Arunish Chawla â?? Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India

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Dr Arunish Chawla details the policy strategies underlying the explosive prospected growth of Indiaâ??s pharmaceutical sector to USD 120-150 billion by 2030, including rigorous adherence to international quality standards. Highlighting regulatory reforms and Indiaâ??s nuanced stance on intellectual property, Dr Chawla envisions India as a balanced player in healthcare across the world, fostering innovation while ensuring affordability. His insights underscore Indiaâ??s commitment to becoming a global pharma hub, seamlessly blending policy certainty with international collaboration to shape a more accessible and advanced healthcare future.

The Indian economy has been turbocharged in recent years and, with many multinationals now employing a â??China Plus Oneâ?? diversification strategy, it seems that India has a golden opportunity for further growth. Against this backdrop, how would you assess the prospects for the Indian pharmaceutical industry?

For starters, Indiaâ??s prospects are based on much more than â??China Plus One.â?? Indian pharma has turned a new leaf, performing excellently over the last few years to reach USD 50 billion in value, half of which is made up of exports. Indian firms are supplying quality generic medicines

which conform to global standards, and which bring down the high costs of medicines across the world. These high costs are a universal problem, not one unique to developing countries alone. Treatment costs are rising as new therapies come online, with both insurance companies and public health providers struggling to meet them.

For this reason, the US FDA and several European standards organisations are increasingly looking to India. Many of the Indian manufacturers that have already achieved economies of scale are now taking US FDA and European quality certifications and India already has the largest number of plants outside these countries that are certified to their quality standards. Additionally, we have been able to set up a network of quality institutions within our own country, which helps us achieve those standards. Going forward, you will see this industry grow by double digits to attain USD 120-150 billion in size by 2030.

All of this is in line with Prime Minister Modiâ??s vision of â??One Earth, One Family and One Future.â?• As a democratic country, we have fair open practices and â?? while I cannot say that there are no problems â?? we are addressing those problems transparently.

And another fast-rising sector is medtech, covering everything from medical devices to consumables, disposables, medical instruments, industrial machinery, and imaging devices. Moreover, next generation precision medicine therapies will also gain in importance over the coming decade. For example, we believe that regenerative AI is going to change the way in which healthcare is practised; almost all of us will have assistive precision devices or implants which are tailor-made to our own bodies. The age of smart medicine is fast approaching, and we are enacting forward looking policies and working with industry to support it.

If India is to create a truly innovative global pharma industry, how important is it that the national regulator achieves the highest levels of accreditation, in line with global gold standard bodies like the US FDA and EMA?

This is an important aim and one we have been grappling with for some time. Thankfully, the central regulator, the CDSCO, and the state regulators are now working together more closely. Additionally, we have introduced recently new quality standards, known as â??Schedule M,â?? which on par with WHO Good Manufacturing Practice (GMP) standards and almost on the level of US and EU standards. Over the next year, the entire quality framework will be upgraded, meaning that manufacturing plants will apply for Schedule M and GMP certifications in one go. This will save time, be more cost-effective, and propel the entire industry to a new level.

How might Indiaâ??s approach to medical innovation developed in other countries adjust over time? A greater openness to international innovators could have positive knock-on effects in several areas, including R&D collaborations, but global stakeholders still worry about intellectual property (IP) protection, pricing, and access times.

We are both local and global concurrently. Our aim is to provide policy certainty and we have been welcoming to foreign medtech and pharma companies to become part of the India growth story by setting up â??Make in Indiaâ?? facilities that can supply both the Indian and export markets. While doing so, we will ensure that they get a fair deal.

As far as IP is concerned, the philosophy in India is divided. We are a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), have adopted several international frameworks on this issue, and have upgraded our own IP law. However, we cannot permit the kind of

patent evergreening that can be seen in other countries which increases treatment costs for all.

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