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 bisoprolol, the scientific conclusions are as follows:

In view of the available data from the literature on the risk of hypoglycaemia with concomitant use of β-blockers with sulfonylureas and consistent with the PRAC conclusions from bisoprolol / hydrochlorothiazide PSUSA (PSUSA/00000420/202411), hydrochlorothiazide / nebivolol PSUSA (PSUSA/00001658/202311), nebivolol PSUSA (PSUSA/00002129/202403) and timolol (PSUSA/00010432/202410), the PRAC considers that a causal relationship between the increased risk of hypoglycaemia and the concomitant use of β-blockers and sulfonylureas is at least a reasonable possibility. The PRAC concludes that the product information of products containing bisoprolol should be amended accordingly. Taking into account the already existing wordings in some nationally authorised products, the text may need to be adapted by marketing authorisation holders to individual products.

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 bisoprolol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing bisoprolol 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 existing warning should be amended as follows:

…may mask the symptoms of hypoglycaemia. **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 existing information on the interaction with antidiabetics should be amended as follows:

Concomitant use with insulin and oral antidiabetic drugs may lead to the intensification of the blood sugar lowering effects of these drugs. **The concomitant use of beta-blockers with sulfonylureas could increase the risk of severe hypoglycaemia.** Symptoms of hypoglycaemia may be masked by beta-blockers **(see section 4.4).**

Package Leaflet

The existing information on the interaction with antidiabetics should be amended as follows:

- Other medicines and <Invented name>

In particular, tell your doctor if you are taking any of the following:

- Insulin or medicines that you take by mouth for diabetes **including sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide). Bisoprolol could increase the risk of severely low blood glucose levels when used with these medicines.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 August 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 October 2026