

## **Annex III**

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

Note:

This product information is the outcome of the referral procedure to which this Commission decision relates.

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.

The valid summary of product characteristics, labelling and package leaflet are the final versions achieved during the Coordination group procedure with the following amendments (insertion, replacement or deletion of the text as appropriate) to reflect the agreed wording as provided below:

## A. Summary of Product Characteristics

### 4.2 Posology and method of administration

[...]

#### *Paediatric population*

**The safety and efficacy of Cardioxane in children aged 0 to 18 years have not been established. Currently available data are described in section 4.3, 4.4, 4.8, 5.1 and 5.2.**

~~Cardioxane is contraindicated in children and adolescents up to 18 years of age (see section 4.3).~~

[...]

### 4.3 Contraindications

~~Children and adolescents up to 18 years of age (see sections 4.4 and 4.8).~~

**Cardioxane is contraindicated in children aged 0 to 18 years who are planned to receive a cumulative dose of less than 300 mg/m<sup>2</sup> of doxorubicin or the equivalent cumulative dose of another anthracycline (see sections 4.4 and 4.8).**

**Cardioxane is also contraindicated in the following circumstances:**

- [...]

## B. Package Leaflet

### 2. What you need to know before you are given Cardioxane

#### **You must not be given Cardioxane**

- If you are under 18 years old **and your planned dose of anthracycline is considered low – talk to your doctor about this.**

[...]

#### **Children and adolescents**

**The long-term benefits and risks of this medicine in children and adolescents are not yet clear. Your doctor will advise on benefits and risks of this medicine.**

[...]

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

[...]

#### **Paediatric population**

**The safety and efficacy of Cardioxane in children aged 0 to 18 years have not been established.**

Cardioxane is contraindicated in children and adolescents up **aged 0** to 18 years of age **who are planned to receive a cumulative dose of less than 300 mg/m<sup>2</sup> of doxorubicin or the equivalent cumulative dose of another anthracycline.**