GALDERMA

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Quality, Safety & Medical at Galderma

Our primary focus is to protect our consumers and patients by delivering the right products and ensuring their quality and safety. Our trusted premium brands, and the innovation behind them, drive our growth, and the consumers and patients we serve come first.

Product & Service Quality and Safety

Quality and Vigilance are key in our industry. As a responsible company committed to the health and safety of patients and consumers, we take the monitoring of our products' quality and safety very seriously. Vigilance activities include Pharmacovigilance, Cosmetovigilance and Materiovigilance Vigilance, hence covering our entire portfolio.

Galderma developed a collection of policies and procedures based on internationally acknowledged best practices and guidance (also known as "**GxP**" guidelines and regulations) to set the framework for a robust global quality management system, focusing on delivering safe and effective products to our consumers and patients as well as ensuring global consistency across quality processes and product safety. Our policies ensure continuous monitoring of Galderma products' risk-benefit balance to safeguard public health and patient and consumer protection. Quality processes embed "good practices", quality guidelines and regulations as described in international regulatory requirements and standard (such as "**ISO**" and "**ICH**").

Moreover, we have also deployed a state of the art auditing strategy, including a strategic regular audit program and a yearly audit program. In addition to internal Vigilance and Quality audits, we are regularly subject to inspections by health and regulatory authorities and other recognized certification organizations, which continuously ensure regulatory compliance and the highest product quality and safety at our manufacturing plants as well as the efficient distribution and supply of our products.

Managerial Responsibility for Product & Service Quality and Safety

Galderma has set up a multi-disciplinary management board (the "**Product Quality and Safety Sub-Committee**"), including – among others – the Global Head of R&D, the Global Head of Operations, the Chief Scientific Officer and the Global Heads of Quality and Safety. This sub-committee is responsible for ensuring overall product quality and patient/consumer safety, for monitoring product safety key performance indicators, for endorsing mitigation actions in case of quality/safety issues and for ameliorating our Quality Management System ("**QMS**") and monitoring its effectiveness.

Product & Service Quality and Safety Risk Assessment

We have constructed and maintain a robust Quality and Vigilance system to assess product and service quality and safety risks through a comprehensive set of policies and standard operating procedures. These documents organize integrated medical safety evaluations and risk-benefit assessments, quality risk assessments and execution of audits and also provide a framework for managing and monitoring deviations and mitigating risks.

Regular Employee Training on GxPs

All Galderma employees as well as staff acting on behalf of Galderma (permanent and temporary staff and trainees included), regardless of their location and role within Galderma, receive adequate GxP training to ensure that all Quality and Vigilance requirements are known, applied and maintained, and that all safety and quality information is properly channeled to the established Galderma network.

Regular Testing of Emergency Response Procedures to Ensure Product & Service Safety and Incident Management

In addition to clear guidelines regarding the collection, management, evaluation, correction/prevention and submission of post-marketing reports of adverse events or undesirable effects, we also have relevant guidelines for the management of major quality events and product recalls, as well as emergency response procedures. All these activities are regularly tested through mock inspections and mock recalls.

Public Reporting on Quality and Safety Issues

We encourage patients, consumers and healthcare professionals to report personal health concerns, adverse events or quality issues via this link – in doing so, you help us to ensure the quality and safety of our products.

Anti-Counterfeiting Measures and Actions

Protecting our consumers and patients also means minimizing the probability that they encounter counterfeit versions of our brands. Galderma therefore implemented several measures and undertakes targeted actions to combat counterfeits across three main pillars:

- **Brand protection:** Galderma ensures its intellectually property ("**IP**") is adequately protected in all relevant markets through trademark registrations and patent fillings. To enforce brand protection, we perform customs recordals and train customs officials to rapidly and efficiently identify IP infringements. Galderma collaborates closely with authorities to take enforcement measures such as investigations and seizures when appropriate.
- **Anti-counterfeiting:** Galderma proactively assesses product and market risks to anticipate and mitigate counterfeit threats. Specifically, it allows us to prioritize anti-counterfeit efforts on products and geographies most at risk of experiencing issues. Measures include product serialization to ensure full value chain traceability, direct and indirect (i.e., through third parties) monitoring of offline/online channels to detect potential counterfeits and takedowns to remove counterfeit products from offline/online listings. As counterfeit products is a problem that no company can solve on its own, Galderma collaborates with local/global industry organizations to share intelligence and support joint anti-counterfeiting initiatives. This includes partnering with large e-commerce platform providers to strengthen the identification and swift removal of listed counterfeit products.

- **Internal governance and procedures:** Galderma has established specific internal reporting mechanisms for suspected counterfeits. Specific Standard Operating Procedures ("**SOP**s"), a dedicated reporting mailbox and data reporting further enable timely notifications to local authorities and govern how internal checks and investigations are handled.

Galderma's position on Quality Standards and Quality Management System

Quality Standards Applied at Galderma

At Galderma, to respect high-quality standa-rd and ensure products are safe, effective and appropriate for their intended use throughout their lifecycle from early development phases until, and during, commercialization, we have embedded, in our Quality Management System, globally recognized regulations such as those published by health and regulatory authorities ("**GxP**"), the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("**ICH**") and ISO Standards.

Therefore, Galderma's Quality Management System supports the implementation of GxP from health and regulatory authorities worldwide, including, but not limited to, the U.S. Food and Drug Administration ("**FDA**"), the European Medicines Agency and SwissMedic. Implementation of GxP is guaranteed through organization, personal, process and documentation.

Note that GxP is an umbrella term, where the "G" stands for "good", the "P" for "practices" and the "x" for various regulated areas. Of the latter, the main ones applicable to Galderma are:

- Good Manufacturing Practices ("**GMP**")
- Good Distribution Practices ("**GDP**")
- Good Clinical Practices ("**GCP**")
- Good Laboratory Practices ("**GLP**")
- Good Vigilance Practices ("**GVP**")

Some regulatory requirements and GxP are also published as ISO standards, mainly for medical devices (such as ISO 13485) and cosmetics (ISO 22715/22716), and form part of Galderma's Quality Management System as well.

Galderma's Quality Management System also incorporates several ICH standards. The ICH brings together the medicines regulatory authorities and pharmaceutical industry around the world, aiming to achieve greater harmonization worldwide for the development and approval of safe, effective and high-quality medicines in the most resource-efficient manner.

Roles and Responsibilities of the Quality Functions

Within Galderma, the Quality organization has the necessary independence and objectivity in the performance of their responsibilities. The roles and responsibilities of the Quality organization comply with applicable regulations and quality standards (e.g., applicable health and regulatory authorities' regulatory requirements, ISO, Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme ("**PICs**"), World Health Organization ("**WHO**"), ICH) and are documented within controlled documents.

Each applicable local and global regulatory requirement areas in Galderma are evaluated according to an internal audit program. In addition, global and local processes are evaluated during health and regulatory authorities' inspections, notified body inspections and, when applicable, external

partner/customer audits. These quality audits and inspections are essential to ensure continued compliance with applicable local and global regulatory requirements.

Galderma is proud to hold and regularly renew all GxP and ISO certifications required from health and regulatory authorities and notified bodies to manufacture, distribute and sell medicinal products, medical devices and cosmetics in all relevant countries.