



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

<29-4-2010>

## 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

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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](mailto:roadmap@ema.europa.eu) and must arrive by 30 April 2010.*



## 1. General comments

Stakeholder no.	General comment (if any)	Outcome (if applicable)
<i>&lt;to be completed by the Agency&gt;</i>	<p>IVAA welcomes the effort of EMA to have broad consultation for th Road Map until 2015 and appreciates the work of EMA in the last years. IVAA strongly supports the general objective to strengthen the Agency as a central focal point for handling the regulation of medicinal products in the EU.</p> <p>IVAA appreciates as well that the Agency tries to orientate the new Road Map at new developments which strongly influence Public Health at the EU and national levels.</p> <p>One of the new developments is the fact that a growing number of EU citizens and patients look for treatment by CAM (Complementary and Alternative Medicine) and that the EU institutions are aware of this trend. This growing demand of citizens in CAM is best reflected by the Swiss public referendum in May 2009 where 67% of the voters demanded to include CAM therapies in the Swiss constitution.</p> <p>It goes without saying that Switzerland is not the EU, but the outcome of the referendum reflects a trend which is not confined to Switzerland but can be observed in Europe at large. The growing awareness and interest in CAM by the EU institutions is best demonstrated by the 7<sup>th</sup> framework program project "CAMbrella". It should not be overlooked that DG SANCO and the EU Parliament have started to engage the CAM organisations in the development of their health politics.</p> <p>IVAA would appreciate and demands that the EMA Road Map includes the topics and problems of the CAM therapies. This demand needs to be taken up in the general considerations of the Road Map and in the different strategic areas accordingly.</p> <p>Looking at "Setting the Scene", IVAA would like to draw the attention e.g. to the following points:</p>	<i>&lt;to be completed by the Agency&gt;</i>

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	<ul style="list-style-type: none"> <li>- 2.2 Collaboration with the Agency´s Partners It has been and it continues to be the aim of the Agency to foster the establishment of networks of excellence. This objective should include the CAM sector.</li>   <li>- 2.3 Interaction with the Agency´s Stakeholders IVAA strongly urges that the different CAM organisations of patients, doctors and other healthcare professionals should be included in the intended growing involvement and participation of the civil society representatives.</li>   <li>Looking at “The Agency´s Drivers for Progress and Change”, IVAA would like to draw the attention e.g. to the following topics: <ul style="list-style-type: none"> <li>- Addressing public health needs: IVAA agrees with the topics and issues as outlined in the EU Commission´s White Paper (Together for Health...) but would strongly underline that the listed issues do not incorporate the existing relevance and growing demand for CAM as an indispensable therapeutic approach for individual patients as well as for public health. EU as well as national health institutions have to realise that at least 100 million EU citizens use these therapies.</li>   <li>- The model for regulation of medicines EMA regrets that in the field of herbal medicinal products the innovative concept of list entries and monographs was not followed by the expected marketing authorisation applications. This fact is not surprising because the existing regulations for CAM medicinal products are insufficient. They do not address the efficacy, quality and safety of these products in an adequate scientific and economic framework. IVAA expects that the regulative framework for the CAM medicinal products is taken up in the EMA road map for the next 5 years leading to adequate proposals for a renewed regulation for</li> </ul> </li> </ul>	

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	<p>political and legislative institutions. At present, the stakeholders of Anthroposophic Medicine are working to establish a new scientific approach (European Scientific Cooperative on Anthroposophic Medicinal Products, ESCAMP) which could enable EU institutions to better assess the quality, safety and efficacy of anthroposophic medicinal products. IVAA offers its active cooperation with EMA on these issues.</p>	

## 2. Specific comments on text

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>
224-245		<p>Comments:</p> <p>The increasing microbial resistance to antibiotics results mainly from the widespread use of these drugs. On the one hand, the use is not always evidence based. On the other hand, there are effective and scientifically proofed CAM therapies provided for many indications (e.g. bronchitis, laryngitis, sinusitis) with could help to reduce the use of antibiotics. Thus, alternative CAM treatments replacing antibiotics should be included in the strategies to resolve this problem.</p> <p>Proposed change (if any):</p>	
470-479		<p>Comments:</p> <p>IVAA agrees on the emphasis put on pharmacovigilance issues in the Road Map. This issue is of high importance for Anthroposophic Medicine as well. For this reason, the EVAMED pharmacovigilance center in Berlin has been developed in Germany to monitor drug safety of anthroposophic and CAM medicinal products. In October 2008, it was transformed into a pharmacovigilance center for the CAM sector in general (anthroposophic medicine, homeopathy, phytotherapy). The documentation of 750.000 prescriptions per year is its expected volume. This is the first European pharmacovigilance project for the CAM sector in the EU and is</p>	

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		<p>accepted to be scientifically adequate by the german regulative authorities (BfArM) and the german Medical Council. IVAA would appreciate that the results and expertise of EVAMED are incorporated into the Network of Centres for Pharmacoepidemiology and Pharmacovigilance led by the Agency.</p> <p>Proposed change (if any):</p>	
		<p>Comments:</p> <p>Proposed change (if any):</p>	

*Please feel free to add more rows if needed.*