

## **Annex III**

### **Amendments to relevant sections of the Product Information**

*Note:*

These amendments to the relevant sections of the Product Information are 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.

## **Amendments to relevant sections of the Product Information**

*[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]*

### **Summary of product characteristics**

*[...]*

#### **4.1 Therapeutic indications**

*[For all products, indications in respiratory tract conditions should be replaced by the below ones for adults and for children]*

##### *IN ADULTS*

*[For product indicated in respiratory tract infections in adults, the indication should be revised follows]*

Prophylaxis of recurrent respiratory tract infections (RTI) in adults.

*[For product indicated only in upper respiratory tract infections in adults, the indication should be revised follows]*

Prophylaxis of recurrent upper respiratory tract infections (RTI) in adults.

##### *IN CHILDREN*

*[For product indicated in respiratory tract infections in children, the indication should be revised follows]*

Prophylaxis of recurrent respiratory tract infections (RTI) in <age group>.

*[For product indicated only in upper respiratory tract infections in children, the indication should be revised follows]*

Prophylaxis of recurrent upper respiratory tract infections (RTI) in <age group>.

*[With regards to the age group, minimal age should be reflected as follows:*

*Luivac and associated names: children from 4 years of age*

*Buccalin and associated names: children from 2 years of age*

*For Respivax, Lantigen B, Ismigen, Broncho-Vaxom, Ribomunyl, Polyvaccinum and their associated names no change is needed to the minimal age currently authorised; however the age cut off should also be reflected in the indication, in line with the SmPC guideline.]*

*[Related changes should be implemented as needed throughout the SmPC]*

*[...]*

#### **4.4 Special warnings and precautions for use**

*[For products authorised in the prophylaxis of unspecified recurrent RTI a warning should be added as follows and related changes should be implemented as needed throughout the SmPC]*

*[...]*

No data from clinical studies are available to demonstrate that the use of <product> can prevent pneumonia. Therefore, the administration of <product> to prevent pneumonia is not recommended.

*[...]*

## Package leaflet

[...]

### 1. What <product> is and what it is used for

*[For all products, indications in respiratory tract conditions should be replaced by the below ones for adults and for children]*

#### IN ADULTS

*[For product indicated in respiratory tract infections in adults, the indication should be revised follows]*

Prophylaxis of recurrent respiratory tract infections (RTI) in adults.

*[For product indicated only in upper respiratory tract infections in adults, the indication should be revised follows]*

Prophylaxis of recurrent upper respiratory tract infections (RTI) in adults.

#### IN CHILDREN

*[For product indicated in respiratory tract infections in children, the indication should be revised follows]*

Prophylaxis of recurrent respiratory tract infections (RTI) in <age group>.

*[For product indicated only in upper respiratory tract infections in children, the indication should be revised follows]*

Prophylaxis of recurrent upper respiratory tract infections (RTI) in <age group>.

*[With regards to the age group, minimal age should be reflected as follows:*

*Luivac and associated names: children from 4 years of age*

*Buccalin and associated names: children from 2 years of age*

*For Respivax, Lantigen B, Ismigen, Broncho-Vaxom, Ribomunyl, Polyvaccinum and their associated names no change is needed to the minimal age currently authorised; however the age cut off should also be reflected in the indication]*

*[Related changes should be implemented as needed throughout the PL]*

[...]

### 2. What you need to know before you use <product>

[...]

#### Warnings and precautions

[...]

*[For products authorised in the prophylaxis of unspecified recurrent RTI a warning should be added as follows and related changes should be implemented as needed throughout the PL]*

The use of <product> in the prevention of pneumonia is not recommended, as no data from clinical studies are available to demonstrate such effect.