli Lilly runs an initiative for gynaecology oncology, which includes the establishment of an oncology research institute. Eli Lilly is also the only company to report that it has committed human capital to capacity building efforts: it

Figure 5. Companies' cancer access initiatives are very diverse

16 pharmaceutical companies are involved in a diverse range of cancer access initiatives in low- and middle-income countries – reporting 129 initiatives in total. The largest proportion relate to some form of health system strengthening.



deployed 13 employees to AMPATH in Eldoret, Kenya, in 2016.

mHealth/eHealth

Four companies (Eli Lilly, Merck KGaA, Roche and Pfizer) run programmes that involve mobile or digital technology (i.e., mHealth or eHealth), with a focus on education and training. From the information disclosed per programme, it is difficult to determine which could have the biggest impact. An online training programme for sub-Saharan Africa by Roche is being used by the highest number of partners (9). The initiative by Pfizer, comprising a networking and oncology education session, states it will improve the management skills and operational capabilities of more than 400 civil society organisations and patient groups throughout Mexico.

Capacity building through funding

Four companies (Bristol-Myers Squibb, GSK, Pfizer and Takeda) report that they engage in capacity building though funding. Bristol-Myers Squibb funds 13 projects, including one also funded by GSK and Takeda. Pfizer funds four projects. However, sponsorship is common within capacity building activities. At least three other companies (Eli Lilly, Johnson & Johnson and Roche) report that sponsoring is involved in certain capacity building and stakeholder engagement projects. All funding projects are focused on cervical cancer; 10 also focus on breast cancer. One programme states it focuses on "female cancers", which makes it likely to cover both breast and cervical cancer. Bristol-Myers Squibb has disclosed the levels of funding for the majority of these projects. The largest grant awarded is USD 500,000 over three years to AMREF

Health Africa for Ask4Cancer, a project on breast and cervical cancers in Ethiopia. The only initiative for which impact was reported is The Swaziland Breast and Cervical Cancer Network, which received a grant from Bristol-Myers Squibb, leading to an additional 16,000 women being screened in 2015-2016.



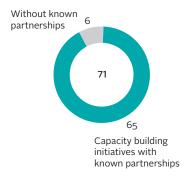
Women in Kenya queue for cervical cancer screening offered by the Novartis Healthy Family programme, known as "Familia Nawiri"

MAJORITY OF INITIATIVES INVOLVE PARTNERS

The majority (at least 65) of capacity building initiatives involve partners (see Figure 8). The partners range from international organisations (e.g., the UN, Union for International Cancer Control, Gavi the Vaccine Alliance, and WHO), to local and/or international NGOS (e.g., Pink Ribbon Red Ribbon,

Figure 8. Almost all capacity building initiatives involve partnerships

Pharmaceutical companies work with a range of partners in their capacity building initiatives, including international organisations, local and national NGOs, governments and other private sector partners. At least 65 initiatives involve partnerships.



Max Foundation), to governments, private sector partners, foundations, universities and/or non-profit organisations (e.g., Axios Internaional, V Care, Cervicusco). Two partners stand out for their wide involvement with pharmaceutical companies addressing access to cancer care: the Access Accelerated Initiative (AAI) and the Union for International Cancer Control (UICC).

The Access Accelerated Initiative is a global initiative addressing the rise of non-communicable diseases (NCDs), including cancer. Its overarching aim is to work towards the United Nations Sustainable Development Goal target to reduce premature deaths from NCDs by one-third by 2030. AAI supports on-the-ground work to improve cancer prevention, diagnosis and treatment. Fifteen companies in scope are partnering with AAI: Astellas, Bayer, Bristol-Myers Squibb, Daiichi Sankyo, Eisai, Eli Lilly, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis, Pfizer, Roche, Sanofi, and Takeda. As part of this effort, the coalition of companies will serve as a foundational partner of



Roche works with the Indonesian Ministry of Health to teach breast examinations.



AstraZeneca's Phakamisa project works with the Breast Health Foundation in South Africa to raise awareness of breast cancer.



Bayer's Go West programme helps train local physicians in rural hospitals such as this one in China.

the UICC's City Cancer Challenge (C/ Can 2025). C/Can 2025 will engage cities around the world with a population over 1 million to improve cancer treatment and care, working with specific 'learning cities' in low- and middle-income countries which require international support to develop effective, sustainable cancer care delivery for their citizens. Additionally, the World Bank Group will conduct pilots in primary care to improve NCD outcomes in several countries.

The Union for International Cancer Control is a membership-based, non-governmental organisation that is dedicated to uniting the cancer community to reduce the global cancer burden, to promote greater equity, and to integrate cancer control into the global health and development agenda. UICC works to empower voluntary cancer leagues and societies, patient support networks, and advocacy groups, through education and training in cancer policy issues, building capabilities, convening opportunities to engage governments and other stakeholders. UICC also strives to ensure all countries adopt funded and resourced National Cancer Control Plans and cancer registries. Thirteen companies in scope are partnering with UICC: AbbVie, Astellas, AstraZeneca, Bayer, Bristol-Myers Squibb, Boehringer Ingelheim, Johnson & Johnson, Merck KGaA, Merck & Co., Inc., Novartis, Pfizer, Roche and Sanofi.

Stakeholder engagement

Two companies, Johnson & Johnson and Pfizer, have organised stakeholder engagement meetings to address access to oncology. Johnson & Johnson sponsored a global cancer "hack-athon" intended to spur innovation in cancer care around the world. The company also lent human resources to the event. Pfizer has held several meetings, including an oncology innovation and treatment workshop focused on the sub-Saharan region. It has also held a training event focused on metastatic breast cancer in Africa-Middle East, and an access-to-cancer medicine meeting with several patient advocates from LMCs.

Landscape study | Access to cancer care | capacity building

Appendices

Scopes of analysis

This study analyses data collected by the Access to Medicine Foundation on large research-based pharmaceutical companies – namely, the 20 companies ranked in the 2016 Access to Medicine Index. The Access to Medicine Index is published every two years by the Foundation, and evaluates 20 of the world's largest pharmaceutical companies (by market capitalisation) according to their efforts to improve access to medicine in developing countries. This paper used the same Company Scope and Geographic Scope as the Access to Medicine Index.

The Access to Medicine Index independently ranks 20 of the world's largest pharmaceutical companies by revenue on their efforts to improve access to medicine for people living in developing countries. Funded by the Bill & Melinda Gates Foundation and the UK and Dutch governments, the Index has been published every two years since 2008. By publicly recognising companies' access-related policies and practices, the Index raises awareness of relevant issues within pharmaceutical companies and provides them with a transparent means of assessing, monitoring and improving their own performances as well as their public and investment profiles. Consistent iterations of the Index highlight industry trends and provide a basis for multi-stakeholder dialogue and solution building.

COMPANY SCOPE

The Index assesses 20 of the world's largest research-based pharmaceutical companies on their policies and practices to improve access to medicine for people living in low- and middle-income countries. Considering their size, resources, pipelines, portfolios and global reach, these companies have a critical role to play in improving access to medicine.

Company	Ticker	Stock Exchange	Bloomberg	Reuters	Country	MarketCap* (billion USD)	Revenue** (billion USD)
AbbVie Inc.	ABBV	New York Stock Exchange	ABBV:US	ABBV.N	USA	94.39	19.96
Astellas Pharma Inc.	4503	Tokyo Stock Exchange	4503:JP	4503.T	JPN	35.32	11.35
AstraZeneca plc	AZN	London Stock Exchange	AZN:LN	AZN.L	GBR	85.44	42.98
Bayer AG	BAYN	Frankfurt Stock Exchange	BAYN:GR	BAYGn.DE	DEU	117.15	56.07
Boehringer Ingelheim GmbH	n/a	n/a	n/a	n/a	DEU	-	17.68
Bristol-Myers Squibb Co.	BMY	New York Stock Exchange	BMY:US	BMY.N	USA	99.28	15.88
Daiichi Sankyo Co. Ltd.	4568	Tokyo Stock Exchange	4568:JP	4568.T	JPN	11.03	8.37
Eisai Co. Ltd.	4523	Tokyo Stock Exchange	4523:JP	4523.T	JPN	15.47	4.99
Eli Lilly & Co.	LLY	New York Stock Exchange	LLY:US	LLY.N	USA	75.97	19.62
Gilead Sciences Inc.	GILD	NASDAQ	GILD:US	GILD.O	USA	155.81	24.89
GlaxoSmithKline plc	GSK	London Stock Exchange	GSK:LN	GSK.L	GBR	113.27	37.89
Johnson & Johnson	JNJ	New York Stock Exchange	JNJ:US	JNJ.N	USA	279.80	74.33
Merck & Co. Inc.	MRK	New York Stock Exchange	MRK:US	MRK.N	USA	167.63	42.24
Merck KGaA	MRK	Frankfurt Stock Exchange	MRK:GR	MRCG.DE	DEU	43.32	14.99
Novartis AG	NOVN	SIX Swiss Exchange	NOVN:VX	NOVN.VX	CHE	245.07	58.00
Novo Nordisk A/S	NOVO B	Copenhagen Stock Exchange	NOVOB:DC	NOVOb.CO	DNK	17.85	15.81
Pfizer Inc.	PFZE	New York Stock Exchange	PFE:US	PFE.N	USA	216.67	49.61
Roche Holding AG	RO; ROG	SIX Swiss Exchange	RO:SW; ROG:VX	ROG.VX	CHE	231.16	51.88
Sanofi	SAN	EURONEXT Paris	SAN:FP	SASY.PA	FRA	132.68	44.83
Takeda Pharmaceutical Co. Ltd.	4502	Tokyo Stock Exchange	4502:JP	4502.T	JPN	40.29	16.18

*Market cap from Bloomberg & Yahoo Finance 19 Feb 2015 (Exchange rate from www. oanda.com 19 Feb 2015)

**Revenue = ttm (trailing twelve months); meaning the timeframe of the past 12 months from Annual reports 2014; for Japanese companies fiscal years from their reports in March 2015 (Exchange rate from www.oanda.com 1 Apr 2014 - 31 Mar 2015 for Japanese companies and 1 Jan- 31 Dec 2014 for others)

GEOGRAPHIC SCOPE

The geographic scope for the 2016 Access to Medicine Index comprises 107 countries. Several additional countries in the Americas have been included (Jamaica, Mexico, Panama and Peru), as well as Iran. Countries excluded include Jordan, Venezuela and Fiji, as improving socio-economic conditions have moved these countries out of the Index scope. Tonga was excluded due to a lack of

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available data. All countries defined by the World Bank as low income or lower middle-income are included. All countries defined by the UNDP as either low or medium human development are included. This ensures that several central measures of human development (life expectancy, education, and standard of living) are taken into account. All countries that receive a score of less

Middle East & North Africa	
Djibouti	LMIC
Egypt, Arab Rep.	LMIC
Iran, Islamic Rep.	HiHDI
Iraq	MHDC
Morocco	LMIC
Palestine, State of	LMIC
Syrian Arab Rep.	LMIC
Yemen, Rep.	LMIC
South Asia	
Afghanistan	LIC
Bangladesh	LMIC
Bhutan	LMIC
India	LMIC
Maldives	MHDC
Nepal	LIC
Pakistan	LMIC
Sri Lanka	LMIC
Sub-Saharan Africa	
Angola	LHDC
Benin	LIC
Botswana	MHDC
Burkina Faso	LIC
Burundi	LIC
Cameroon	LMIC
Cape Verde	LMIC
Central African Rep.	LIC
Chad	LIC
Comoros	LIC
Congo, Dem. Rep.	LIC
Congo, Rep.	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	MHDC
Eritrea	LIC
Ethiopia	LIC
Gabon	MHDC
Gambia, The	LIC
Ghana	LIC
Guinea	LIVIIC
Guinea-Bissau	LIC
Kenya	LIC
Lesotho	LMIC
Liberia	LIVIIC
Madagascar	
Madagascar Malawi	LIC LIC
Malawi Mali	
Maii Mauritania	
	LMIC
Mozambique	LIC

than 0.6 on the UN Inequality-Adjusted Human Development Index are included. This measure takes account of how health, education and income are distributed within each country. All Least Developed Countries (LDCs), as defined by the Committee for Development Policy of the UN Economic and Social Council (ECOSOC).

Namibia		MHDC
Niger		LIC
Nigeria		LMIC
Rwanda		LIC
São Torr	né and Principe	LMIC
Senegal		LMIC
Sierra Le	eone	LIC
Somalia		LIC
South A	frica	MHDC
South S	udan	LIC
Sudan		LMIC
Swazilar	nd	LMIC
Tanzania	a, United Rep.	LIC
Togo		LIC
Uganda		LIC
Zambia		LMIC
Zimbaby	we	LIC
Legend		
LIC	Low-income coun	-

Legend	
LIC	Low-income country
	World Bank income classifications
LMIC	Lower-middle-income Country
	World Bank income classifications
LDC	Least Developed Country
	UN Human Development Index
LHDC	Low Human Development Country
	UN Human Development Index
MHDC	Medium Human Development Country
	UN Human Development Index
HiHDI	High Human Development Country
	with high inequality
	UN Inequality-Adjusted Human Devel-
	opment Index
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🗌 Cour	ntries added to the 2016 Index Country
Scop	De

PRODUCT TYPE SCOPE

This paper captures access initiatives from the companies in scope relating to the following product types:

Medicines

All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, regardless of formulation, are included. Medicines used only for symptomatic relief are not included.

Therapeutic vaccines

This covers vaccines intended to treat infection.

Preventive vaccines

This covers vaccines intended to prevent infection.

Diagnostics

Diagnostic tests designed for use in resource-limited settings (cheaper, faster, more reliable, ease of use in the field) are included.

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