

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 atenolol, the scientific conclusions are as follows:

In view of available data on risk of hypoglycaemia with concomitant use with sulfonylureas from the literature, and, in view of a plausible mechanism of action, the PRAC considers a causal relationship between the increased risk of hypoglycaemia, and the concomitant use of beta-blockers and sulfonylureas is at least a reasonable possibility. The PRAC concluded that the product information of products containing atenolol 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 atenolol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing atenolol 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, in particular, tachycardia. **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, particularly tachycardia, may be masked (see section 4.4).

Package Leaflet

- Warnings and Precautions

The existing warning should be amended as follows:

You have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster. **Atenolol could also 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).**

- Other medicines and....

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

Insulin or medicines that you take by mouth for diabetes **such as drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)**

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	October 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	30 November 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	29 January 2026