Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisation

National competent authorities of Member State(s) or reference Member State(s) if applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

Conditions	Date
The Marketing Authorisation Holders of testosterone-containing medicinal products should, with the next PSUR: • monitor cardiovascular risk (including literature review, clinical trials data and all other relevant data) and discuss the finding in the next PSUR. • report on venous thrombolic events (VTE) including deep venous thrombosis (VTE) and pulmonary embolism (PE) in a separate section in the next PSUR. This section should also include literature case reports and review. The spontaneous reports shall not be presented as a listing of the individual cases, but rather as a general discussion of the aggregated cases, and include all relevant information, e.g. time to onset (when available), haematocrit/haemoglobin level (when available), indication, age, confounding factors and other. • discuss a possible mechanism of VTE and the potential association between CV/VTE events and testosterone levels (whether low or high levels compared to eugonadal level may contribute to the risk), and discuss if the information should be included in the product information. • discuss the usage in elderly, taking into account the naturally lower level of testosterone in this age group of patients. Furthermore the discussion on the adverse events in this group should be compared with the pattern of adverse events in other age groups. • submit the PSUR within 90 days following the DLP of 31 December 2015.	31 March 2016