

### **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 and package leaflet 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.

[the wording below should be inserted in the relevant sections]

### **Summary of Product Characteristics**

#### **Section 4.1 “Therapeutic indications”**

Testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests.

[...]

#### **Section 4.4 “Special Warnings and Precautions for Use”**

[...]

In patients suffering from severe cardiac, hepatic, or renal insufficiency or ischaemic heart disease, treatment with testosterone may cause severe complications characterised by oedema with or without congestive cardiac failure. In such case, treatment must be stopped immediately.

Testosterone may cause a rise in blood pressure and <name of product> should be used with caution in men with hypertension.

Testosterone level should be monitored at baseline and at regular intervals during treatment. Clinicians should adjust the dosage individually to ensure maintenance of eugonadal testosterone levels.

In patients receiving long-term androgen therapy, the following laboratory parameters should also be monitored regularly: haemoglobin, and haematocrit, liver function tests and lipid profile.

There is limited experience on the safety and efficacy of the use of <name of product> in patients over 65 years of age. Currently, there is no consensus about age specific testosterone reference values. However, it should be taken into account that physiologically testosterone serum levels are lower with increasing age.

[...]

#### **Section 4.8 Undesirable effects**

[...]

Haematocrit increased, Red blood cell count increased, Haemoglobin increased  
Frequency common.

[...]

### **Package Leaflet**

[...]

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

<name of product> is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This should be confirmed by two separate blood testosterone measurements and also include clinical symptoms such as:

impotence

infertility

low sex drive

tiredness

depressive moods

bone loss caused by low hormone levels

[...]

#### **2. What you need to know before you take <name of product>**

[...]

If you are suffering from severe heart, liver or kidney disease, treatment with <name of product> may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

Tell your doctor if you have high blood pressure or if you are treated for high blood pressure, as testosterone may cause a rise in blood pressure.

[...]

#### **4. Possible side effects**

Frequency common: Increase in red blood cell count, haematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen), identified by periodic blood tests.

[...]