



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 April 2014  
EMA/PRAC/178703/2014

## PRAC List of questions

To be addressed by the marketing authorisation holder(s) for testosterone containing medicinal products

Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1396

INN/active substance: testosterone



The marketing authorisation holders MAH(s) for testosterone - containing medicinal products authorised in the EU are requested to provide the following:

Question 1

Concerning your testosterone- containing medicinal product(s), please provide:

- a) information on approved indication(s), doses, treatment duration, cardiovascular related contraindications and warnings and precautions included in your summary of product characteristics (SMPC). Please provide this information in a tabular format (see below example). Please also tabulate the main differences between the SMPCs in the different countries in the EU;

Product name	Formulation	Indication	Age restrictions	Doses	Treatment duration	Contraindication
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- b) an overview of the approved indication(s) of testosterone - containing medicinal product(s) outside the EU;
- c) information on marketing and legal status in different EU Member States;
- d) figures on patient exposure by product and by country.

Question 2

Provide a detailed analysis of the available data from clinical trials in relation to the cardiovascular risks.

- These analyses should be stratified by relevant criteria, such as indication, dose, pharmaceutical form, age, time to onset, concomitant medications, concomitant illnesses or any other factors.

Question 3

Provide a review of all other available clinical safety data including from observational studies that are relevant to evaluate the cardiovascular risks of medicinal products containing testosterone.

Question 4

Provide a full benefit/risk assessment of your testosterone containing medicinal product(s) in all approved indication(s) in the EU. This should include an assessment on the impact of cardiovascular risks on the benefit/risk balance in each patient population.

Question 5

Provide proposals and justification with supportive evidence for any measures, including changes to the summary of product characteristics and package leaflet, which could be taken in order to improve the benefit/risk of testosterone - containing medicinal product(s). Please also comment on how the impact of such measures should be monitored.