

## **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 clenbuterol, the scientific conclusions are as follows:

In view of available data on the serious health risks associated with clenbuterol drug abuse from the literature and spontaneous reports and in view of the serious and potentially life-threatening or fatal consequences of such use, the Lead Member State (LMS) considers that warnings in the Summary of Product Characteristics of clenbuterol should be introduced to raise awareness of serious health risks and discourage such a behaviour. The LMS concluded that the Package leaflet of products containing clenbuterol 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 clenbuterol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing clenbuterol 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 clenbuterol 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 4.4

A warning should be amended as follows:

**Abuse of [product name] may result in severe, potentially life-threatening side effects and is to be discouraged (see also section 4.9). Fatal outcomes even in young adults have been observed following abuse of clenbuterol with other appearance-enhancing and performance-enhancing drugs.**

- Section 4.9

The signs and symptoms of overdose should be amended as follows:

**[...]**

**Life-threatening and fatal outcomes have been observed following abuse of clenbuterol particularly when used in combination with other appearance and performance enhancing drugs.**

### Package Leaflet

2. What you need to know before you are given [product name]

Warnings and precautions

**You should not abuse [product name] because it carries serious, potentially life-threatening, health risks. See also section "If you take more [product name] tablets than you should".**

3. How to take [product name]

**Do not take more [product name] than you should, since you may experience serious, life-threatening and fatal outcomes.**

### **Annex III**

#### **Timetable for the implementation of this position**

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|  |                       |
|--|-----------------------|
| 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): | 07 September 2023     |