PART VI. SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Champix [1]

This is a summary of the RMP for Champix. The RMP details important risks of Champix, how these risks can be minimised, and how more information will be obtained about Champix's risks and uncertainties (missing information).

Champix's SmPC and its Patient Information Leaflet (PIL) give essential information to Healthcare Professionals and patients on how Champix should be used.

This summary of the RMP for Champix should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The Medicine and What It Is Used For

Champix is authorised for treatment of smoking cessation in adults (see SmPC for the full indication). It contains varenicline tartrate as the active substance and it is given by oral route of administration.

Further information about the evaluation of Champix's benefits can be found in Champix's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/champix

II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Champix, together with measures to minimise such risks and the proposed studies for learning more about Champix'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 PIL 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;

[1] Changes are considered important if they relate to the following: new safety concerns or important changes/removal to a known safety concerns, major changes to the pharmacovigilance plan (e.g. addition of new studies or completion of ongoing studies), any 'additional risk minimisation measure' which is added or removed, routine risk minimisation activities recommending specific clinical measures to address the risk.

- The medicine's legal status — the way a medicine is supplied to the public (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 events is collected continuously and regularly analysed, including 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 Champix not yet available or limited, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of Champix 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 Champix. 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).

Table 1. List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	• Use in Patients with CVD • Use in Pregnancy

CVD = Cardiovascular Disease

II.B. Summary of Important Risks and Missing Information

Table 2. Missing Information: Use in Patients with CVD

Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.4 (Special warnings and precautions for use) and Section 5.1 (Pharmacodynamic properties); PIL Section 2 Additional risk minimisation measures: none

Table 3. Missing Information: Use in Pregnancy

Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.6 (Fertility, pregnancy and lactation) and Section 5.1 (Pharmacodynamic properties); PIL Section 2 Additional risk minimisation measures: none

II.C. Post-Authorisation Development Plan

Studies which are conditions of the MA.

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 Champix.

II.C.2. Other Studies in Post-Authorisation Development Plan

There are no studies required for Champix.