PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Clindamycin 10 mg/g + Benzoyl Peroxide 50 mg/g Gel (herein referred as Clindamycin and Benzoyl Peroxide Gel):

This is a summary of the risk management plan (RMP) for Clindamycin and Benzoyl Peroxide Gel. The RMP details important risks of Clindamycin and Benzoyl Peroxide Gel, how these risks can be minimised, and how more information will be obtained about Clindamycin and Benzoyl Peroxide Gel's risks and uncertainties (missing information).

Clindamycin and Benzoyl Peroxide Gel's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Clindamycin and Benzoyl Peroxide Gel should be used.

Important new concerns or changes to the current ones will be included in updates of Clindamycin and Benzoyl Peroxide Gel's RMP.

I. The medicine and what it is used for

Clindamycin and Benzoyl Peroxide Gel is indicated for the topical treatment of mild to moderate acne vulgaris, particularly inflammatory lesions, in adults and adolescents aged 12 years and above.

Clindamycin and Benzoyl Peroxide Gel contains clindamycin phosphate and hydrous benzoyl peroxide as the active substances and it is applied on the skin.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Clindamycin and Benzoyl Peroxide Gel, together with measures to minimise such risks and the proposed studies for learning more about Clindamycin and Benzoyl Peroxide Gel's risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised 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 (e.g. with or without prescription) can help to minimise its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including periodic safety update report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Clindamycin and Benzoyl Peroxide Gel are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Clindamycin and Benzoyl Peroxide Gel. Potential risks are concerns for which an association with the use of this medicine is possible based on available

data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	• None
Important potential risk	• None
Missing information	• None

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal product *"Clindoxyl".*

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Clindamycin and Benzoyl Peroxide Gel.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Clindamycin and Benzoyl Peroxide Gel.