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

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

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

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

I. The Medicine and What it is Used For

IMODIUM PLUS is authorized for:

- The control of acute diarrhea of any cause and its commonly associated symptoms. These are often attributed to "trapped wind" and include abdominal discomfort, bloating, cramping and flatulence.

See country/territory-specific SmPCs for the full indications. It contains loperamide HCl in combination with simethicone (loperamide HCl/simethicone) as the active substance and it is given by oral caplets (2 mg loperamide HCl and simethicone).

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

Important risks of IMODIUM PLUS together with measures to minimize such risks and the proposed studies for learning more about IMODIUM PLUS'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 PLUS 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 PLUS.

II.B. Summary of Important Risks

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

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 PLUS.

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

There are no studies required for IMODIUM PLUS.