Implementation of the Road Map to 2015; Implications for patients/consumers

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- How was the plan prepared?
- Priority activities in the strategic areas (examples with particular impacts for patient and consumer)
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- Status and next steps

The Agency's Road map to 2015 – Contribution to science, medicines and health

- Adopted and published December 2010
- Identified current environment: Setting the scene
  - Public health, new and emerging science, increasing globalisation, transparency and openness…
- Drivers for progress and change
- Addressing the drivers for progress and change in three strategic areas:
  - Addressing public-health needs
  - Facilitating access to medicines
  - Optimising the safe and rational use of medicines
- Key objectives and impact/results indicators identified

How will the Agency implement its Road Map to 2015?

- Priorities outlined in Implementation Plan: From Vision to Reality
- Gradual approach proposed
- Further elaboration in work programmes
- 'Living document' – Subject to regular monitoring and review
- Influence of external factors outside the Agency's control e.g.
  - Legislative changes
  - Resource constraints

Current legislative tasks – ‘core business’

Agency’s primary focus: Performing and delivering on its tasks in line with current and upcoming legislation.

Vision to Reality details activities designed to improve performance in the three strategic areas identified in the Road Map and which support the Agency’s current legislative tasks.

‘Core business’ is defined as the Agency’s involvement in the authorisation and supervision of medicinal products for human and veterinary use, in accordance with EU legislative provisions, including the processes supporting these tasks

Implementation in a climate of ‘zero growth’

- Process Improvement and Operational Excellence
- Focus on efficiency, effectiveness and value for money
- Project launched to achieve ‘operational excellence’ across all business processes
- Revised approach to the strategy, ICT architecture and governance of information

How has it been prepared?

Structured following the strategic areas outlined in the Road Map

Takes into account:

- The content of the Road Map
- The comments received as part of the Road Map consultation
- The Agency's work programmes for 2011 and draft work programme for 2012
- EMA staff have provided input on the relevant projects planned or in progress from the work programmes of the committees and working parties

What does it look like?

- Listing of priority activities (39 in total)
- Activities grouped under headings and objectives as described in the Road Map
- Additional listing of other actions that support Road Map objectives
- Supported by internal document, with deliverables and responsibilities assigned (to facilitate work programme preparation)

Implications for patients and consumers

In theory everything…

However some are more obvious than others..

- Geriatric strategy
- Public health threats
- Conduct of clinical trials in non-EU countries
- Access to Non-prescription medicines
- Involvement in benefit/risk decision making and communication
- Pharmacovigilance and provision of information
- Communicating use of medicines outside approved indications

Strategic Area 1: Addressing Public-Health Needs

Grouping of Activity areas		Road Map Objective
Addressing unmet medical needs	→	Bridging gaps in medicines development and supply
Improving focus on needs of geriatric patients	→	
Exploring options for new and effective antibiotic treatments	→	
Promoting the availability of veterinary medicines	→	

Strategic Area 1: Addressing public-health needs - 1.1 Gaps in medicine development – priority activities impacting patients/consumers

- Developing an EMA geriatric medicines strategy to address challenges stemming from demographic changes such as population ageing
  - Strategy developed and published
  - Advisory group established
  - Revised template for assessment report
  - Workshop March 2012

Strategic Area 1: Addressing public-health needs - 1.3. Public Health Threats- priority activities – consumer/patient impact

- Improving communication between regulatory bodies and public-health bodies
  - Post-pandemic experience
  - Ensure consistency of messages and mutual understanding of respective roles

Strategic Area 2: Facilitating access to medicines

Grouping of Activity areas	Road Map Objective
Optimising the scientific advice process and establishing earlier and continuous dialogue	Addressing the high attrition rate during development and improving the process for approval
Utilising information from failed development studies	
Addressing the challenges of globalisation	
Strengthening advice and incentive frameworks for veterinary medicines	

Strategic Area 2: Facilitating Access to Medicines 2.1 Medicines development process, early assessment and continuing dialogue – priorities with consumer / patient impact

- Addressing the growing numbers of patients recruited to clinical trials in countries outside the EU
  - Agency's draft reflection paper and within the framework of the review of the clinical trial legislation
  - focus on ethical approaches
  - transparency of review
  - international collaboration aspects include the need to support training and capacity building

Benefit-risk assessment and communication

Grouping of Activity areas	Road Map Objective
Enabling a consistent approach to benefit-risk assessment	Reinforcing the benefit-risk balance assessment and communication model
Improving and adapting existing legal tools	
Improving communication on benefit-risk review to stakeholders	
Exploring the balance between early approval with limited data and later approval with more extensive data package	
Embedding benefit-risk methodology in the assessment procedure for veterinary medicines	

Strategic Area 2: Facilitating Access to Medicines 2.1 Medicines development process, early assessment and continuing dialogue – priorities with patient/consumer impact

- Updating process for guideline development to improve planning and prioritisation
  - Clarify interactions with stakeholders (academia/learned societies/patient organisations)

Strategic Area 2: Facilitating Access to Medicines

2.2 *Benefit-risk assessment and communication* – priorities with patient/consumer impact (Part 1)

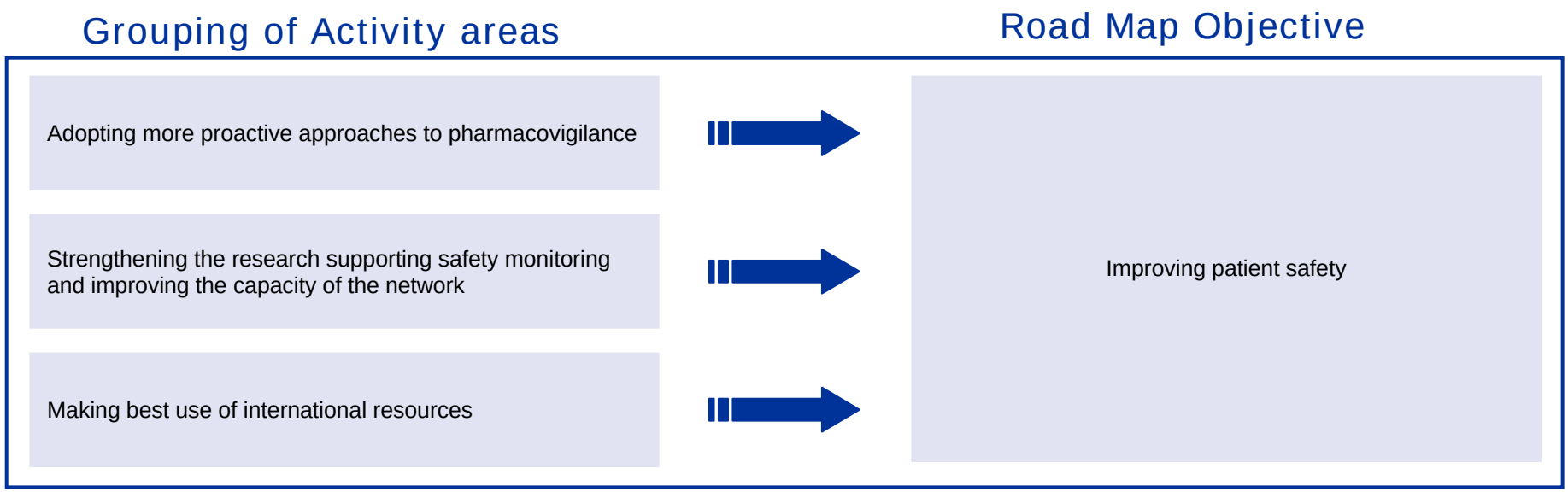
- Strengthening the monitoring of the benefit-risk balance of medicines
  - development of innovative tools and methods to collect data from consumers
  - proactively detect signals
  - Improve the design and conduct of pharmacoepidemiological studies
- Analysing the CHMP's approach to access of non-prescription medicines and to "switching" from prescription to non-prescription status in the centralised procedure
  - propose remedial action

Strategic Area 2: Facilitating Access to Medicines

2.2 *Benefit-risk assessment and communication* – priorities with patient/consumer impact (Part 2)

- Adapting the structure and content of the European Public Assessment Report
  - new website tools to improve communication of B/R decisions to stakeholders
  - more emphasis on the quantitative aspects of the benefit-risk assessment
- Increasing the involvement of patients, academia and health care professionals
  - to ensure that stakeholder views are taken into account in B/R decision making

Strategic Area 3: Optimising the Safe and Rational Use of Medicines



Strategic Area 3: Optimising the Safe and Rational Use of Medicines - 3.1 Patient Safety - priorities with patient/consumer impact

- Implementing the new pharmacovigilance legislation

  (to be addressed by Dr. Arlett)

Strategic Area 3: Optimising the Safe and Rational Use of Medicines - 3.2 Post-authorisation follow-up – priorities with patient/consumer impact

- Increasing contribution from patients and healthcare professionals on assessment of benefit-risk, particularly by obtaining information on the use of medicines in real life
  - Recommendations to be included in the framework
  - Development of new methods of data collection

3.3 Authoritative source of information

Grouping of Activity areas	Road Map Objective
The EMA as an information provider within the EU regulatory Network	Ensuring high quality availability of information on medicines
Improving the quality and consistency of information	
Adapting to the needs of patients and healthcare professionals	
Meeting the needs of the veterinary stakeholders	

Strategic Area 3: Optimising the Safe and Rational Use of Medicines - 3.3. Authoritative source of information – priorities with patient/consumer impact

- Strengthening the EMA's collaboration with the EU national regulatory agencies and decision makers in the area of provision of information
  - developing an appropriate model and structure
  - improving communication with the various stakeholders
  - development of a communication strategy
  - development of a transparency policy
  - involvement of patient and healthcare professionals
  - building up a network of excellence
- Better communication to HCPs and patients on the reasons what the medicinal product is not indicated for use outside the approved indications

Some other activities (non-priority)

Exploring how better to take into account patient values in benefit risk assessments

Increasing the collection of information from real-life use (ENCePP)

Supporting appropriate prescribing of medicines (link with e-prescribing)

Monitoring the use of medicines

Status and Next steps

- Preliminary discussion took place at Management Board (MB) December 2010
- Input from EMA management collected and compiled
- Circulation to Scientific Committees
- Review and reorientation at MB June 2011
- Revised version endorsed at October MB and published
- Road map actions will be identified as such in the annual work programmes
- Periodic monitoring and review envisaged

THANK YOU FOR YOUR ATTENTION!

Implementation plan

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/10/WC500115960.pdf