

# India's biopharmaceutical business: an evolving success story

Over the past few decades, India has established itself as a leader in the production of high-quality, low-cost generic drugs and vaccines. More recently, India has emerged as a global leader in the production of biosimilars, which are lower-priced versions of monoclonal antibodies (mAbs) that are clinically equivalent to the original product in terms of safety, purity and potency.

In 2007, before biosimilars were approved in many countries, Dr. Reddy's Reditux (rituximab) for the treatment of lymphomas was the first Indian biosimilar to enter the market. Since then, 36 biosimilars, mostly for treating cancers and immune disorders, have been introduced in India<sup>1-13</sup>. Now, more than 100 Indian biopharmaceutical companies are investing in manufacturing and commercialising biosimilars<sup>14</sup>. Bolstered by government support and multinational partnerships, India is investing in technologies to support the development of and access to both biosimilar and innovative mAbs for a broad range of infectious and non-communicable diseases. The Department of Biotechnology (DBT) is taking steps through its National BioPharma Mission to achieve its target of capturing 5 per cent of the global biopharmaceutical market share by 2025<sup>15</sup>.

Leading Indian companies marketing biosimilars include Biocon, Lupin, Reliance Life Sciences, Zydus Cadila, Enzene and Intas<sup>16</sup>. In 2017 Biocon successfully registered Ogivri (a trastuzumab biosimilar) in partnership with Mylan, making it the first Indian company to have a biosimilar approved by the U.S. Food and Drug Administration<sup>17</sup>.

## A global leader?

Currently, the export of biosimilars from India is limited<sup>14</sup>. However, harmonisation of international regulatory and patent guidelines could help overcome barriers to export of Indian biosimilar

products<sup>18,19</sup>. India amended its patent laws in 2005 in accordance with Trade-Related Aspects of Intellectual Property Rights obligations, and in 2012, India's Central Drugs Standard Control Organisation, in collaboration with DBT, published regulatory guidelines to ensure approvals are consistent with stringent regulatory agencies (SRAs) to make it easier for Indian companies to gain approval in other jurisdictions<sup>20</sup>.

Product patents in India generally exclude secondary patent protections for novel formulations and expanded indications. This allows biosimilar mAbs to enter the market earlier there than in high-income countries, where patent extensions can delay access to biosimilars. As more blockbuster mAb products go off patent, India is looking to dominate biosimilar mAb development and manufacturing and expand international sales.

The Indian government, through DBT, is also supporting efforts to strengthen national product development capabilities. The government is supporting the development of two to three biosimilars, setting up shared facilities for process development and early stage manufacturing, characterisation, and cell-line repositories, and promoting application of indigenous technology for efficient biosimilar manufacturing<sup>21</sup>. It is anticipated that this programme will increase the production capacity of biosimilar manufacturers and increase the number of new biosimilars entering the market to address a wider breadth of diseases<sup>22</sup>.

Academic institutions are also developing new technologies to lower the cost of biosimilar production. These include efforts at the Centre of Excellence in Bioprocessing at the Indian Institute of Technology (IIT)-Delhi\* to lower the cost of biosimilar manufacturing through improvements in continuous processing and lower-cost media and resins. Similarly, an initiative at the Institute of Chemical

\*IIT-Delhi phone consultation. 1 July 2019. Phone interview conducted by IAVI.

Technology in Mumbai was set up to provide strategic and analytical support, including evaluating different expression systems and cell lines, in collaboration with leading biosimilar companies in India, including Intas Pharmaceuticals.

## Innovative mAb development

While efforts to discover and optimise innovative antibodies are more limited in India, many companies are leveraging their extensive experience in biosimilar development and manufacturing to address endemic diseases<sup>23</sup>. BIOMAb-EGFR<sup>®</sup> was India's first indigenously produced, innovative mAb. It is used to treat head and neck cancer. ALZUMAb<sup>®</sup>, the first anti-CD6 monoclonal antibody for psoriasis, is another novel mAb developed by India's Biocon.

Low-cost/high-volume pharmaceutical and vaccine manufacturers in India, including the Serum Institute of India Private Ltd., Genova Biopharmaceuticals and Sun Pharma, are also investing in both biosimilar and novel mAb development<sup>5,8</sup>. Genova Biopharmaceuticals, a subsidiary of Emcure, is researching mAbs for snakebite envenoming, which is a major burden in India, Africa and South America. Genova is collaborating with University of Delhi to utilise their indigenous naive phage display library to isolate antibodies against snakebite toxin. They are also developing innovative antibodies against human papillomavirus, dengue, chikungunya and Nipah\* viruses to address domestic health priorities. The Serum Institute of India is developing biosimilar mAbs for cancers and innovative mAbs for infectious diseases including HIV, antimicrobial resistance (AMR) and dengue virus.

The Indian government also plans to establish a programme to develop novel mAb products against HIV, snakebite envenoming and AMR (National Biopharma Mission 2019).

## Making Indian mAbs more affordable

The introduction of biosimilars can create competition that drives down mAb prices. This is particularly evident in India, where biosimilars are discounted on average by 57 per cent<sup>24-27</sup>, and increasing competition has resulted in some biosimilars being 70 per cent less expensive than the mAbs that they copy. In high-income countries,

conversely, biosimilars are typically 10 per cent to 35 per cent less than the price of innovators.

In some cases, competition from biosimilars even spurs manufacturers to reduce the price of the originator mAb to retain market share. However, even with these price reductions, mAbs remain unaffordable for much of the population and there are still no mAbs available in Indian public health systems.

To address this, DBT initiated the National Biopharma Mission programme. Its goal is making India a hub for the design and development of novel, affordable biopharmaceutical products that are widely available.

Key areas of consideration for this mission include:\*\*

- the manufacturing of indigenous high-quality, low-cost raw materials for biomanufacturing (including media and buffers)
- promoting partnerships between academic/research institutions and private industry to develop and test innovative technologies for low-cost biomanufacturing
- structured training of academic students to understand industry challenges
- establishing shared clusters/facilities dedicated to manufacturing batches of mAbs for preclinical toxicity and early clinical studies
- planning regular conventions for biopharma companies and academia to share early results on new technologies for production of low-cost biopharmaceuticals
- training regulators on the applications of new manufacturing technologies for low-cost mAbs to accelerate regulatory approval of products developed with these novel technologies.

Investments in biopharmaceuticals, including mAbs, in both the public and private sectors in India are rapidly increasing. Given this, the country is poised to be a model for addressing both global and indigenous health needs if broad and affordable access to mAbs is achieved in public health systems.

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\*Genova phone consultation. 1 July 2019. Phone interview conducted by IAVI.

\*\*Government of India, Ministry of Science and Technology, Department of Biotechnology Meeting "Adopting Modern Production Technologies for Biologicals by India Companies". March 27th 2019; New Delhi, India.

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SUPPLEMENT TO THE REPORT

## Expanding access to monoclonal antibody-based products: A global call to action

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