



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2010

Submission of comments on The European Medicines Agency Road Map to 2015: The Agency's Contribution to Science, Medicines, Health

Comments from

Name of organisation or individual

European Vaccine Manufacturers (EVM)

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Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

Comments should be sent to the European Medicines Agency electronically and in Word format (not pdf).

Comments should be sent to roadmap@ema.europa.eu and must arrive by 30 April 2010.



1. GENERAL COMMENTS

Stakeholder no. <to be completed by the Agency>	General comment (if any)	Outcome (if applicable) <to be completed by the Agency>
	<p>EVM welcomes the EMA consultation on the EMA Roadmap 2015. It is essential that EMA develops a long-term strategy, which identifies areas of improvement based on the experience. In addition, it is critical to make sure the Agency's strategy is adapted to the evolutions of the external environment.</p> <p>EVM considers that the Roadmap sets pretty well the scene by identifying drivers for progress, establishing long-term objectives and priorities. However, in order to better evaluate the objectives and strategy it would be useful to see the detail of EMA's plans to achieve these objectives, together with Impact/Result indications.</p> <p>Therefore, EVM considers that it would be essential that the document "From Vision to Reality" be open to consultation.</p> <p>EVM agrees with the areas of concern raised by EFPIA. The following comments are mainly focused on areas that have specific implications for the vaccine sector.</p> <ul style="list-style-type: none"> ▪ <u>The EMA's mission to foster scientific excellence should not lead to requirements aiming solely at developing scientific knowledge without direct link/added value to the evaluation and supervision of medicinal products.</u> <p>EVM would expect that the scope/mission of the Agency, as mentioned under Section 2.1 does not shift toward requirements essentially targeted at the development of scientific knowledge without direct links to evaluation and supervision of medicinal products. Such a trend has for instance been observed in the context of the implementation of the Paediatric Regulation, with</p>	

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	<p>the requirements imposed by the PDCO for vaccines PIPs.</p>	
	<ul style="list-style-type: none"> ▪ <u>Mechanisms to improve early-stage dialogue should foresee open dialogue and exchange of views</u> <p>EVM appreciates the various attempts to improve dialogue at very early stage in development and throughout the process, and the involvement of CHMP [through early appointment of (Co)-Rapporteurs] may indeed be a way to ensure consistency between authorities' requirements/expectations during development (PDCO) and regulators' requirements/expectation in terms of data to support new MA approvals (CHMP).</p> <p>However EVM considers that such a proposals should be adjusted to a case-by-case to prevent implementing a very bureaucratic approach with no added value for public health.</p> <p>EVM believes that the PIP procedure should not be used as model for mandatory engagement of dialogue in early phase development. Early dialogue should remain optional. Practical experience of EVM members with the PIP procedure shows additional burden with no added value for public health rather than promotion of paediatric vaccine development</p> <ul style="list-style-type: none"> ▪ <u>Improve coordination and consistency among the various scientific Committees and working groups involved in the process</u> <p>EVM agrees that consistency is critical for the efficiency of the Agency. Improving the management of the interfaces between the different EMA committees and working parties is a key challenge, but it is essential to optimise/guarantee the Agency's efficiency.</p>	

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	<p>EVM member companies have indeed experienced divergent opinions or requests coming from the various EMA scientific committees and working groups (e.g. Scientific Working Party, CHMP and PDCO, to name just a few). This leads to confusion, uncertainty, and conflicting situations, which are difficult to manage. EVM encourages EMA to reflect this need for a better coordination/consistency among scientific committees and working groups in the Roadmap. EVM believes that the idea of an overarching process, as proposed in the EMA Roadmap, could be a useful concept provided that the appropriate scientific expertise is ensured at all necessary steps.</p> <ul style="list-style-type: none"> ▪ <u>Vaccine expertise should be developed both as support to vaccine development and in the evaluation process</u> <p>EVM would like to remind that more than half of the vaccines used worldwide are developed and produced in Europe. Over the many years of operation of the European Medicines Agency, EVM has had a positive experience with the specific expertise provided by the Vaccine Working Party (VWP). The availability of appropriate vaccine expertise within the EMA committees and working parties is a key parameter to ensure an optimal regulatory/scientific environment for the development, evaluation and supervision of vaccines. Therefore, EVM would like to call on the EMA to ensure that the best European vaccine expertise continues to be involved at all critical steps and with all key scientific committees, both in supporting vaccine development and in ensuring appropriate scientific evaluation and supervision.</p> <ul style="list-style-type: none"> • <u>Need to reinforce Communication strategies</u> <p>H1N1 experience showed that communication constituted a</p>	

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	<p>major aspect of Health Threat management. Poor vaccination coverage in the population, including Health Care Workers, could have been improved by a more effective communication strategy aiming at mitigating unfounded concerns from various stakeholders regarding the safety and efficacy of authorised H1N1 pandemic vaccines. Therefore EVM encourages EMA to rethink its approach to communication, as the traditional channels of communication seemed insufficient. This new approach would probably require better coordination and collaboration among all stakeholders.</p>	

2. SPECIFIC COMMENTS

Line No of the first line(s) affected <e.g. Line 20-23>	Stakeholder no. <to be completed by the Agency>	Comment and rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">	Outcome <to be completed by the Agency>
<p><u>Strategic Area 1:</u> <u>Line 228-30</u> <u>Page 10/22</u></p>		<p>EVM considers that vaccines are preventive medicines and, as such, play a major role in the safeguard of public health. Therefore, vaccines should be mentioned in the strategic area 1 of the Roadmap on "addressing public health needs. Therefore EVM proposed to reword the sentence as follows: "<i>In addition to infectious diseases, other filed of concerns are disease prevention (role of vaccines), rare and neglected diseases, leading in particular to challenges to developing countries</i>".</p>	
<p><u>Strategic Area 1</u> <u>Line 237-241</u> <u>Page 10/22</u></p>		<p>A desire to increase the use of Art 58 is mentioned, but it is not clear how this would be achieved. In addition, manufacturers faced some difficulties with the implementation of Art 58, as third countries tend not to recognise Art 58 as equivalent to a license. EVM would recommend that EMA discuss the experience with art 58 with the WHO in order to facilitate its recognition in third countries.</p>	
<p><u>Strategic Area 1</u> <u>Line 242-45</u> <u>Page 10/22</u></p>		<p>Vaccination can also play an important role in the measures/strategies to fight against antimicrobial resistance by leading to a reduction of antimicrobial prescriptions and preventing some antimicrobial resistant diseases (See EVM Briefing Sheet http://www.evm-vaccines.org/pdfs/EVM%20Briefing%20Sheet%20AMR%20March%202010%20FIN.pdf) A programme to combat antimicrobial resistance will need to combine a number of different approaches including a rational use of antibiotics, the</p>	

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		prevention of carriage or infection, and the discovery and development of new antimicrobial agents. EVM proposes EMA to consider including the role vaccines could play in limiting antimicrobial resistance.	
<u>Strategic Area 1</u> <u>Lines 246-249</u> <u>Page 11/22</u>		The Roadmap indicates that the Agency will undertake additional efforts to ensure that the needs of elderly people are taken into account in the development and evaluation of new medicines. Although EVM is supportive of legislation that provides incentives for development of vaccines for key age groups, the EVM experience shows that the practical implementation of paediatric legislation, in particular for vaccines, where development is generally initiated in children prior to adults has resulted in restricting development. In addition, it has raised inconsistencies and conflicts between what is important from a regulatory viewpoint and what is perceived of scientific interest but which does not necessarily contribute to registration nor to public health. EMA should keep striving to improve the existing system in collaboration with all the stakeholders.	
<u>Strategic Area 1:</u> <u>Lines 263-266,</u> <u>Pages 11/22</u>		EVM welcomes the Agency proposal to advise, through pooling of specialist expertise, on the necessary adaptation of the regulatory framework to the new technologies. R&D activities in pharmaceutical companies are more and more investing in such new areas like nanotechnologies, synthetic biology and personalised medicine indications (pharmacogenomics, biomarkers, etc.). It would therefore be essential that this pooling of expertise also include relevant experts from industry.	
<u>Strategic Area 1</u> <u>Lines 298-303,</u> <u>pages 11-12/22,</u>		EMEA Roadmap envisages that EMA will investigate the need to revise its preparedness mechanisms, and conduct a “lessons learnt” exercise after each major event. The Roadmap should reflect the importance of involving the vaccine industry as one of EMA’s key stakeholders when carrying out such activities	

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		(especially “lessons learnt” exercises, where a joint sharing of experience is critical to further improve preparedness mechanisms).	
<u>Strategic Area 2: Lines 316-320, Page 13/22</u>		EVM welcomes the EMEA Roadmap proposal to strengthen the guideline preparation process by involvement of stakeholders at a very early stage of development. However, we encourage EMA to explicitly mention Industry as a legitimate stakeholder. EVM considers essential that industry is involved, together with other stakeholders, in early stages of guideline development.	
<u>Strategic Area 2 Lines 321-326 Page 14/22,</u>		The EMA Roadmap states that mandatory engagement in early phase development plans facilitates the scientific review process, and proposes exploration of the concept that early dialogue could be introduced for adult medicines. We welcome the proposal to improve dialogue opportunities throughout development, but again an optional system should be put in place. The vaccine industry experience with the Paediatrics Regulation shows that this is not a model offering the necessary open dialogue to stimulate development and innovation (<i>see also comment on lines 246-249</i>).	
<u>Strategic Area 2 Lines 346-364, Page 14/22</u>		EVM is concerned that the terminology used (“overarching regulatory process”) is rather vague and abstract. EVM favours the idea of having an overarching regulatory body (or committee) that ensures consistency between the various scientific Committees and working groups involved in the whole process (e.g. PDCO, SAWG, CHMP, etc.) and provided that the appropriate scientific expertise is ensured at all necessary steps.	
<u>Strategic Area 2 Lines 463-467 Page 17/22</u>		An increased dialogue between regulatory agencies and HTA bodies is welcome, but it is also key that there is agreement on the roles they play and what the limitations for the role of each party are. EVM believes that industry should be a natural partner in HTA discussions and vaccines expertise should be ensured.	

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<u>Strategic Area 3:</u> <u>Optimising the safe use of medicines</u> <i>Lines 495-518, page 19/22</i>		EVM considers that an open and interactive collaboration between regulators, public health and industry is also key to ensure optimal post-authorisation activities: vaccine companies are very dependent on public health agencies with respect to both assessing the safety and implementing risk minimization measures. Therefore, EVM considers this should be reflected in the Roadmap.	

Please feel free to add more rows if needed.