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 metoprolol, the scientific conclusions are as follows:

In view of available data on the risk of severe hypoglycaemia with the concomitant use of sulfonylureas from the literature and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between the increased risk of severe hypoglycaemia and the concomitant use of metoprolol and sulfonylureas is at least a reasonable possibility. The PRAC concludes that the product information of medicinal products containing metoprolol should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for metoprolol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing metoprolol is unchanged subject to the proposed changes to the product information.

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

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 4.4

The following warning should be added to the existing paragraph regarding diabetes mellitus/glucose metabolism:

Beta-blockers could further increase the risk of severe hypoglycaemia when used concurrently with sulfonylureas. Diabetic patients should be advised to carefully monitor blood glucose levels (see Section 4.5).

- Section 4.5

The following interaction should be added to the existing paragraph regarding antidiabetic products:

The concomitant use of beta-blockers with sulfonylureas could increase the risk of severe hypoglycaemia (see Section 4.4).

Package Leaflet

Section 2

Other medicines and <X>

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

The following update should be added to the existing paragraph regarding diabetes mellitus/antidiabetic products:

[X] could increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	05 January 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 February 2026