Annex III

Amendments to relevant sections of the summary of product characteristics and package leaflets

Note:

These amendments to the relevant sections of the Summary of Product Characteristics, labelling and package leaflet is the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

A. Summary of Product Characteristics

[For all products in Annex I, the existing product information shall be amended (insertion, replacement or deletion of the text, as appropriate) to reflect the agreed wording as provided below]

[…]

4.4 Warning and precautions

[…]

[The below paragraph should be reflected in this section for all ambroxol- and bromhexine-containing medicinal products]

There have been reports of severe skin reactions such as erythema multiforme, Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and acute generalised exanthematous pustulosis (AGEP) associated with the administration of <active substance>. If symptoms or signs of a progressive skin rash (sometimes associated with blisters or mucosal lesions) are present, <active substance> treatment should be discontinued immediately and medical advice should be sought.

[…]

4.8 Adverse events

[…]

[The following adverse events should be listed in this section for all ambroxol- and bromhexine-containing medicinal products]

Immune system disorders

Rare: hypersensitivity reactions

Not known: anaphylactic reactions including anaphylactic shock, angioedema and pruritus

Skin and subcutaneous tissue disorders

Rare: rash, urticaria

Not known: Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalized exanthematous pustulosis).

[…]

[The following sub-heading should appear at the end of this section]

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via *[the national reporting system listed in Appendix V*]*.

[…]

B. Package Leaflet

[For all products in Annex I, the existing product information shall be amended (insertion, replacement or deletion of the text, as appropriate) to reflect the agreed wording as provided below]

[…]

2. What you need to know before you take <active substance>:

[…]

Warnings and precautions

[…]

[The following warning should be reflected in this section for all ambroxol- and bromhexine-containing medicinal products]

There have been reports of severe skin reactions associated with the administration of <active substance>. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using <invented name> and contact your doctor immediately.

[…]

4. Possible side effects

[…]

[The following adverse events should be listed in this section for all ambroxol- and bromhexine-containing medicinal products]

Rare: may affect up to 1 in 1,000 people:

Hypersensitivity reactions

Rash, urticaria

Not known: frequency cannot be estimated from the available data

Anaphylactic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous, mucosa or submucosal tissues) and pruritus

Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis).

[…]

[The following sub-heading should appear at the end of this section]

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via *[the national reporting system listed in Appendix V*]*. By reporting side effects you can help provide more information on the safety of this medicine.

[…]