PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN - IMODIUM® (Loperamide Hydrochloride [HCl])

Summary of Risk Management Plan for IMODIUM® (Loperamide Hydrochloride [HCl])

This is a summary of the Risk Management Plan (RMP) for IMODIUM (also known as IMOSEC®) The RMP details important risks of IMODIUM, how these risks can be minimized, and how more information will be obtained about IMODIUM's risks and uncertainties (missing information). IMODIUM's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how IMODIUM should be used.

Important new concerns or changes to the current ones will be included in updates of IMODIUM's RMP.

I. The Medicine and What it is Used For

IMODIUM is authorized for the symptomatic control of acute and chronic diarrhea. In patients with an ileostomy it can be used to reduce the number and volume of stools and to harden their consistency (see SmPC for the full indication). It contains loperamide HCl as the active substance and it is given by orally by capsules (1 or 2 mg), tablets (2 mg), granules (0.5 mg/g [0.05%] or 1 mg/g [0.1%]), oral solution (2 mg/10 mL), oral liquid (2 mg/15 mL), and orodispersible fast dissolving tablets (2 mg).

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of IMODIUM together with measures to minimize such risks and the proposed studies for learning more about IMODIUM's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of IMODIUM is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

There are no important identified risks, important potential risks, or missing information for IMODIUM.

II.B. Summary of Important Risks

There are no important identified risks, important potential risks, or missing information for IMODIUM.

II.C. Postauthorization Development Plan

II.C.1. Studies Which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of IMODIUM.

II.C.2. Other Studies in Postauthorization Development Plan

There are no studies required for IMODIUM.