



16 June 2016  
EMA/MB/3373/2016 v.4 Adopted  
Management Board meeting of 16 June 2016

## Agenda for the 92nd meeting of the Management Board

Held on 16 June 2016, Room 2A (08:00 - 15:00)

Chair: Christa Wirthumer-Hoche

| Item     |  |  |
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| 1.       | Draft agenda   | For adoption,<br>EMA/MB/3373/2016*   |
| 2.       | Declaration of conflicts of interest related to current agenda                                   | Oral report  |
| 3.       | Minutes from the 91st meeting, held on 17 March 2016 adopted via written procedure on 3 May 2016 | For information,<br>EMA/MB/206400/2016*  |
| <b>A</b> | <b>Points for automatic adoption/endorsement</b>   |  |
| A.1      | Management Board meeting dates 2017-2018   | For adoption,<br>EMA/MB/245471/2016*   |
| A.2      | EMA New Working time rules   | For information,<br>EMA/MB/294876/2016<br>For adoption,<br>EMA/56681/2016  |
| A.3      | Revision of the EMA Code of Conduct  | For information,<br>EMA/MB/308158/2016;<br>For endorsement,<br>EMA/385894/2012 rev.1*;<br>For information,<br>EMA/306912/2016* |
| <b>B</b> | <b>Points for discussion</b>   |  |
| B.1      | Highlights of the Executive Director   | Oral report  |
| B.2      | Report from the European Commission  | Oral report  |



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| B.3  | Assessment of the Executive Director's Annual Activity Report (AAR) 2015   | For information,<br>EMA/MB/356802/2016;<br>EMA/140840/2016*;<br>For adoption,<br>EMA/323238/2016*   |
| B.4  | Multiannual Work Plan to 2020  | For information,<br>EMA/MB/388475/2016;<br>For adoption,<br>EMA/319713/2016*  |
| B.5  | 2015 Annual reports of Audit Activities at the Agency<br><br>a) Annual Internal Audit Report (IAS-EC) 2015<br>– IAS Audit on Paediatric Regulation Procedures in EMA<br><br>b) Annual Report of the Internal Audit of EMA 2015 | For information,<br>EMA/MB/337671/2016<br><br>For information,<br>Ares(2016)2309382 -<br>18/05/2016;<br>For information,<br>EMA/278688/2016 |
| B.6  | Criteria for EMA involvement in externally funded projects (e.g. IMI, FP & H2020)  | For endorsement,<br>EMA/MB/294875/2016  |
| B.7  | Criteria to be fulfilled by Industry Stakeholders organisations involved in European Medicines Agency (EMA) activities   | For information,<br>EMA/MB/323682/2016<br>For adoption,<br>EMA/323235/2016*   |
| B.8  | EMA Stakeholder Relations Management Framework   | For information,<br>EMA/MB/331273/2016;<br>For adoption,<br>EMA/48651/2016*   |
| B.9  | Pharmacovigilance Programme: EudraVigilance high level audit plan update   | For information,<br>EMA/MB/321035/2016;<br>EMA/452911/2015  |
| B.10 | Principal elements for a vision for a European Medicines Web portal  | For information,<br>EMA/MB/385463/2016;<br>For endorsement,<br>EMA/385484/2016  |
| B.11 | Clinical Trial EU Portal and Database  | Oral Report   |
| B.12 | Report by the Steering Group on the Management Board data gathering initiative   | For information,<br>EMA/MB/344089/2016  |
| B.13 | Annual report on the performance of the Agency's scientific procedures   | For information,<br>EMA/MB/3373/2016<br>EMA/384685/2016;<br>For endorsement,<br>EMA/271473/2016   |

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| B.14     | Draft Management Board decision on derogation from Commission Decision on the implementation of telework in Commission Departments | For information,<br>EMA/MB/375574/2016;<br>C(2015) 9151 final;<br>For adoption,<br>EMA/368608/2016 |
| <b>C</b> | <b>Points for information**</b>  |  |
| C.1      | Report on EU Telematics  | For information,<br>EMA/MB/335100/2016,<br>EMA/334790/2016   |
| C.2      | Feedback from the Heads of Medicines Agencies  |  |
| C.3      | Outcome of written procedures finalised during the period from 20 February 2016 to 11 May 2016                                     | For information,<br>EMA/MB/241599/2016*  |
| C.4      | Summary of transfer of appropriations in the budget 2016   | For information,<br>EMA/MB/294536/2016*  |
| C.5      | European Medicines Agency's Interaction with Industry Stakeholders – Annual Report 2015  | For information,<br>EMA/MB/335826/2016;<br>EMA/774549/2015   |
| C.6      | Report on the 10 <sup>th</sup> Anniversary of the SME Initiative   | For information,<br>EMA/MB/330352/2016;<br>EMA/155560/2016*  |
| C.7      | Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2015                             | For information,<br>EMA/MB/305561/2016   |
| C.8      | Outcome of SME office survey on the implementation of the SME regulation - Commission Regulation (EC) No 2049/2005                 | For information,<br>EMA/MB/330379/2016;<br>EMA/242286/2016*  |
| C.9      | Annual report on the EMA interactions with patients, consumers and healthcare professionals and their organisations (2015)         | For information,<br>EMA/MB/337783/2016;<br>EMA/727872/2015*  |
| C.10     | Framework Strategy for Corporate Communications 2016-2020  | For information,<br>EMA/MB/336448/2016,<br>EMA/338964/2016   |

\* Documents marked with a star \* are intended for publication on the external website.

\*\* Documents in *Additional documents for information* section are not intended for discussion unless specifically requested