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 fenoterol (respiratory indications), the scientific conclusions are as follows:

In view of available data published in the scientific literature including clinical trials and large population-based observational studies on short-acting beta-2 agonist use, and in view of a plausible mechanism of action, the PRAC Lead Member State considers that overuse of fenoterol-containing reliever medication is significant and associated with deteriorating asthma control and the risk of life-threatening asthma exacerbations. Furthermore, providing asthma patients solely with fenoterol-containing reliever medication leaves the underlying inflammatory condition untreated and exposes patients to fenoterol overuse with its untoward consequences. Risks of fenoterol overuse should be re-emphasized for patients and healthcare professionals including a recommendation against fenoterol monotherapy in intermittent/mild asthma. The PRAC Lead Member State concluded that the product information of products containing fenoterol 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 fenoterol (respiratory indications) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing fenoterol (respiratory indications) 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 fenoterol (respiratory indications) 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 (pressurised inhalation, solution)

- Section 4.4

The existing warning should be replaced with the new wording as follows:

~~Particular warning for regular use~~

- ~~On demand (symptom-oriented) treatment is preferable to regular use.~~
- ~~Patients must be evaluated for the addition or the increase of anti-inflammatory therapy (e.g. inhaled corticosteroids) to control airway inflammation and to prevent long-term lung damage.~~

~~If bronchial obstruction deteriorates it is inappropriate and possibly hazardous to simply increase the use of beta2-agonist containing drugs such as BEROTEC. Beyond the recommended dose over extended periods of time. The use of increasing amounts of beta2-agonist containing products like BEROTEC on a regular basis to control symptoms of bronchial obstruction may suggest declining disease control. In this situation, the patient's therapy plan, and in particular the adequacy of the anti-inflammatory therapy, should be reviewed to prevent potentially life-threatening deterioration of disease control.~~

Patients who are prescribed regular anti-inflammatory therapy should be advised to continue taking their anti-inflammatory medication even when symptoms decrease and they do not require <invented name>.

If a previously effective dosage regimen no longer gives the same symptomatic relief, the patient should seek medical advice as soon as possible as this could be a sign of worsening asthma and warrants a reassessment of the asthma therapy.

Overuse of short-acting beta-agonists may mask the progression of the underlying disease and contribute to deteriorating asthma control, leading to an increased risk of severe asthma exacerbations and mortality.

Patients who take more than twice a week "as needed" fenoterol, not counting prophylactic use prior to exercise, should be re-evaluated for proper treatment adjustment as these patients are at risk for overuse of fenoterol.

Package Leaflet

Section 3: How to use <invented name>

<Invented name> should be used as required rather than regularly.

Seek medical attention right away if your asthma symptoms (cough, breathlessness, wheezing or tight chest) are getting worse or if you are too breathless to speak, eat or sleep.

If you use <invented name> more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., "inhaled corticosteroid", it is important to continue using it regularly, even if you feel better.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 July 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	7 September 2023