EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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
International Society of Pharmacoepidemiology (ISPE)

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.

The International Society for Pharmacoepidemiology (ISPE) is very pleased to have the opportunity to offer our perspectives and suggestions, and submits for your consideration the following comments on the European Medicines Agency document.

ISPE is an international, nonprofit, professional membership organization dedicated to promoting the health of the public by advancing pharmacoepidemiology, the science that applies epidemiological approaches to studying the use, effectiveness, values and safety of pharmaceuticals. ISPE is firmly committed to providing an unbiased scientific forum to the views of all parties with interests in drug, biologics, and devices development, delivery, use, costs and value, adverse and beneficial effects, and therapeutic risk management.

Moreover, the Society provides an international forum for the open exchange of scientific information among academia, government, and industry and for the development of policy; a provider of education; and an advocate for the fields of pharmacoepidemiology and therapeutic risk management.

The Society's more than 1,000 members represent 45 countries. ISPE members work in academic institutions, the pharmaceutical industry, government agencies, and non-profit and for-profit private organizations. ISPE members are researchers with background and training in epidemiology, biostatistics, medicine, public health, nursing, pharmacology, pharmacy, law, and health economics.

Our comments are based on a careful review of the EMA document by the Society's membership at-large as well as by ISPE Fellows, Past Presidents, members of the Board of Directors and Executive Committee and Public Policy Committee. Due to the development process of the draft documents in which many ISPE members from academia, research centers and regulatory bodies were involved, some of these comments may have been sent directly to EMA.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

We thank EMA for allowing us the opportunity to comment on this document. ISPE welcomes any future dialogue with EMA.

Sincerely,

Public Policy Committee,

Board of Directors,

International Society for Pharmacoepidemiology (ISPE)

1. General comments

Stakeholder no. *<to be completed by the Agency>*	General comment (if any)	Outcome (if applicable) *<to be completed by the Agency>*
	The International Society of Pharmacoepidemiology, ISPE, welcomes the Consultation paper — "The European Medicines Agency {EMA} Road Map to 2015: The Agency's Contribution to Science, Medicines, Health." We are encouraged that the EMA has identified the need for high quality studies, using sound science and quality data to "Strengthen the evidence base in the post-authorisation phase to enable better regulatory decision-making" (Objective for Strategic Area 3, line 468). Recognizing the Road Map provides general direction for achieving 2015 goals, the ISPE would like to underscore the need for very specific details in this document or companion documents on the following issues: 1. We would wish to see more explicit description of the requirement that Pharmacoepidemiology of the highest quality is carried out. Description of good scientific practices, including validation, related to pharmacoepidemiology and pharmacovigilance data and methodologies is critical to provide a sound infrastructure for science-based regulatory and public health decision making, and to ensure the reliability of information on which learned	

Stakeholder no. <to be completed by the Agency>	General comment (if any)	Outcome (if applicable) <to be completed by the Agency>
	intermediaries and patients rely for making individual benefit-risk assessments. This is especially important when "conditional marketing authorisations" are used. 2. When "conditional marketing authorisations" are granted, there must be clear procedures in place to ensure that the benefit-risk balance in the post-authorization setting is planned, conducted and reported in a timely manner. 3. Where "new data sources" are referenced, (line 489), the potential role of the new data sources (informing benefit/risk/utilization) should be described cautiously with recognition of potential limitations and highlighting the need for validation. 4. We welcome the note (line 490) that "capacity building for post-authorisation monitoring" is to occur but we propose that Strategic Area 3 should include a section on how the Agency plans to strengthen the methodology, resources and network of the core pharmacoepidemiology discipline. The monitoring must be of the highest possible scientific standard and should be sufficient in scope, recognizing the limitations of spontaneous report monitoring.	

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>*
Line 80		Comments: The Agency's 'core business' is nowhere explicitly defined in this document. If it is equivalent to the 'mission of the Agency' (item 2.1) then it ought to be so-identified. Proposed change (if any):	
Line 97		Comments: Antimicrobial resistance is properly identified as one of several challenges which require a new strategic approach (section 3, line 97, under 'Addressing public health needs'). It is widely-accepted that a major, or even *the* major, contributor to antimicrobial resistance is erratic, on-again/off-again exposure to antimicrobial drugs under conditions of everyday use (so-called 'real-life use' in the evolving jargon for comparative effectiveness research). That being so, it deserves to be pointed out that sound measurements of exposure to antimicrobial drugs are a fundamental in attacking the problem of emergent antimicrobial resistance. So, if regulators are to be 'attuned to the new technologies and to learn from research and experience in other industry sectors' (lines 123-4), it is only logical that the sound measurement of exposure to drugs in general, and of course antimicrobial drugs in particular, be made a priority item in the near-term future.	

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>*
		Proposed change (if any):	
		Comments: Proposed change (if any):	

Please feel free to add more rows if needed.