Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) codeine camphosulphonate / sodium benzoate, codeine camphosulphonate / sulfogaiacol / grindelia soft extract the scientific conclusions are as follows:

Codeine as an opioid exposes users to risks of dependence, abuse, and misuse, which are classified as important identified risks. These risks are currently not adequately addressed in the product information. Therefore, product information update is required to warn prescribers and patients about potential for drug abuse, misuse and dependence.

The PRAC concluded that the product information of products containing codeine camphosulphonate / sodium benzoate, codeine camphosulphonate / sulfogaiacol / grindelia soft extract should be amended accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for codeine camphosulphonate / sodium benzoate, codeine camphosulphonate / sulfogaiacol / grindelia soft extract the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing codeine camphosulphonate / sodium benzoate, codeine camphosulphonate / sulfogaiacol / grindelia soft extract is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing codeine camphosulphonate / sodium benzoate, codeine camphosulphonate / sulfogaiacol / grindelia soft extract are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

The following changes to the product information of medicinal products containing the active substance codeine camphosulphonate / sodium benzoate, codeine camphosulphonate / sulfogaiacol / grindelia soft extract are recommended (new text **underlined and in bold**, deleted text ~~strike-through~~):

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

Dependence, abuse and misuse

Neo-codion contains codeine whose regular or prolonged use may produce psychological and physical dependence. This product should be used with caution in patients with current or past history of substance abuse or dependence (including drug or alcohol) or mental illness (e.g., major depression). Abuse or misuse may result in overdose and/or death (see Section 4.9). ~~Prolonged treatment at high doses can lead to a dependence state.~~

Package Leaflet

2. What you need to know before you take Neo-codion

Warnings and precautions

Talk to your doctor or pharmacist before taking Neo-codion:

- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances

Taking codeine (an active ingredient of this medicine) regularly for a long time can lead to addiction and misuse, which may result in overdose and/or death. Do not take this medicine longer than needed. Do not give this medicine to anyone else.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	1 November 2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	31 December 2020