



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 September 2012  
EMA/MB/607587/2012 Noted

## Outcome of written procedures finalised during the period from 18 May 2012 to 19 September 2012

Management Board meeting 4 October 2012

### Background note

This document is presented in accordance with Article 4 (5) of the Management Board rules of procedure regarding the outcome of the written procedures.

### Matters for consideration

During the period from 18 May 2012 to 19 September 2012, the Board was consulted 10 times via written procedures, out of which six consultations concerned new memberships in the CVMP and CHMP, one consultation concerned the adoption of the minutes of the 76<sup>th</sup> MB meeting, one consultation regarded amendments to the Fee Regulation Implementing Rules, one related to the Agency's Final Accounts 2011, and one consultation concerned the PRAC rules of procedure, as follows:

- Consultation no. 08/2012 on the appointment of Bruno Sepodes as CHMP member, proposed by Portugal, ended on 13 August 2012. The mandate of the nominee commenced on 14 August 2012.
- Consultation no. 09/2012 on the appointment of Dinah Duarte as CVMP alternate, proposed by Portugal, ended on 13 August 2012. The mandate of the nominee commenced on 14 August 2012.
- Consultation no. 10/2012 on the appointment of Leona Nepajchalova as CVMP alternate, proposed by Czech Republic, ended on 29 August 2012. The mandate of the nominee commenced on 30 August 2012.
- Consultation no. 11/2012 on the appointment of Stanislav Primožič as CHMP member, proposed by Slovenia, ended on 10 September 2012. The mandate of the nominee commenced on 11 September 2012.
- Consultation no. 12/2012 on the appointment of Hans Kristian Ostensen as CVMP member, proposed by Norway, ended on 13 September 2012. The mandate of the nominee commenced on 14 September 2012.



- Consultation no. 13/2012 on the appointment of Stephen Spiteri as CVMP member, proposed by Malta, ended on 14 September 2012. The mandate of the nominee commenced on 15 September 2012.
- Written procedure for adoption of the Agency's Final Accounts, ended on 26 June 2012. The document was adopted.
- Written procedure for adoption of 76<sup>th</sup> Management Board meeting minutes ended on 27 July 2012. The minutes were adopted.
- Written procedure for adoption of Fee Regulation Implementing Rules ended on 23 August 2012. The document was adopted.
- Consultation procedure on Pharmacovigilance and Risk Assessment Committee (PRAC) Rules of procedure ended on 24 August 2012. Due to Members comments received during the procedure, the topic was presented for discussion and endorsement at the next Management Board meeting.

### ***List of re-nominations to the CHMP and CVMP***

In accordance with the Board's decision of 18 March 2010 relating to the *Procedure for the consultation of the Management Board on new appointments of CHMP and CVMP members and alternates* (EMA/MB/353835/Rev.2), the Board shall be provided with a periodic overview of renewed memberships in the CHMP and CVMP. Renewed memberships include also those memberships where the member has been re-nominated as an alternate or vice versa:

<b>Country</b>	<b>Name</b>	<b>Membership<sup>1</sup></b>	<b>Committee</b>
Germany	Cornelia Ibrahim	Member	CVMP
Portugal	Joao Pedro Duarte da Silva	Alternate	CVMP

<sup>1</sup> Membership referred in this column is the membership that was indicated in the nominating correspondence.