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## European Risk Management Strategy (ERMS) Facilitation Group

### Summary

At the meeting in Edinburgh in July 2005, HMA Human agreed the membership and remit of a permanent working group of the HMA and the EMEA – The ERMS Facilitation Group. A rolling 2-year Work Programme (2005-2007) has been agreed and is available via the following link (add website link)

### Background

The HMA Human Ad Hoc Working Group on ERMS was first established in July 2002. The Working Group, comprising participants from Denmark, France, Germany, Spain, UK and EMEA and later joined by the Netherlands and Sweden, produced an initial report on the establishment of the Strategy which was published in January 2003. On 2 May 2005 in Luxembourg, HMA Human agreed to the publication of a progress report on implementation of the ERMS and of an Action Plan. These were published on the HMA and EMEA websites on 11 May 2005.

The ERMS Group met on 15 June 2005 to consider how the ongoing work on the Strategy should be taken forward. Noting that the existing core membership of the Group encompassed members from HMA Human, PhvWP, the CHMP and the EMEA, it was suggested that the strengths of the existing Group as a forum be maintained in the form of a permanent working group of HMA Human. A revised remit reflecting a role in delivering implementation of the Action Plan and of further development of the strategy was agreed as follows:

- Further development of the ERMS in the context of wider initiatives
- Monitoring of the delivery of the ERMS Action Plan – in particular the priorities for action and timeframes for delivery
- Develop of a rolling 2 year action plan for agreement by HMA Human annually
- Preparation of an annual status report for publication by HMA Human, co-ordinating and facilitating between the key stakeholders as appropriate.

HMA Human also agreed to extend an open invitation to attendance by Member State Competent Authorities but the core membership will remain unchanged. It is anticipated the Group will meet between two and four times per year, with the cost of meetings being met by the members. A revised name of ERMS Facilitation Group was agreed, to better reflect the group's role with all the stakeholders mentioned earlier and the CMDh.

### Interface with the HMA Strategy on the Future European Regulatory Network

The work of the ERMS Facilitation Group will need to be taken forward in the context of the development of the HMA Strategy on the Future European Regulatory Network and the drafting group considering pharmacovigilance. Since both groups will report to the HMA, there will be an opportunity to ensure their work is complementary.

The HMA and the EMEA are pleased to be able to publish the first rolling 2-year Work Programme (2005-2007).

Public

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