

PHARMACOVIGILANCE POLICY

1- Introduction

This Policy establishes the principles for the appropriate management of the Pharmacovigilance duties and responsibilities within the Company and shall be applicable to all employees in Almirall.

Almirall maintains one single Pharmacovigilance system that is common for all Almirall group of companies and staff.

The main objective is to establish an effective Pharmacovigilance system, based on Good Pharmacovigilance Practices, in order to ensure that adequate and updated safety information with the best quality is available to Almirall, in order to inform Authorities, Healthcare Professionals and Patients as necessary, according to the applicable international and local regulations and guidelines.

This Pharmacovigilance System will involve the following processes: (i) capture and processing of Pharmacovigilance information, (ii) analysis of Pharmacovigilance information, and (iii) reporting to Regulatory Authorities and to appropriate receptors the required and requested Pharmacovigilance information.

These processes will be performed with the best quality possible and with the aim of fulfilling the regulatory timelines

2- Principles

The Pharmacovigilance Policy is based on all applicable international regulations in the pharmaceutical industry and covers all Almirall products along its life cycle.

All the Directors and managers of the company will ensure that the company adopts this Policy, and provides the resources needed to achieve its objectives.

All members of relevant staff at Almirall must receive adequate Pharmacovigilance training to ensure that all the safety information is properly channeled to the Almirall safety network.

Corporate Drug Safety department will be responsible for the design, planning and implementation of such training at corporate level. At local level, the responsibility falls under the Pharmacovigilance responsible of the corresponding Almirall affiliate.

Barcelona, May 6, 2021