

Interview: Pallavi Darade - Commissioner, Food & Drugs Administration (FDA), Maharashtra State, India



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Newly appointed commissioner of the Food & Drugs Administration (FDA) of the Indian state of Maharashtra, Dr. Pallavi Darade,

shares her objectives to further consolidate the FDA's positioning as a transparent, efficient and trusted regulatory institution by involving the industry in any consultation and make them an integral part of policy making.

Dr. Darade, you took office in June this year, can you introduce yourself to the international readers of Pharmaceutical Executive with reference to your background in healthcare and the mandate that you were assigned?

I have a background in medicine and prior to this I pursued a degree in law. I am in the Indian revenue services on deputation to the state government and I have completed nearly twenty years of my service as I joined at the age of 23. During my career within the state of Maharashtra, I held various positions, such as the commissioner at the Mumbai municipal corporations, I worked at the National Commission for Scheduled Tribes and currently I am the commissioner for the Maharashtra state FDA. I am very much looking forward for the upcoming three years, as my role might change again over his period of time. Maharashtra in India is the lead when it comes to any policy formulation and implementation. The government of India always holds the Maharashtra state as an example to look up to and references every policy currently in place or any initiative that we have flagged. We are one of the very progressive states in India, we lead the way.

In terms of the overall health ecosystem of the country, how does the Maharashtra FDA

collaborate with other healthcare entities, for instance, does the FDA and CDSCO consult on its processes, share expertise and know-how?

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We extensively collaborate with the central government. Most meetings are conducted between the Central Drugs Standard Control Organization (CDSCO) and the Drug Controller General of India (DCGI) and the state drug controller is obviously an integral part of the committee. Whenever we identify an issue to be tackled we highlight it to the CDSCO and we use a collaborative approach to decide what needs to be done.

How do you assess the current status of licensing and registration of products in the state of Maharashtra compared to other federal states?

In Maharashtra, we have the highest number of licenses in India and more than 80 000 people have licenses in the state itself. These comprise manufacturing units, pharmacies, medical stores and wholesalers. Maharashtra has the highest number of US FDA approved units too - 230 in total, so more than 50 percent are here. The remaining ones are WHO GMP/EMA approved. In addition to this, export of pharmaceutical products is also maximum in Maharashtra - as I am sure you are aware all the big names are in Maharashtra, like Sun pharma, Dr. Reddy's and Lupin to name a few. Around 70 percent of the pharmaceutical industry has its headquarters here. The growth of the industry exceeds the 10 percent.

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In terms of the actual evaluation procedures, how does the FDA Maharashtra evaluate different products, e.g. pharma versus medtec, and especially drug-device combinations, which can be tricky when it comes to performance assessment?

The approval of the actual drug formulations is carried out by the DCGI in Delhi. However, we ensure that the various compliances are respected as per the act right from the quality of production. We have three major laboratories in Maharashtra: one in Aurangabad, Nagpur and Mumbai, where around 6000 samples are checked as to their quality with the help of a drug scientific officer, chemists and r. scientists who look after these laboratories.

When it comes to quality, how does it differ for those drugs that get exported abroad and those catered to Indian patients?

Our quality standards are the same as the US FDA ones - we do not make any difference as such. The Maharashtra FDA as well as the DCGI, along with ensuring that drugs meet the highest quality requirements, are also the custodian of public health which is a crucial aspect for a socialist country like us. We have a big set up of administrative machinery for drug inspection across the state of Maharashtra and every division is headed by a joint commissioner. This means that we also keep a constant watch on supply of medicines, so whenever we receive complaints from the

patients or general citizens on the quality of the drug we take actions and ensure that the supply of drugs is properly maintained in medical stores. For instance, when we had the swine flu crisis we set up several meetings with companies like Hetero - which produces the swine flu drug - and we asked what their status of supply for the needed drugs was at the time and how they were ensuring that it reached the flu spot. Government has its own supply machine, too.

There is often a discussion of tension between industry and government, which may be inevitable given the different roles that they play. How does the FDA Maharashtra conduct its dialogue with industry to achieve the best outcomes for patients?

We are in constant talks with industry and we have a high degree of collaboration on this matter especially when it comes to policy measures. At the moment, we are in the process of formulating a new pharmaceutical draft policy which was to a very large extent built on the comments provided during several consultations with the industry. While it falls within the scope of responsibilities of Delhi, the central government regularly sends the drafts to us for us to integrate them with our insights which, in turn, are built on the observations and the remarks of the trade associations. Once we have gathered the material, we send everything back to the central government. I believe it is always beneficial for both parties to consult on this topic as industry is an equal partner in the ecosystem and their concerns need to be taken into account whenever we come up with new policy measures.

Can you share one or more major hot topics that the pharmaceutical industry is facing?

Of course, we do not necessarily agree on everything. For instance, a major hot topic is loan licensing, the practice according to which a company manufactures its product at other's premises or plants and then markets it under its own name. However, the new draft pharmaceutical policy document prepared by the department of pharmaceuticals, under the ministry of chemicals and fertilizers, states that loan licensing raises many quality maintenance and assurance issues. Given that 88 percent of the current industry is on loan licensing, eliminating it all would be very detrimental, so we suggested the central government to do in a faced manner.

Another concern is obviously Chinese API production - this is not a secret. For some of the APIs China has increased the price 350 percent meaning that for the small and medium units which were here over the past five years died out as industry started buying from China instead of the local market. Industry is quite concerned on this behaviour that has happened internationally. The pharmaceutical industry obviously wanted the government to intervene.

Life sciences is obviously an important industry for the Indian economy - as the FDA Maharashtra, how can you make it more attractive for companies to launch innovative medicines in this state first?

We went ahead with a huge interaction with the pharmaceutical industry to open new units in

Nagpur. We are currently in talks with pharmaceutical companies to explore investment opportunities in special economic zones (SEZ) in and around Multi-Modal International Air Cargo and Hub (MIHAN) in Nagpur which will pave the way for the development of a pharma hub in the state of Maharashtra. This is expected to complement the much-awaited Centre's policy on bulk drugs and medical devices park.

All the basic infrastructures are there, and some big names have already started to export productions like Lupin. About 20-30 percent of the pharma companies we talked to are interested, so we shall see how much out of this turns into investment.

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