Sustainability Infosheet 2022

Product safety & quality

idorsia

Product safety, quality and compliance are key to all aspects of our work and integral to reaching our goal of delivering safe, high-quality therapies to those who need them. Our robust quality system – with processes and procedures in place such as regular audits of marketed and pipeline products, benefit-risk assessments, and other safety evaluations – is the foundation of our success.

Product safety & quality management approach

Idorsia's purpose is to discover, develop and bring more innovative medicines to patients. This puts product safety and quality among our top priorities, as reflected in our **2020 materiality assessment.**

The pharmaceutical industry is subject to stringent regulations, with specific approval and authorization procedures. This means that, from the investigational phase to commercialization, our products must satisfy the highest quality standards, and we are required to ensure that they are safe for people and the environment when used under normal conditions.

The safety and quality of our products are continuously monitored and reported in line with our robust internal policies and guidelines, as well as applicable international and local regulations.

For each investigational or marketed Idorsia drug, a cross-functional Safety Management Team (SMT) regularly reviews and assesses safety data received from a variety of sources. When a safety signal is identified, the signal management process is performed, including safety signal validation, prioritization, impact assessment, evaluation and recommendation for action. The SMT is governed by a Drug Safety Committee (DSC), which ensures that potential safety risks for any investigational or marketed product are identified as early as possible and optimally managed and communicated. The DSC reviews the safety measures/actions taken to mitigate and/or communicate risks to internal or external stakeholders as deemed necessary.

The Quality Assurance (QA) group comprises designated personnel whose focus is on ensuring product safety and quality in the product lifecycle, from research and development to commercialization. The QA group verifies compliance by conducting internal and external audits of Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and Good Pharmacovigilance Practice (GVP). The QA group ensures that adequate preventive and/or corrective actions are taken to address audit findings in order to ensure full compliance with international regulations.

The QA group's main goal is to implement, maintain, ensure and continuously improve the development, manufacturing and distribution of high-quality products, as well as patient safety protection throughout the entire product lifecycle. Idorsia's management is regularly informed about the results of Quality Assurance activities. The global Drug Regulatory Affairs (DRA) group is responsible for preparing and submitting regulatory dossiers to health authorities with the aim of obtaining approvals for conducting clinical trials and marketing medicinal products.

We base our decisions on robust scientific evidence, as well as applying the precautionary principle, meaning that we adopt conservative measures when scientific evidence about an environmental or human health hazard is uncertain.

Product safety & quality

Assessment of the health and safety impacts of product and service categories

We are fully committed to safety and quality in the manufacturing, packaging and testing of all our products, from the investigational phase through to marketed products. We adhere to current and new regulations set out by health authorities regarding product safety and quality throughout the product lifecycle. To ensure patient safety, we strive to exceed applicable regulatory authority requirements for current Good Manufacturing, Distribution, Clinical, Laboratory and Pharmacovigilance Practices.

Product safety and quality audits

We carry out regular audits at all our manufacturing sites, laboratories and contract manufacturing organizations (CMOs) to ensure the highest safety and quality standards are being met, and that the harmonized processes and procedures we have put in place are being followed. We are also subject to regular inspections by health authorities in all countries in which we operate (e.g. Swissmedic in Switzerland) to ensure compliance with applicable regulations.

Suppliers

When it comes to the quality and safety of our products, we are committed to ensuring that all suppliers share our internal standards as well as meeting regulations. To ensure product safety and quality, all potential new suppliers for our products must undergo a due diligence process. If the outcome is positive, suppliers are required to sign a quality agreement which, among other things, requires them to notify Idorsia of any changes or issues relating to the products. If Idorsia is notified of any changes, a designated team will assess the impact and decide whether any corrective or preventive measures are required.

Regular audits are carried out to ensure that all conditions are being met. Idorsia does not knowingly engage with suppliers who are non-compliant with health regulations.

To discover more about how we ensure quality in our supply chain, see our **Supply Chain Management info sheet.**

Training

Effective and timely training of our employees is recognized by Idorsia as fundamental to ensuring the ongoing quality of business activities, including research, development, manufacturing and drug distribution. Frameworks and policies are provided to ensure that employees undergo appropriate training to meet both internal and external requirements (GxP) and have the necessary opportunities for personal development.

All employees or persons involved in tasks that may have an impact on product quality or patient safety must be qualified and trained to perform their assigned function in accordance with internal standards, regulations and other relevant safety or GxP requirements. Examples of these include training on the Adverse Event Reporting Policy and the GxP Quality Policy.

New employees joining the company may not perform unsupervised work until they have completed all the necessary training and are considered competent by their line manager to perform the task without supervision. Training is appropriately documented in individual training records. Idorsia regularly carries out audits of training programs of employees, third-party suppliers and service providers.

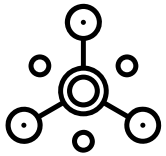
Product labeling

By law, product labeling must reflect the most up-to-date results of safety evaluations and overall benefit-risk assessments, as well as provide information on the safe use and disposal of the product. Any change in product safety labeling is submitted to health authorities for approval, and the approved labeling changes must be promptly implemented by all Idorsia affiliates.

In the event of a recall of a commercial or investigational medicinal product, Idorsia follows strict internal standard operating procedures, which include informing relevant stakeholders and notifying health authorities.

More information on our approach to product stewardship and responsible marketing can be found in our **Compliance & Business Ethics info sheet.**

About this report



Company profile

Headquartered in Allschwil, Switzerland – a European biotech hub – Idorsia is a high-potential biopharmaceutical company, specialized in the discovery, development and commercialization of innovative small molecules, with the aim of transforming the horizon of therapeutic options. The company has an experienced team of over 1,300 highly qualified professionals covering all disciplines from bench to bedside, and commercial operations in Europe, Japan, and the US – the ideal constellation for bringing innovative medicines to patients.

We are committed to achieving our ambitious goals in an economically, socially and environmentally responsible manner, and, as the company grows, our commitment to sustainability remains as important as ever.

We have a diversified and balanced clinical development pipeline covering multiple therapeutic areas, including CNS, cardiovascular and immunological disorders, as well as orphan diseases. Two Idorsia products are commercially available – QUVIVIQ™ (daridorexant) in the US and Europe, and PIVLAZ® (clazosentan) in Japan.

Idorsia Ltd is the Group's holding and finance company, with 14 subsidiaries across Europe, Asia and the US. Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017.

About our sustainability reporting

The information contained in this info sheet covers the period from January 1, 2020 to December 31, 2022 and pertains to all significant locations of operation. In the context of its sustainability reporting, Idorsia considers significant locations of operation to be those with more than 20 permanent employees. Currently, this includes locations in Switzerland, the US and Japan. Any deviations from this reporting framework are indicated on a case-by-case basis.

The content of our sustainability reporting is aligned with the results of a materiality assessment and references the internationally recognized guidelines of the **Global Reporting Initiative (GRI).**

For the full set of ESG info sheets, visit **www.idorsia.com/sustainability**

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