



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2012
EMA/598943/201212 Noted

Pharmacovigilance and Risk Assessment Committee – first experience

Management Board meeting 4 October 2012

Background note

At its 7 June 2012 meeting, the Management Board was informed on the arrangements being made to establish the PRAC. Efforts have been made to develop cost-efficient processes supporting the functioning of the PRAC, whilst respecting the new framework provided by the new legislation. A continuous monitoring of the functioning of the PRAC will be undertaken and remedial action will be proposed and discussed within the EU Regulatory Network as the need arises.

Matters for consideration

So far, 2 PRAC meetings have taken place, on 19-20 July 2012 (inaugural meeting) and on 3-5 September 2012. First experiences have been summarised in the attached presentation. Of particular note is that the PRAC Rules of Procedure, following the adoption by the PRAC at its inaugural meeting, were circulated to the Management Board in order to obtain a favourable opinion. Since comments were raised during the written procedure such procedure was suspended (see separate documents).

