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) for delapril / manidipine, delapril / indapamide, the scientific conclusions are as follows:

Based on the review of data on safety and efficacy by the Lead Member State and taking into account any comments provided by the PRAC, the PRAC considers that the risk-benefit balance of medicinal products containing the active substance delapril / manidipine, delapril / indapamide remains unchanged but recommends that the terms of the marketing authorisation(s) should be varied as follows:

Update of section 4.8 of the SmPC of the combination delapril / indapamide to add the adverse reactions disgeusia/ageusia and loss of consciousness/syncope with a frequency not known. Furthermore, section 4.8 of the SmPC of the same FDC should be updated to remove a statement concerning the association with significant variations in serum potassium levels. The Package leaflet is updated 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 delapril / manidipine, delapril / indapamide the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing delapril / manidipine, delapril / indapamide 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 delapril / manidipine, delapril / indapamide 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)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~).

Summary of Product Characteristics

- Section 4.8

[The following text should be deleted as follows]

[…]

~~*"Unlike ACE inhibitors and thiazide diuretics used in monotherapy, the fixed combination has not been associated with significant variations in serum potassium levels*~~".

[The following adverse reactions should be added under the SOC gastrointestinal disorders with a frequency 'not known']

dysgeusia / ageusia

[The following adverse reactions should be added under the SOC nervous system disorders with a frequency 'not known']

loss of consciousness / syncope

Package Leaflet of delapril / indapamide containing products

- Section 4: Possible side effects

[The following adverse reactions should be added as follows]

Not known side effects (frequency cannot be estimated from the available data)

[…]

Impaired sense of taste (dysgeusia)

Inability to taste (ageusia)

Loss of consciousness / fainting

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	March 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	22 April 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	21 June 2018