PART VI- Summary of the risk management plan

This is a summary of the risk management plan (RMP) for <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges. The RMP details important risks of <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges, how these risk can be minimized, and how more information will be obtained about <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges´risks and uncertainties (missing information).

<Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges should be used.

Important new concerns or changes to the current ones will be included in updates of <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges's RMP.

I. The medicine and what it is used for

<Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges are authorised for relief of symptoms of sore throat in adults and adolescents over 12 years of age (see SmPC for the full indication). They contain Lidocaine hydrochloride monohydrate, Amylmetacresol and 2, 4-Dichlorobenzyl Alcohol as active substances and they are given by oromucosal use.

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

Important risks of <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges, together with measures to minimise such risks and the proposed studies for learning more about <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges ' 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 package leaflet 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 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 <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges. 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 risk and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

Summary of safety concerns

II.B Summary of important risks

The safety information in the proposed Product Information is aligned with the reference medicinal product.

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 <Product name> mint lozenges, <Product name> orange lozenges and <Product name> honey-lemon lozenges.

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

There are no studies required for <Product name> mint lozenges, <Product name> orange

lozenges and <Product name> honey-lemon lozenges.