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Teva's Position on Quality Manufacturing

Teva Pharmaceutical Industries Ltd (hereinafter “Teva”), including all its directors, executives, employees and subsidiary and affiliated companies, is committed to business practices that promote quality manufacturing of our medicines and ensure patient safety. As the world's leading manufacturer of generics, and with a portfolio of more approximately 3,000 medicines, we have a responsibility to ensure the safety and quality of our medicines that reach nearly 200 million people each day. At Teva, we never compromise on quality or safety because we care about supplying medicines people can trust.

We operate more than 61 manufacturing sites around the world, along with a network of 580 contract manufacturing operations (CMOs) that support the development, manufacturing and packaging of medicines. Our medicines undergo exhaustive safety monitoring and quality assurance measures at every stage of the process, from sourcing raw materials, to R&D, to clinical trials, to production and all the way through delivery and patient use. Our robust safety monitoring and quality management systems help us continuously monitor our manufacturing processes, detect and manage safety issues, prevent future issues and ensure appropriate reporting to applicable regulatory agencies in accordance with their guidelines. Teva's commitment to quality and compliance is fundamental to delivering on our mission to be a global leader in generics and biopharmaceuticals, improving the lives of patients.

Our position on quality manufacturing is part of our environmental, social and governance (ESG) strategy. It applies to all companies owned or operated by Teva, as well as our active pharmaceutical ingredient (API) suppliers and other supply chain partners.

Our Quality Manufacturing Approach and Commitments

Complying with regulatory standards: We operate in 60 countries and are committed to complying with the regulatory requirements of the countries where a biological or drug product is made and/or distributed. This includes standards defined by the International Council for Harmonization and the Current Good Manufacturing Practices (CGMP) as stipulated by all major authorities, including but not limited to, the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), UK's Medicines and Healthcare Products Regulatory Agency (MHRA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), China's National Medical Products Administration and Russia's Ministry of Health.

Implementing Corrective and Preventive Actions (CAPA): Teva has a CAPA system in place to collect and analyze information, identify and investigate product and quality problems and to take appropriate and effective corrective and/or preventive action to prevent recurrence. We monitor the execution of these actions on a monthly basis to ensure product or quality events are managed responsibly.

Adhering to our high standards: In addition to adhering to applicable regulatory requirements in all countries, we also hold our production systems and manufacturing operations to rigorous internal standards, including:

- **Right First Time (RFT) for manufacturing and packaging:** RFT is an indication of the level of process capability for our manufacturing and packaging operations. It is also related to the level of product quality.
- **Manufacturing investigation performance:** A deviation is any failure to follow documented procedures, methods, or batch records, or to operate within controlled conditions. As part of the manufacturing investigation, we monitor for various types of deviations, including recurring, human error and inconclusive deviations.
- **Laboratory investigation performance:** We conduct investigations related to analysis performed in in-house chemistry and biological laboratories for all commercial batches, but also for clinical trial supply or experimental batches, that are intended to be submitted in a registration file.
- **Stability performance:** We perform initial stability studies on submission batches and validation batches, and we conduct ongoing stability studies on commercial batches that support the expiration dates for products approved and in the market.
- **Regulatory inspection performance:** We continuously prepare for regulatory agency and/or third-party inspections that assess the compliance of sites within Teva's global network with CGMP and other relevant regulations.
- **Complaints performance:** A quality complaint is any report indicating a suspected or possible deviation from the product specification or performance (i.e., changes in, or deterioration of, the physical and/or chemical characteristics of the product or packaging). These reports may concern the product, packaging or labeling of our medical devices, biologics or drug products.
- **Annual Product Review (APR) Product Quality Review (PQR):** APR is required by regulatory agencies and/or Teva's standard. The APR/PQR includes the review of the API.

Maintaining a responsible supply chain: Teva is the leading international manufacturer of APIs—the ingredients that produce a medicine's intended effects—with more than 350 quality API products supplied to customers around the world. We also operate a network of 580 CMOs that expand the scope and breadth of our capabilities. Guided by our [Supplier Code of Conduct](#), we ensure our core values—and the principles, standards and expectations behind them—are reflected across our vast supply chain.

Governance Structure for Quality Manufacturing Management

Quality compliance is the responsibility of the Senior Vice President and Chief Quality Officer, who ensures the design, implementation and continuous improvement of Teva's Quality Management System. Teva's Global Quality Leadership Team is responsible for facilitating the development and implementation of the Global Quality Strategy across Teva.

Application of this Position

This position is endorsed by Teva's Board of Directors. We communicate this position to our employees and publicly on our website, and we share our progress in our annual ESG Progress Report.