Interview: Hemant Koshia – Commissioner, Food and Drug Control Administration, Gujarat, India



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Dr. Hemant Koshia, commissioner of the FDCA Gujarat, the regulatory authority of the state of Gujarat – India's leading hub for the production of pharmaceutical and healthcare products - provides insights into the global significance of the Gujarat-based pharmaceutical industry, the collaboration initiatives bolstered by the FDCA and the agency's endeavor to operate as a front runner among India's regulatory landscape.

Few external observers actually know this fact, but the state of Gujarat proudly stands as India's main pharmaceutical hub and –given the tremendous importance of the Indian industry globally – this state therefore emerges a pharmaceutical hub of global importance. Could you provide us with some details showcasing this significance?

Gujarat actually holds a long-standing history of manufacturing fine chemicals and pharmaceutical products, which goes back more than 110 years. Furthermore, the L M College of Pharmacy in Ahmedabad was established in 1947 *[the year marking the independence of India – Ed]* and therefore stands as the oldest pharmacy institute in India.

Although India's pharmaceutical industry is scattered across several hubs including Mumbai (Maharashtra state), Hyderabad (Telangana), Bangalore (Karnataka), and New Delhi, the state of Gujarat alone accounts for over 33 percent of India's pharmaceutical turnover (i.e. USD 6.7 billion in FY15-16) and 28 percent of the country's pharmaceutical exports (i.e. USD 3.6 billion in FY 15-

16).

Gujarat gathers together over 4,000 manufacturing licensees and 40 percent of India's CRAMS companies are based in our state, as well as 40 percent of the country's CROs. Among many global achievements, Gujarat stands as the largest producer of contraceptive pills in the world, and our state's pharmaceutical industry employs over 85,000 people. The state also holds more than 280 WHO-GMP compliant manufacturing facilities and accounts for 53 percent of the total medical devices manufacturers in India.

Moving forward, we do not plan to rest on our laurels and the FDCA Gujarat is playing a prominent role in sharpening the attractiveness and competitiveness of the state's pharmaceutical and healthcare industry. Every week, we review the dossiers of the companies wishing to establish and/or extend their footprints in Gujarat, and we guide them with regards the next steps and regulatory milestones they must comply with. By striving to proactively accompany the development of the pharmaceutical industry, the FDCA Gujarat undoubtedly proves that is stands as one of the most supportive regulatory agencies in the country.

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How do you ensure that Gujarat's regulatory framework is perfectly enforced and aligned with those of the most advanced markets in the world?

The ultimate objective of the FDCA is to protect and enhance the public health outcomes in the State of Gujarat and in India overall. As the State Food and Drugs Authority of Gujarat, we leave no stone unturned to ensure effective implementation of robust and legally binding regulatory mechanisms by providing strategic, tactical and operational direction and support to the Pharmaceutical and Food Industries.

Adopting the key learning from mature and developed regulatory frameworks across the globe, the Gujarat State FDCA is steadfast to achieve and sustain operational efficiency, flawless implementation of regulations, in-depth and high-science review mechanisms, self-correction mechanism and collaborative stakeholder partnerships. In this regard, we do not aim at compromising the development of the industry: backed by a favorable industrial policy, Gujarat works with the vision of "maximum governance and minimum government".

In an effort to adopt the best regulatory practices implemented in the world's most advanced ecosystems, we closely and regulatory interact with our peers from the US FDA, UK MHRA, Health Canada, and the WHO – among others.

As per the US FDA for example, we are closely working towards capacity building, training, networking and knowledge sharing through one to one meetings conducted on regular bases.

To ensure transparency, traceability, simplicity, effectiveness, efficiency, accuracy and accountability in various G2G (government to government), G2C (government to consumers), G2B (government to business) ways, the FDCA has taken many innovative initiatives encompassing e-governance, collaborative partnerships and knowledge sharing platforms gathering together international regulators, the pharmaceutical industry and the academia. As a matter of fact, a large number of these initiatives have been pioneered by the FDCA and replicated by other state's regulatory agencies across the country.

Can you highlight some of these initiatives?

Gujarat was the first state in India to set up a pioneering, cloud-based e-governance system which has since then been rolled out across 16 states, covering 70 percent of the country's population. All 3,000 pharmaceutical companies across these states are thereby linked through this digital, cost and time saving platform, thereby enhancing a direct dialogue between the industry and the regulators. To give you a better idea of its mind-blowing comprehensiveness, this unique database encompasses 250,000+ pharmaceutical and healthcare products. This initiative and the tremendous improvements it allowed prompted the Government of India to award the National e-Governance Gold Award to the FDCA Gujarat.

Among other initiatives, the FDCA Gujarat also launched India's first mobile testing lab in June 2017. The latter is able to test 450 molecules and is equipped with handheld instruments that enables on-site testing, and it also stands as an initiative that is meant be more widely developed in the future.

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What types of challenges are you facing in your mission of protecting the health and well being of the Indian population?

On the operational level, regulation enforcement remains a key area of focus for the FDCA. We must ensure that no manufacturer overlooks the regulations laid down by the different regulatory agencies, which stand as building blocks to guarantee the quality, safety and efficacy of pharmaceutical products manufactured and consumed in Gujarat. Strict actions, including license cancellation, have been implemented in the past against companies that are now abiding by the

FDCA’s requirements.

Another aspect that should not be overlooked relates to the FDCA’s commitment to combating substandard, spurious, and counterfeit medicines. According to the World Customs Organization (WCO), the fake drug market is estimated at USD200 billion, and the Gujarat FDCA pays the utmost attention to this phenomenon through our post-marketing surveillance program, which notably allows us to assess drug quality directly from retail chains.

At a strategic level, we must fully acknowledge that medical technologies are rapidly evolving but the regulations in the country seem to be keeping pace. In the last few years, gigantic efforts have been made to streamline the regulatory procedures by relaxing, rationalizing and modifying the existing provisions of the different regulatory agencies. The aim is to accelerate approvals and clearances without compromising the safety, quality and performance of the medicinal products.

Moving forward, I consider that the key priorities for India’s regulators and the Indian pharmaceutical industry alike are to build stronger quality systems and continuously achieve full compliance with current regulations, re-focus efforts on operational excellence, alternate sourcing and self-sufficiency in APIs and intermediates, and work hand-in-hand on shaping India’s future pharmaceutical regulatory framework.

What is your final message to our international readers?

As India continues year after year to entrench its position as “the pharmacy of the world”, Gujarat will be able to leverage strong growth enablers and its stringent regulatory framework to strengthen its reputation as one of the world’s leading pharmaceutical hubs. In this vein, the government of India announced in October 2016 the establishment of three pharmaceutical and healthcare clusters in our state: an API-Active Pharma Ingredients Park, a formulations hub and a medical devices cluster. Furthermore, India’s first national government medical devices laboratory will also be established in Gujarat.

To support the growth trajectory of the pharmaceutical industry and to enable accessibility, availability, and affordability of medicines, the key focus of the State Food and Drug Regulation is to further strengthen its capacities with regards to our organization’s strategy and policy, operations, and regulation enforcement. As part of the FDCA Gujarat’s threefold objective of achieving excellence, better protecting the health of the Indian citizens, and contributing to the global development of the Indian pharmaceutical industry, the FDCA will tirelessly strive to improve its processes and strengthen Gujarat’s regulatory framework moving forward.

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