**Wockhardt Ltd**

**Small/medium-sized enterprise**

Stock exchange: NSE • Ticker: WOCKPHARMA • HQ: Mumbai, India • Employees: 5,840

**PERFORMANCE**

Wockhardt is a hybrid company with both an R&D pipeline and portfolio of marketed products, but is evaluated like a small and medium-sized enterprise. Wockhardt performs well in Research & Development when compared to other small and medium-sized enterprises in scope.

**R&D:** Wockhardt has nine antibacterial projects in its pipeline that target priority pathogens. Reports project-specific access plans for all late-stage projects.

**SALES AND OPERATIONS**

**Therapeutic areas:** Anti-infectives; Cardiovascular diseases; Dermatology; Diabetes; Pain management; Respiratory diseases

**Products on the market:** 59 antibacterial and antifungal products

**R&D grants received since 2016:** None

**Financing and investment structure:** Wockhardt is a publicly listed company. It completed its IPO in May 2004.

**M&A since 2018:** None in the antibacterial and/or antifungal sectors

**PIPELINE for diseases in scope**

**Pipeline size:** 9 projects for priority pathogens* (9 antibacterial medicines)

**Development stages:** 4 clinical projects, including levonadifloxacin, a Phase III clinical candidate for the treatment of acute bacterial skin and skin structure infections and three different types of bacterial pneumonia including hospital-acquired bacterial pneumonia, and 5 pre-clinical projects

**Novelty:** No novel clinical-stage medicine projects

**Regulatory approvals:** 0 approvals for priority pathogens

**Access plans:** 4 of the 4 late-stage R&D projects with project-specific access plans, which are all commitments to register the products in India (with registration in other access countries simultaneously) but with no information on affordability

**Stewardship plans:** No late-stage R&D medicine projects with a project-specific stewardship plan

**PORTFOLIO for diseases in scope**

Wockhardt maintains a portfolio of marketed products as well as an R&D pipeline of candidates targeting priority pathogens.

**Mid-sized portfolio:** At least 59 products (43 unique INNs): 54 antibacterial medicines; 1 antibacterial vaccine; 3 antifungal medicines; 1 antibacterial and antifungal combination

**Essential medicines:** 46% (27) products are on the 2019 WHO EML

**AWaRe medicines****: 7 Access group; 13 Watch group; 1 Reserve group

**Anti-TB medicines**: 2 (incl. 1 Watch group)

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* Bacteria and fungi that have been identified as priority R&D targets for limiting AMR, by either the WHO and/or the Centers for Disease Control and Prevention (CDC). See Appendix V.

** Listed on the 2019 WHO EML (Section 6).
OPPORTUNITIES FOR WOCKHARDT

Expand access plans for levonadifloxacin, cefepime/tazobactam, cefepime/zidebactam and nafithromycin. Wockhardt's access plans for its four projects in late stages of development (levonadifloxacin, cefepime/tazobactam, cefepime/zidebactam and nafithromycin) focus on filing for registration and availability. Wockhardt can expand its plans by taking affordability into consideration as well. For example, it can commit to implement equitable pricing strategies. Publicly share raw data from its surveillance programme ASPIRE. Wockhardt can share publicly (e.g., with the AMR Register) the raw data collected for its long-term surveillance programme ASPIRE, which focuses on nosocomial clinical infections in 16 medical centres across India.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT Evaluated: medicine & vaccine pipelines for priority* bacteria & fungi

A.1 R&D investments Wockhardt invested USD 156.1 million in Research & Development during 2017 and 2018. This figure represents its investments in the development of antibacterials and antifungals as well as medicines in other therapeutic areas. As with all other small and medium-sized enterprises (SMEs) evaluated, Wockhardt was not scored in this indicator.

A.2 No clinical-stage novel projects Wockhardt's clinical-stage medicine pipeline for priority pathogens consists of adapted and new R&D projects. It does not currently include candidates that are considered novel. However, it is developing three clinical-stage new R&D projects, including a fixed-dose combination of cefepime/zidebactam for the treatment of complicated urinary tract and intra-abdominal infections and sepsis, among others.

A.2.1 Pipeline size of nine projects Wockhardt reports nine projects targeting priority pathogens. The company focuses on antibacterial medicine development, and has four projects in clinical development, and five in pre-clinical development.

A.2.2 No clinical-stage novel projects Wockhardt's clinical-stage medicine pipeline for priority pathogens consists of adapted and new R&D projects. It does not currently include candidates that are considered novel. However, it is developing three clinical-stage new R&D projects, including a fixed-dose combination of cefepime/zidebactam for the treatment of complicated urinary tract and intra-abdominal infections and sepsis, among others.

A.2.3 Vaccines in the pipeline Wockhardt is not eligible for this indicator as it is not active in vaccine development.

A.2.4 Four candidates targeting critical and/or urgent priorities Wockhardt's clinical pipeline includes one combination medicine candidate in Phase II: cefepime/zidebactam targeting CRE and possibly CRPA and CRAB. The company's pre-clinical pipeline includes three further projects targeting critical R&D priorities for limiting AMR as identified by WHO and/or urgent priorities as identified by the US Centers for Disease Control and Prevention (CDC). These are: meropenem/WCK4234, targeting CRAB and CRPA; WCK6777, targeting CRPA; and one of its beta-lactam and non-beta-lactam combination projects, also targeting CRPA.

A.3 Intellectual capital sharing As an SME, Wockhardt was not scored for this indicator, in line with the external stakeholder consensus defined by the Foundation.

A.4 Access and/or stewardship plans for four of four projects Wockhardt has four late-stage R&D projects targeting priority pathogens. Wockhardt plans to register these projects in India and other access countries, simultaneously. However, the detailed plans do not address affordability. The company also reports that it conducts susceptibility tests for its marketed products, as well as for projects in development, which supports stewardship.

Performance by research area:

A.4 Access and/or stewardship plans

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<tr>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approval</th>
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<tr>
<td>Beta-lactam and non-beta-lactam combination project 1 - Enterobacteriaceae, certain carbapenem-resistant Pseudomonas spp.</td>
<td>Cefepime/tazobactam (WCK 4282) - Enterobacteriaceae (including ESBL-producing strains) and P. aeruginosa - Adaptation (new FDC of an approved beta-lactam and beta-lactamase inhibitor) - cUTI including pyelonephritis, cIAI, bloodstream infections, sepsis, HABP and VABP</td>
<td>Nafithromycin (WCK 4873) - Multidrug-resistant S. pneumoniae, Group A Streptococcus, S. aureus and H. influenzae - CABP</td>
<td>IV levonadifloxacin (WCK 771) &amp; oral alavondifloxacin (WCK 2340) - MRSA, VRSA, S. pneumoniae, Group A Streptococcus and H. influenzae - ABSSSI, CAB-P, HABP and VABP</td>
<td>ABSSSI = Acute bacterial skin and skin structure infection CABP = Community-acquired bacterial pneumonia cIAI = Complicated intra-abdominal infection CRAB = Carbapenem-resistant Acinetobacter baumannii CRE = Carbapenem-resistant Enterobacteriaceae cUTI = Complicated urinary tract infection ESBL = Extended-spectrum beta-lactamase FDC = Fixed-dose combination HABP = Hospital-acquired bacterial pneumonia MRSA = Methicillin-resistant S. aureus VABP = Ventilator-associated bacterial pneumonia VRSA = Vancomycin-resistant S. aureus</td>
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* Bacteria and fungi that have been identified as priority R&D targets for limiting AMR, by either the WHO and/or the Centers for Disease Control and Prevention (CDC). See Appendix V.

CHANGES SINCE 2018

- Recently received market approval for IV levonadifloxacin & oral alavondifloxacin in India.
- Involved in an AMR-related educational programme aimed at healthcare professionals (HCPs), from 2018 onwards.
- Newly reports fully decoupling incentives for sales agents from sales volumes to help prevent the inappropriate use of its antibacterial and/or antifungal medicines.
B RESPONSIBLE MANUFACTURING

As an SME, Wockhardt is not evaluated in this Research Area. It has antibacterial products on the market. The Benchmark notes that Wockhardt reports manufacturing antibacterial APIs and/or drug products at three manufacturing sites, all of which possess on-site wastewater-treatment plants. Wockhardt also reports that it is implementing an environmental risk-management strategy to minimise the impact of manufacturing discharge of antibacterial APIs and/or drug products at all three sites in a phased manner. It is unclear how this strategy considers the risk of AMR.

C APPROPRIATE ACCESS & STEWARDSHIP

As an SME, Wockhardt is not evaluated in this Research Area. It does, however, have antibacterial and/or antifungal products on the market. The Benchmark notes that Wockhardt has plans to register such products in access countries.***

Further, it has some strategies in place to mitigate conflict of interest (COI) for its AMR-related educational programme aimed at HCPs. Specifically, Wockhardt reports that it develops the content independently from its marketing department.

It also adapts sales practices to address the appropriate use of its antibacterial and/or antifungal medicines. Wockhardt reports fully decoupling incentives for sales agents from sales volumes to help prevent the inappropriate use of its antibacterial and/or antifungal medicines.

Further, Wockhardt is active in one AMR surveillance programme, ASPIRE, a long-term programme which focuses on clinical nosocomial infections in India. Wockhardt was not scored for these activities.

*** 102 low- and middle-income countries where better access to medicine is most needed. See Appendix VI.