Co-ordination group for Human Use
EMEA/H/A-31/1396
EMA/CMDh/706121/2014

Agreementof the co-ordination group for mutual Recognition and decentralised procedures for human use, pursuant to article 107k(1) and (2) of directive 2001/83/EC,

Medicinal products:

Invented names:	see Annex I
International non-proprietary name:	testosterone
Pharmaceutical forms:	see Annex I
Strengths:	see Annex I
Routes of administration:	see Annex I

Basis for agreement

Pursuant to Article 31 of directive 2001/83/EC, Estonia initiated a procedure on 27 March 2014. The notification for the procedure is appended to this agreement.

The evaluation procedure started on 10 April 2014.

The steps taken for the assessment of the referred matter are detailed in the PRAC assessment report appended to this agreement.

The recommendation was adopted by the PRAC on 9 October 2014 and is appended to this agreement.

The Co-ordination Group for Mutual Recognition and Decentralised Procedures for human use (CMDh) has considered the recommendation of PRAC in accordance with Article 107k(1) and (2) of Directive 2001/83/EC.

Agreement

1. The CMDh, having considered the PRAC recommendation, agreed by consensus that the marketing authorisations for testosterone containing medicinal products should be varied.

The Icelandic and the Norwegian CMDh member(s) agree(s) with the above-mentioned agreement of the CMDh.

2. The scientific conclusions and the detailed explanation of the scientific grounds for the differences from the PRAC recommendation are set out in Annex II.

3. The amendments to be introduced to the product information of testosterone containing medicinal products are set out in Annex III.

4. The conditions to the marketing authorisation(s) of testosterone containing medicinal products are set out in Annex IV.

5. The timetable for the implementation of the agreement is set out in Annex V.

To the extent that other medicinal products containing testosterone not included Annex I are currently authorised in the EU, or are subject to future authorisation procedures by the Member States, the CMDh recommends that the Member States concerned take due consideration of the scientific conclusions set out in Annex II.

This agreement is forwarded to the Member States, to Iceland and Norway and to the marketing authorisation holders for the above mentioned medicinal products, together with its annexes and appendices.

London, 19 November 2014

On behalf of the CMDh

Dr Peter Bachmann, Chair