Guide to Report Cards

The Guide to Report Cards provides a description of each section of the
Report Cards for the 2020 Antimicrobial Resistance Benchmark.

Section	Description	Source
General company information (header)	Company name, Stock exchange(s), Stock exchange ticker(s), Location of headquarters, Number of employees (as FTE)	• Annual report for the fiscal year ending 31 December 2018 or later (or, equivalently, forms 10-K or 20-F) • Company website
Performance in the Benchmark (figure)	This figure shows the company's overall score.	• Benchmark analysis
Performance by Research Area (RA) (figure)	This figure shows the company's scores for each of the RAs in which it was scored.	• Benchmark analysis
How company was evaluated: (by indicator)	This figure shows the indicators that were applicable to the company.	• Benchmark Methodology Report 2019 • Benchmark analysis
Performance (text)	This section summarises the company's overall performance in the Benchmark. It covers: • Drivers behind its scores • Main areas where the company scores well or below par compared to peers	• Benchmark analysis
Sales and Operations (text)	The structure of this section varies per company type. *For large research-based pharmaceutical companies and generic medicine manufacturers:* Therapeutic areas: Therapeutic areas the company focuses on, as available in public sources, and standardised by the Benchmark across companies. Business segments: How the company is operationally organised, as presented in official company sources. Product categories: product types the company markets, as available in public sources, and standardised by the Benchmark across companies. Manufacturing and supply: Size of the company's manufacturing network for antibacterial active pharmaceutical ingredients (APIs) and drug products and reach of its antibacterial and antifungal product supply. M&A since 2018: Merger & acquisition activity since 2018 specifically relevant for antibacterial or antifungal products. *For small- and medium-sized enterprises:* Therapeutic areas: Therapeutic areas the company focuses on, as available in public sources, and standardised by the Benchmark across companies. Products on the market: Products the company currently markets. R&D grants received since 2016: Amount received and providers of R&D grants since 2016. Only the latest grant is described in detail. Financing and Investment Structure: Summary of financial information and main investments in the company. M&A since 2018: Merger & acquisition activity since 2018 specifically relevant for antibacterial or antifungal products.	• Annual report for the fiscal year ending 31 December 2018 or later (or, equivalently, forms 10-K or 20-F) • Company website • Press releases by company or pharmaceutical news websites • Stock exchange communications • Benchmark questionnaire
Revenues by product (figure)	This figure shows, where possible, a breakdown of the company's revenues in fiscal year 2018 into: antibacterial and antifungal medicines; antibacterial vaccines; other pharmaceuticals; other (non-pharmaceuticals). If such breakdown is not possible, categories are based on companies' business segments or may show only the total revenue.	• Benchmark questionnaire • Annual report for the fiscal year ending 31 December 2018 or later (or, equivalently, forms 10-K or 20-F)

Revenues by region (figure)	This figure shows a breakdown of the company's revenues by geographic region in fiscal year 2018. The categories are based on official company reports but may be aggregated. If no breakdown by region is possible, the figure shows only the total revenue. If this is the case for both the regional and product breakdowns, there is a single figure showing the total revenue.	• Annual report for the fiscal year ending 31 December 2018 or later (or, equivalently, forms 10-K or 20-F)
Pipeline (text)	This section characterises a company's R&D pipeline for priority pathogens in scope with respect to the following points: Pipeline size: Provides the number of projects in scope, including a breakdown by type. Development stages: Provides a count of the company's projects in clinical stage (listing examples), followed by a count of projects in discovery or pre-clinical stage. Novelty: Lists projects that are considered novel by the Benchmark, as per the WHO innovativeness criteria (see Sources column). Regulatory approvals: Lists regulatory approvals for projects targeting priority pathogens, as at 16 October 2019. Access plans: Provides the number of late-stage projects (i.e. Phase II onwards) that have project-specific or portfolio-wide access plans. Phase IV or technical lifecycle projects are excluded. Stewardship plans: Provides the number of late-stage projects (i.e. Phase II onwards) that have project-specific or portfolio-wide stewardship plans. Phase IV or technical lifecycle projects are excluded.	• Benchmark analysis • The WHO innovativeness criteria are listed in: World Health Organization. (2017). Antibacterial agents in clinical development: an analysis of the antibacterial clinical development pipeline, including tuberculosis. • World Health Organization. (2018). Update of antibacterial agents in clinical development. • World Health Organization. (2019). Antibacterial agents in clinical development • The Pew Charitable Trusts. Antibiotics currently in global clinical development - Sep 2019 update • The Pew Charitable Trusts. Nontraditional products for bacterial infections in clinical development - Sep 2019 update
Pipeline for priority pathogens (figure)	This figure shows, where possible, a breakdown of the company's pipeline for priority pathogens into: antibacterial vaccines; antibacterial medicines; antifungal medicines; and projects that are combinations of antibacterial and antifungal medicines.	• Benchmark questionnaire • Company website and clinical trials registries
Portfolio (text)	This section characterises a company's antibacterial and antifungal product portfolio, starting with a comparative statement on the number of products in scope, including a breakdown by type. The total number of products considers different formulations separately and the number of unique INNs is provided in brackets. The following information is also listed, as applicable: Essential medicines: number and percentage of the company's products that are on the 2019 WHO EML AWaRe medicines: number of medicines in each WHO AWaRe group for antibacterials (Access, Watch, Reserve) Anti-TB medicines: number of anti-tuberculosis medicines, including breakdown by AWaRe group Product formulation is taken into account in all categories above. The percentage of Essential medicines for a given company was calculated as the number of the company's INN and formulation pairs for which at least one marketed strength appears on the 2019 WHO EML divided by the total number of INN and formulation pairs on the company's portfolio. The classification of products as "Anti-TB medicines" follows the 2019 WHO EML. Some of the medicines in this category may not have received market approval for this indication. For products with a square box, alternative products listed on ATC/DDD Index are also treated as on EML.	• Benchmark questionnaire • Registered products identified from the EMA, FDA, and the company's website • IQVIA MIDAS® 2017 anti-infectives data • WHO EML, 21st List, 2019 (several sections, as listed in Benchmark Methodology Report 2019, Appendix II)
Products on the market (figure)	This figure shows, where possible, a breakdown of the company's marketed products in scope into: antibacterial vaccines; antibacterial medicines; antifungal medicines; and products that are combinations of antibacterial and antifungal medicines. The number of products is based on data from public sources, IQVIA MIDAS®, and data submitted by the company. It may not account for the company's entire product portfolio.	• Benchmark questionnaire • Registered products identified from the EMA, FDA, and the company's website • IQVIA MIDAS® 2017 anti-infectives data

Opportunities (text)	This section outlines opportunities for the company to do more to address AMR. The opportunities listed take into account company- specific characteristics as far as possible.	• Benchmark analysis
Changes since 2018	This section provides an update on where the company's actions to curb AMR have changed most notably since the 2018 Benchmark. It includes a selection of new or expanded commitments, strategies, activities and programmes. These may have taken place after the period of analysis and are not necessarily scored by the Benchmark.	• Benchmark analysis • Benchmark questionnaire • Public sources such as company website or press releases
Performance by RA: A. Research & Development (text)	This section summarises company performance for the RA of Research & Development, by indicator. The paragraphs describe the company's performance and highlight (where available) relevant examples of its activities. In indicator A.2.2, novelty is analysed for clinical-stage projects only and based on the innovativeness criteria defined by the WHO (see Sources column). In indicator A.2.4, the assessment is based on the number of unique candidates (i.e. unique INNs) within the projects that target critical or urgent priorities. In indicator A.4, detailed portfolio-wide or project-specific access and stewardship plans are analysed for late-stage projects only. This includes projects in clinical Phase II or III as well as projects awaiting approval or approved during the period of analysis (2017/09/09 to 2019/06/21) but not Phase IV or technical lifecycle projects. For medicine projects, the Benchmark looks at both access and stewardship plans, whereas for vaccine projects, where overuse or inappropriate use is not a concern with respect to AMR, only access plans are considered.	• Benchmark analysis • Benchmark Methodology Report 2019 • The WHO innovativeness criteria are listed in: World Health Organization. (2017). Antibacterial agents in clinical development: an analysis of the antibacterial clinical development pipeline, including tuberculosis. • World Health Organization. (2018). Update of antibacterial agents in clinical development • World Health Organization. (2019). Antibacterial agents in clinical development • The Pew Charitable Trusts. Antibiotics currently in global clinical development - Sep 2019 update • The Pew Charitable Trusts. Nontraditional products for bacterial infections in clinical development- Sep 2019 update
Pipeline targeting priority pathogens (figure)	This figure shows the company's pipeline of antibacterial and antifungal medicines and vaccines targeting priority pathogens. Phase IV projects, technical lifecycle or other projects are not shown. Where applicable, regulatory approvals (including label extensions) are noted, including the regulatory body/location and date of approval. Data omissions due to confidentiality agreements are noted. Although the figure shows the pipeline as at 16 October 2019, the analysis in the R&D Performance by RA text considers the status of projects at the end of the period of analysis, on 21 June 2019.	• Projects submitted by the company for scoring and analysis in the Benchmark, including verification/cross-reference with publicly available pipeline information. Approval data is verified using public sources, e.g. clinical trial registries or press releases by companies
Performance by RA: B. Responsible Manufacturing (text)	This section summarises company performance for the RA of Responsible Manufacturing, by indicator. The paragraphs describe the company's performance and highlight (where available) relevant examples of its activities. In indicator B.2, discharge limits published in the AMR Industry Alliance website were also considered in the assessment, despite not qualifying as disclosure via an official individual company source. In indicator B.3, two public databases were searched: the FDA inspection classification database and the EU EudraGMP database (see Sources column). For more information, see Appendix I. Results are as at 16 October 2019.	• Benchmark analysis • Official public company sources such as annual or CSR reports, policy documents or company websites • FDA inspection classification database (https://www.fda.gov/inspection-classification-database) • EU EudraGMP database (http://eudragmdp.ema.europa.eu/inspections/displayWelcome.do)

Performance by RA: **C. Access** (text)	This section summarises company performance for each Access indicator in the RA of Appropriate Access and Stewardship. The paragraphs describe the company's performance and highlight (where available) relevant examples of its activities. In indicators C.1.1 and C.2.1, "on-patent products" refers to all on-patent anti-bacterial and antifungal medicines and vaccines that the company markets. In indicators C.1.2 and C.2.2, "off-patent products" refers to a company-specific set of off-patent antibacterial and antifungal medicines based on each company's highest volume sales data globally and in 21 low income markets, as provided by IQVIA Midas® 2017 database for specific product formulations. These products were firstly derived from the 2017 WHO EML and divided into six categories: four based on the 2017 WHO AWaRe classification of Access, Watch, Access/Watch and Reserve and two for antifungals and anti-tuberculosis medicines. Indicator C.3 considers all antibacterial and antifungal medicines and vaccines in scope for this Benchmark. This indicator includes a specific analysis for forgotten antibiotics (Pulcini et al, 2012, see Sources column).	• Benchmark analysis • IQVIA MIDAS® 2017 anti-infectives data • WHO EML, 20th List, 2017 • Appendix II of the Benchmark Methodology Report 2019 • Pulcini C, Bush K, Craig WA, et al. Forgotten Antibiotics: An Inventory in Europe, the United States, Canada, and Australia. Clin Infect Dis. 2012;54(2):268-274. doi:10.1093/cid/cir838
Performance by RA: **C. Stewardship** (text)	This section summarises company performance for each Stewardship indicator in the RA of Appropriate Access and Stewardship. The paragraphs describe the company's performance and highlight (where available) relevant examples of its activities. Only antibacterial and antifungal medicines are in scope for this Research Area.	• Benchmark analysis • Public sources such as accreditation body websites or independent 3rd party websites • The AMR Register (https://amr.the-odi.org/) • AMR Industry Alliance website (https://www.amrindustryalliance.org/)