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(Representative image)

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Indian-manufactured generics and other drugs have significantly contributed to the growth of the Indian pharmaceutical industry through the decades and even more so during the pandemic. With immense manufacturing capacity and high export volume, **the Pharma Industry** not just contributes to the Indian economy

but net foreign exchange for the country. Having said that, the industry has promoted the betterment of the global public health outcomes by lowering the treatment costs of diseases such as **Leukaemia and Hepatitis C** through affordable therapeutics. The unceasing demand for Indian origin pharmaceutical products has enabled the industry to carve a niche for itself in the global ecosystem. In true sense, what '**Atmanirbhar Bharat**' should be as a success model.

India contributed to one-fifth of the world's exports of **generic drugs** in 2019. The country also accounts for 26% of generic drug imports in European markets and 40% in the US. Despite this, there are several misconceptions regarding the quality of Indian generics, especially in the US, which is industry's largest market. A survey conducted by WebMD in collaboration with the USFDA suggested that close to 75% of the healthcare practitioners and patients in the US believe that the quality of drugs manufactured outside the US are of lower quality. There are several such studies instituted by organizations at more local scale, limited to individual countries. While necessary, such studies which consider limited

Taking cognizance of this, a couple of years ago the Government of India launched one of the largest qualitative studies to assess the quality of drugs manufactured in India. Spearheaded by the National Institute of Biologicals (NIB), the exhaustive study spanned over two years and a project report on '*Survey on the Extent of the Problem of Spurious and Not of Standard Quality (NSQ) Drugs in India*' was released. India was one of the first countries in the world to institute such a large scale study with vast sample size.

In this context, it is extremely encouraging that the US has come forward to commission extensive and exhaustive studies to assess the quality of drugs imported. The USFDA's recently released study on '*Quality Testing of Difficult-to-Make Prescription Pharmaceutical Products Marketed in the US*' is a step in the right direction. The USFDA's report concludes that the quality of drugs imported and legally marketed in the US are on-par with those manufactured domestically. With Indian generics accounting for 36% of the sampled products and 9% of finished formulations, the drugs were marked acceptable for patient usage.

### **Why do studies and statistics matter?**

With patient centricity and quality as key tenets, the Indian pharma industry manufactures exports pharmaceutical products to more than 200 countries. India has been supplying life-saving drugs to most of the countries for decades. It is alarming for experts who work in the interest of patients to read media reports claiming India to be a hub of substandard and spurious medicines. The best way to address these misnomers is to conduct more qualitative and quantitative research studies at various capacities. Furthermore, as India is expanding and establishing its footprint in pharma markets across the world, it is imperative to evidence the reality with academic research. The country passed the highest number of USFDA inspections between 2009 and 2016 with 840 FDA inspections in 2016. Such nuances ought to be highlighted to ensure elimination of dubious reports. This is only possible if global organizations like the World Health Organization collaborate with various regulatory authorities and work towards protecting the interests of countries with robust pharmaceutical ecosystems.

### **Bridging the necessary gaps**

The high volume of drugs exported by India is an evidence that countries around the world prefer Indian-origin generics. This should also act as a trigger for the Indian government to heavily invest in the pharmaceutical industry and foster an environment conducive to nurture R&D and innovation which would translate into creation of jobs. India's total healthcare spending stands at 3.6% of GDP which is significantly lower than that of other countries. There is a need to increase the spend to at least 5% of the GDP, in the near future.

The Pandemic has provided the industry to recalibrate and leverage the use of

