



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 May 2012
EMA/MB/326427/2012 Adopted

Analysis and assessment of the 2011 Annual Activity report of the Executive Director

The Management Board,

- having regard to the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004,
 - having regard to the Financial Regulation applicable to the budget of the European Medicines Agency and in particular Article 40 thereof,
 - having regard to the 2011 Work programme of the Agency adopted by the Management Board at its meeting of 16 December 2010,
 - having regard to the Annual Report 2011 of the Agency adopted by the Management Board at its meeting of 22 March 2012.
1. Welcomes the results presented in the Annual report 2011 and the strong contribution of the EMA in support of making high-quality and effective medicines available for use in human and animal populations not only at EU-level but also underlining the efforts of the EMA to contribute to this goal at international level.
 2. Welcomes the launch of the 'operational excellence' initiative which addresses the Agency's need to further strengthen its operations to achieve efficiency gains at a phase of zero-growth due to economic pressures.
 3. Welcomes the Agency's considerable efforts in the preparation for the implementation of the new EU pharmacovigilance legislation and notes that the vast majority of deliverables is on schedule.
 4. Raises concerns however about the observed delays in the ICT field and in particular the implications this might have on the smooth implementation of the new pharmacovigilance legislation.
 5. Notes that the Agency has started the preparation to contribute to the implementation of the new legislation on falsified medicines.



6. Welcomes the new rules on how the EMA handles conflicts of interests of scientific experts and staff which will improve the transparency of the activities and notes the Agency's determination for its implementation.
7. Welcomes the Agency's progress in collaboration with the European Network for Health Technology Assessment (EUnetHTA) in order to gather the requirements from HTAs on how information on the benefits and risks of a medicine should be included in the European public assessment reports (EPARs) and to make a better contribution to relative effectiveness assessments by HTA bodies.
8. Welcomes the establishment of the ad hoc expert group on the 3R's (replacement, reduction and refinement) to reduce the number of animals in regulatory testing.
9. Notes the different efforts of the Agency in combating antimicrobial resistance (ESVAC, TATFAR).
10. Welcomes the initiatives to further strengthen the integration of civil-society representatives in the Agency's activities.
11. Notes the Agency's concerns to respond to the considerable increase of requests for access to documents (92%) and welcomes its initiatives to improve the way to access documents.
12. Notes that the SME-office was having a busy year and welcomes the launch of a simplified SME assignment process, hoping that this will have a positive impact on the introduction of applications for ATMP's.
13. Welcomes the continued policy of the Agency to support applications for veterinary products indicated for Minor Use/Minor Species (MUMS) and limited markets and the introduction of a range of measures to support this.
14. Notes the increased activity in initial evaluation applications and in post-authorisation activities for human medicines, increase in extension opinions for MRLs and significantly more referrals and GMP inspections than forecast.
15. Welcomes the review of 3 prioritised internal control standards, namely 'ethical and organisational values', 'business continuity' and 'document management' and the Agency's plans to continue in 2012 implementing the defined outstanding actions to ensure that these ICS's are fully implemented.
16. Notes the successful migration of the Agency's budgetary system to an integrated system..
17. Thanks the Acting Executive Director for his exceptional commitment and leadership of the organisation for almost the whole year 2011 with a warm welcome to the new Executive Director.

London, 7 June 2012

Signature on file

Sir Kent Woods
Management Board Chair