

# Access to mental healthcare: how should pharma companies channel their efforts?

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*More than 75% of people living with mental illness live in low- and middle-income countries<sup>i</sup>. Most receive no help – no medicines, no professional support – while they and their families battle not only against disease but also against ingrained social stigmas.*

*Effective medicines to help manage these conditions do exist. Indeed, as some of the most important products needed for any basic healthcare system, they are on the WHO's Essential Medicines List (EML). For the companies producing them, this crisis not only speaks to their responsibilities as global citizens, but also offers them a substantial new market. In other words, access to medicine for mental health patients is both a development issue and a commercial opportunity.*

*The use and development of a number of these products has been controversial. Despite this, several companies are implementing initiatives to increase access to their mental health products. Some are also involved in partnerships to reduce stigma and build local skills to help manage these diseases. The WHO and World Bank have recently called for urgent action to ensure that everyone has access to good mental healthcare. But this can only be achieved by involving the companies that produce these essential medicines. In this paper, we report on the current state of industry activities. In sharing our findings, our aim is to start a conversation to channel manufacturers' efforts in the best directions, and to identify where more can be done.*

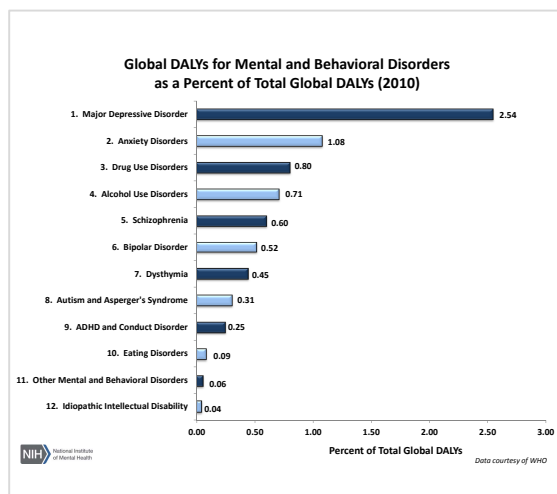
## **The public health urgency and the market opportunity**

Mental illness is the second biggest cause of death and disability in the developing world<sup>ii</sup>, and the economic burden it imposes is greater than that of cancer, diabetes and chronic respiratory diseases combined. A lack of awareness of mental health problems, the difficulty of accessing appropriate health products, poor infrastructure and poor healthcare capabilities in many countries make this a formidable challenge, and one that is often neglected. A framework to ensure

appropriate use is needed but often nonexistent in developing countries, this is important, as people who take medicines for mental disorders are more prone to developing dependence and medication abuse.

The Access to Medicine Foundation independently measures 20 of the world's largest research-based pharmaceutical companies with respect to the efforts they are making to improve access to medicine in low- and middle-income countries. These companies, which are ranked in the Access to

Medicine Index, collectively account for more than 50% of the global pharmaceutical market. This study addresses the four main types of mental illness: psychotic disorders (such as schizophrenia); depression; bipolar depressive disorder; and anxiety disorders (see Fig. 1). The market for mental health is huge. It is estimated that, in China alone, some 180 million people need access to products and services<sup>iii</sup>. Mental health is both a big business opportunity, and an urgent public health challenge.



**Figure 1.** The main cause of mental illnesses globally<sup>iv</sup>  
Source: National Institute of Mental Health

Many important milestones in the pharmaceutical industry have focused on products for treating mental illness. When Valium®, the first blockbuster, reached the market, it sold 2 billion tablets in 1978 alone. Then, in the 1990s, Prozac® became a game-changer for the industry. It became the most widely used antidepressant, and as such generated large revenues. It offered relief to patients, but attracted heavy criticism regarding its usage and effects. Many of these medicines are now off-patent and are being produced by generic medicine manufacturers. Since 2010, the number of drugs being developed for brain diseases by pharma has been cut by half. However, investments of

over US\$ 3 billion are now encouraging companies to develop brain medicines, which includes neurological and mental illnesses. This needs to be channelled to address the needs of the poor (such as more suitable products for children, and longer-lasting treatments).

In other words, global mental health is both a significant market opportunity and an urgent public health challenge needing adequate attention. There is clearly a role here for companies to ensure ethical and fair access to products, while also contributing to the development of healthcare systems.

### Access to essential products

Of the 20 largest research-based pharmaceutical companies we follow, 16 companies produce 95 mental health medicines for these diseases. Often medicines for mental disorders target more than one condition, as pathologies are closely related. Among this group of companies, 13 companies produce at least one of the products listed on the WHO Model List of Essential Medicines – the most important products for a basic health system (see Table 1 and 2).

ATMI disease scope	Product	Company examples	Brand name examples
Anxiety disorders	Alprazolam	Merck KGaA, Pfizer	Xanax®
	Chlorpromazine	Sanofi	Frisium®
	Clomipramine	Sanofi	Anafranil®
	Clonazepam	Roche	Rivotril®
	Diazepam	Roche	Valium®
	Fluoxetine	Merck KGaA, Sanofi, Eli Lilly	Deprex®
	Lorazepam	Pfizer	Temeste®
	Propanolol	AstraZeneca, Takeda	Inderal, Cardix®
Bipolar disorder	Velafaxine	Pfizer	Effexor®
	Carbamazepine	Novartis, Merck KGaA, Sanofi	Actebral®, Tegretol®
	Lithium carbonate*	Sanofi	Priadel®
Depressive disorders	Valproic acid	AbbVie, Eisai, Merck KGaA, GSK, Sanofi	Depakote®, Val.O.K.®, Depakine®
	Amitriptyline	GSK, Novartis, Takeda, Sanofi	Uxen®
	Clomipramine	Novartis	Anafranil®
Schizophrenia	Fluoxetine	Merck KGaA, Eli Lilly, Sanofi	Deprex®
	Bromperidol	Johnson & Johnson	Bromodol®
	Chlorpromazine	Sanofi	Largactil®
	Fluphenazine	Sanofi, Bristol-Myers Squibb	Modecate®
	Haloperidol	Johnson & Johnson	Haldol®, Haldol Deconoate®
	Perphenazine**	Merck KGaA	Decentan®
	Pipamperone	Johnson & Johnson	Dipiperon®
	Risperidone***	GSK, Merck KGaA, Novartis, Johnson & Johnson, Sanofi	Ridkline®, Risperdal®

**Table 1.** Medicines produced by the biggest pharmaceutical companies in the WHO Model Essential Medicines List.

\* Indicates also for Depressive disorders, \*\* indicates also for Bipolar disorder and Anxiety disorders and \*\*\*Indicates also for bipolar disorder.

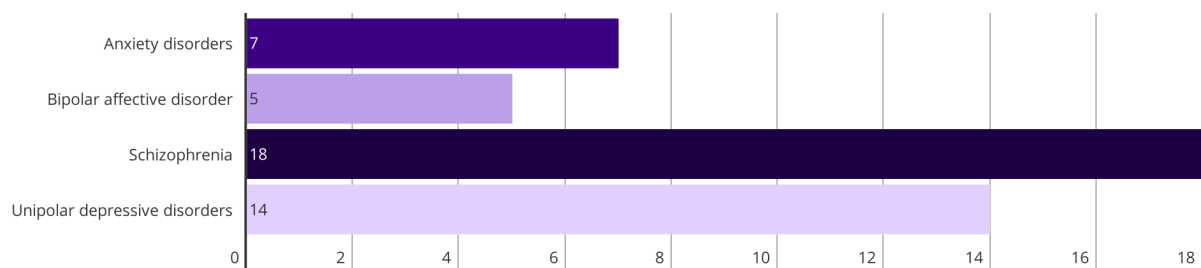
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The product portfolios of GSK, Merck KGaA, Novartis, Pfizer and Sanofi cover the most mental health conditions. Of all companies with mental health products AbbVie, Eli Lilly, GSK, Johnson & Johnson and Sanofi report initiatives that involve improving access to their products in low- and middle-income countries.

## Addressing needs in R&D

There is a need for new and improved mental health medicines in low- and middle-income countries. These include products that improve tolerance, reduce side effects, improve adherence and that are targeted to specific age groups (e.g., children). Developing medicines for mental illnesses is difficult. This is due to various factors, such as our limited

understanding of how products work in the brain, the absence of clear diagnostic markets, and the difficulty of assessing treatment response. All of these factors contribute to the high failure rates and high costs of trials. Moreover, incentives to develop medicines for use in low- and middle-income countries are limited.



**Figure 2.** There are 34 R&D projects to develop medicines for four mental illnesses (some medicines in development target more than one mental health condition, thus leading to 44 different potential treatments if these make it to market).

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There are 34 projects in the pipeline to develop medicines for these four mental illnesses. Companies such as Astellas, Johnson & Johnson, Novartis, Pfizer, Roche and Takeda and have a few projects in the pipeline for developing mental health products with the potential to reach low- and middle-income countries. These projects include the development of new and improved medicines for disorders such as depression and schizophrenia. For example, Johnson & Johnson is developing paliperidone palmitate for adults and children for schizophrenia: this includes the 2015 US FDA approval of the three-month injectable INVEGA TRINZA®. Johnson & Johnson has also declared an open innovation model that includes mental health, whereby analyses of clinical trial data are made available to others. Roche and Pfizer are working on schizophrenia.

However, just being able to develop a suitable product is not enough. Companies also need to be able to make that product accessible around the world, including in low- and middle-income countries. This is not just a public health responsibility; it is also important for a global business. Only a few companies, such as Johnson & Johnson, have disclosed plans to ensure wider accessibility in low- and middle-income countries as soon as a product

has been approved (usually in the form of registration commitments, equitable pricing and/or supply considerations).

### Ensuring access to mental healthcare products

Johnson & Johnson and Sanofi have initiatives in place to ensure access to their products, aligning these activities with, on the one hand, efforts to reduce stigma and raise awareness in communities, and, on the other hand, the training of healthcare personnel to manage and treat mental illnesses.

The most comprehensive initiative is that of Sanofi. This company's portfolio includes products such as Largactil® and Piportil L4®. Their mental health programme reports having trained over 500 healthcare workers, and conducting stigma reduction and advocacy activities across Armenia, Benin, Comoros, Guatemala, India, Madagascar, Mauritania, Morocco and South Africa. Johnson & Johnson reports large-scale initiatives covering pricing, donations and several capacity building initiatives for mental healthcare in countries such as India, China, the Philippines and South Africa. Since 2010, working with Fratelli di Carita, Johnson & Johnson has been donating products such as

Haldol®, Decanoas®, Invenga®, Topamax®, and Risperdal® for over five years. The company also supports surrounding activities, such as community building and family engagement programmes. Eli Lilly works with a partnership that donates products such as Prozac® and Zyprexa® throughout Western Kenya, with a reach of approximately 500,000 people. Finally, AbbVie has been donating Depakote® with Project HOPE to address mental illness in Kosovo via a Strategic Medical Resupply donation programme since 2011.

### **Addressing the affordability of medicines**

In low-income countries, annual spending on mental health is less than US\$ 0.25 per person<sup>v</sup> and therefore remains one of the most neglected disease categories in the health sector. Governments not only need to prioritise mental healthcare as a key priority but also to support affordability, and ensure that healthcare workers are present to counsel patients, prevent misuse and address addiction.

The pharmaceutical industry must ensure that their products are affordable, and thus provide relief to as many patients as possible. Three companies demonstrate that they are addressing the question of affordability of medicines in low- and middle-income countries. For example, GSK has an access pricing strategy for essential medicines in Yemen, and sets prices that take into account the value delivered and the ability of people to pay. Products such as Keppra® and Lamictal® to treat conditions such as depression are included. Johnson & Johnson uses equitable pricing and patient assistance programmes, and it makes products such as generic or long-acting Risperidone, Invega Sustenna® and

Invega Trinza® available to the poor. For example, Invega Sustenna® is currently registered in more than 80 countries. With several partners, Sanofi provides equitable pricing schemes in several countries, such as Benin, Bolivia, Ethiopia, Kenya, Madagascar, Mauritania and Morocco for both epilepsy (e.g. Gardenal®, Depakine/Epilim®) and schizophrenia (e.g. Largactil®, Piportil®).

### **Building capacity beyond the pharmaceutical value chain**

Even with proper treatment, psychiatric patients often do not adhere to treatment or are unstable and need rehospitalisation due to relapse episodes. Treatments combining an antidepressant and an antipsychotic are highly effective but are even less available in developing countries<sup>vi</sup>. Availability is reduced even further due to a lack of healthcare personnel able to provide regular treatment and monitoring, as well as counselling to guide proper usage, monitor side-effects and prevent addiction. The value of strengthening healthcare systems is huge, making mental health a development issue.

While it may not be a company's primary task (and, in many circumstances, there can be a conflict of interest), it is important that companies align their expertise and activities to ensure that the health system is supported. This is often done best in partnerships with NGOs. Pfizer, Novartis, AstraZeneca, Sanofi and Johnson & Johnson, for example, are active in mental health initiatives (Table 2). These include improving awareness of patients and communities, strengthening patient-doctor interactions on mental health, and training healthcare workers.

	R&D projects	Essential medicines	Access initiatives for mental health products	Capacity building activities
AbbVie		■	■	
Astellas	■			
AstraZeneca		■		■
Bristol-Myers Squibb		■		
Eisai		■		
Eli Lilly		■	■	
GSK		■	■	
Johnson & Johnson	■	■	■	■
Merck KGaA		■		
Novartis	■	■		■
Pfizer	■	■		■
Roche	■	■		
Sanofi		■	■	■
Takeda	■	■		

**Table 2.** Companies with products and initiatives in mental illness. Data obtained are reported to the Access to Medicine Foundation or from public sources.

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## Addressing stigma and increasing awareness in communities

People with mental illness often face stigma and discrimination. They also often experience high levels of physical and sexual abuse, which may occur in a range of settings, including prisons, hospitals and homes. Poor mental health is both a cause and a consequence of poverty, compromised education, gender inequality, ill health, violence and other global challenges<sup>vii</sup>. In the last 45 years, suicide rates have increased by 60% worldwide. This is related to the global increase in mental disorders, and the dire need for greater awareness and accessibility<sup>viii</sup>.

To address this issue, several companies are partnering with key organisations in awareness and stigma reduction.

Organisations such as the WHO, Grand Challenges Canada and AMREF are active in this area. South Africa Depression and Anxiety Group (SADAG), which is Africa's largest

mental health support and advocacy group, offers free counselling to support groups throughout South Africa, including in remote regions. It has several corporate sponsors. Pharmaceutical companies are also involved. For example, Novartis's programme in Malawi covers awareness, education and outreach, while Johnson & Johnson's "Healthy Minds" initiative includes disseminating information about mental health to patients. The latter company also supports national initiatives to improve public awareness of mental illness. In China, it supported a national education tour, during which over 1,000 lectures were given to address prejudices and provide assistance to those living with mental illnesses such as depression. Finally, in Indonesia, Johnson & Johnson supported a major public awareness campaign with the government aimed at changing perceptions about schizophrenia. These examples also highlight the role governments play in improving mental health in communities they represent.

The social empowerment of young people is critical when addressing mental health issues. For example, AstraZeneca worked together with PLAN, through its “Young Health Program”, to inform and empower young people in the second-poorest state in Brazil. Pfizer has been partnering with local NGOs to promote the social inclusion of children and young people by means of arts and labour qualification workshops.

### **Enhancing the capabilities of health workers**

The poor accessibility of mental health medicines and services in low- and middle-income countries is mainly due to the lack of a strong infrastructure, a shortage of trained health professionals, and a scarcity of medicines. It also relies on there being a health system in place that prioritises mental healthcare. This includes installing and using effective information systems, and addressing psychosocial issues and other barriers to treatment.

For example, Novartis partners with the WHO and the Tanzanian Training Centre for International Health, where they use a software tool with training materials about psychiatric care, counselling skills and rehabilitation. In 2015, Sanofi, with several partners, developed a telemedicine platform and patient record system to improve healthcare for patients suffering from mental illness in the Comoros.

Meanwhile, a programme called “Into the Light” is a partnership project that establishes the Philippines’ first-ever integrated mental health information system. Here, the government, Johnson & Johnson, doctors and patient groups generate data needed to

improve the treatment and health coverage of people living with mental illnesses. Johnson & Johnson also developed a “Caring for Minds” initiative around a family education toolkit, addressing issues in schizophrenia, such as how to manage the disease and cope with the burden it places on patients’ families.

Psychiatrists and caregivers use the tool to help patients and their families. Ensuring sustainable care is critical, and Johnson & Johnson has held training workshops for psychiatrists in Ghana and Kenya on epidemiology, the treatment and research environment of mental illness.

### **The need for prioritisation and collective action**

In the past, understanding the issue of access to mental healthcare and acting on it has been hindered by a lack of global attention, under-diagnosis, under-treatment and social stigmas. The opportunity to improve mental health in low- and middle-income countries is vast, and will have a tremendous impact on public health, societies and economies. Coordinated collaborative action is required from many stakeholders. What is more, several factors are now coming together that make the time ripe to ramp up efforts. First, many pharmaceutical companies currently have available essential products suitable for use in low- and middle-income countries. Second, the political will to improve global access to medicine is growing. And third, the market potential is huge. If this is now prioritised as a development issue, we can solve both a major public health challenge and ensure that it remains attractive for investment.

A number of companies have been engaged to address the accessibility of existing medicines, investing in projects to improve mental health,

and supporting wider access to mental health services. This study of the global mental health landscape shows that there are many initiatives, but they are scattered around the globe, and each covering only a few products. There are no comprehensive initiatives that fully integrate issues such as dependence and medication abuse, which are critical to ensure appropriate management of disease. Some have impact, but nowhere are they coordinated yet as a collective global action. Ideally, every initiative should be aligned with international and national priorities, and when successful, scaled up and sustained to address the needs of multiple low- and middle-income countries.

The pharmaceutical industry's approach to this development problem is to partner with local organisations and other stakeholders to strengthen healthcare systems. Most activities so far have remained as part of corporate social responsibility (CSR), providing training and awareness raising projects. We need to

engage and encourage them to do more, in an ethical and sustainable manner, beyond their own repertoire of products and really address the many issues that face the families and patients with mental illness. Mental illness requires considerable and constant investment in education, better clinical and psychological management, and access to essential medicines. Wading through the controversy around mental health products and the real fear of addiction for patients, is it time to ensure that systems are developed and to engage the producers of these medicines properly to bring relief to the millions living with mental illness around the world?

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<sup>i</sup> WHO World Mental Health Survey Consortium: Prevalence, severity, and unmet need for treatment of mental disorders in the world health organization world mental health surveys. JAMA 2004;291(21):2581–90

<sup>ii</sup> Murray, C. J. L., et al., 2012. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet, 9859(380): 2197-2223. Vos T. et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet, 380(9859): 2163-96, 2012

<sup>iii</sup> <http://www.forbes.com/sites/shuchingjeanchen/2016/01/26/mental-health-care-chinas-next-big-market/#1b10bf391afe>

<sup>iv</sup> <https://www.nimh.nih.gov/health/statistics/global/global-dalys-contributed-by-mental-and-behavioral-disorders.shtml>. Figure adapted from the WHO

<sup>v</sup> WHO. Mental Health Action Plan 2013–2020. World Health Organization, Geneva; 2013

<sup>vi</sup> Rothschild, A. 2013. Challenges in the Treatment of Major Depressive Disorder With Psychotic Features. Schizophrenia Bulletin 2013 Jul; 39(4): 787–796

<sup>vii</sup> WHO. Mental health and development: Targeting people with mental health conditions as a vulnerable group. World Health Organization, Geneva; 2010

<sup>viii</sup> WHO. Global Health Observatory, 2012