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Healthcare Landscape and Drug Development

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Healthcare always has been – and is even more so today – a vital aspect of human life. The healthcare landscape continues to evolve and transform hand in hand with evolution in the medicinal product development field, now highly influenced by payer reform, technology, scientific advances, consumer demand, and more.

These new realities and challenges impact how medicinal products are developed and approved. Previously, we lacked effective treatments for many life-threatening diseases; now, despite having many more treatments available, public scrutiny of healthcare has intensified. Patients and their families want new treatments sooner with accurate and understandable information on how to use them. While this has led health authorities to support innovation and advances in science and technology, it has also increased the complexity in the global regulatory landscape.

The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) often are the regulators who first review these innovative treatments and lead the way in bringing efficacious and cost-effective treatments to the general and broader population.

In addition, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) plays a critical role in global drug development by developing guidelines based on scientific discussions among regulatory authorities and the pharmaceutical industry. ICH guidelines are updated continuously and applied by an increasing number of health authorities worldwide. The mission of ICH is to achieve greater harmonization worldwide and ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner while meeting high standards.[1]

Food and Drug Administration

FDA, an agency of the US the Department of Health and Human Services (HHS), is responsible for protecting the public health by assuring the safety, efficacy, and security of human drugs and biological products, as well as other products outside the scope of this book. FDA's mission includes advancing public health by supporting innovations that make medicines safer, more effective, and more affordable. The agency is tasked with providing the public with the accurate, science-based information they need to use medicinal products to maintain and improve their health. FDA plays a significant role in US counterterrorism efforts. The agency collaborates with other US agencies, international regulators, academia, trade associations, consumer groups, and others.[2]

Role in Global Regulatory Landscape

Many of the medicinal products consumed by people of leading nations such as the US are produced in other countries. In the US, FDA-regulated products are produced in over 130,000 facilities in more than 150 countries.[3] The agency faces challenges in determining and confirming that its standards and requirements have been applied in the manufacture, distribution, and storage of medicinal products imported into the US. Given that the manufacture of a product may involve multiple parties from different countries, there are chances for the product to be improperly formulated or packaged, contaminated, diverted, counterfeited, or adulterated. Thus, compliance and surveillance activities overseen by regulatory bodies across the product life cycle are a critical part of the drug development process.[4]

Inspections are a big part of such surveillance activities and depend on the stage of drug development. In situations where noncompliance is identified, FDA may issue one of several types of regulatory action letters, such as warning letters, administrative license action letters, and license revocation to cease practices that violate regulations and promote corrective action. If warranted, the FDA also has the authority to impose civil enforcement actions, including seizure, injunction, and prosecution.

FDA oversees the import and export of medicinal products to ensure that the FDA-regulated products comply with the requirements of the Food, Drug, and Cosmetics Act (FD&C Act) and the regulations promulgated under these statutes.[5] Imported products regulated by FDA are subject to inspection at the time of entry by the US Customs and Border Protection (CBP). Imported products not in compliance with US regulations are subject to detention. Moreover, FDA verifies with CPB a company's licensure for imports, may perform random sampling, and will issue import alerts for noncompliant products.[6] A foreign manufacturer must have a US license to import a biological product into the US.

FDA works closely with external organizations and foreign governments to promote product safety and regulatory consistency. Its efforts include:

- developing new enforcement and regulatory tools;
- conducting more foreign inspections;