EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Implementing the European Medicines Agency's Road map to 2015: The Agency's contribution to Science, Medicines, Health

"From Vision to Reality"

Introduction

The European Medicines Agency's Road map to 2015 sets out the Agency's vision, elaborates on the main drivers for progress and change that will impact on it, and explores the main initiatives to be undertaken to successfully meet the challenges it will face. It encompasses the Agency's strategy for both medicines for human and veterinary use in line with the joint responsibility of the Agency.[1] This implementation plan provides information on how the vision outlined in the Road map to 2015 is expected to be developed.

It should be stressed, that as outlined in the Road map, efficient operation of the Agency's core business activities[2] continues to be the primary focus for the Agency over the next five years. Performing and delivering on its tasks in line with current and upcoming legislation is the fundamental cornerstone on which all of the Agency's activities are based. The Agency's Road map and hence this implementation plan is intended to optimise the Agency's performance in the three strategic areas identified. This document therefore concentrates on priority activities in these three areas: **Addressing public-health needs; Facilitating access to medicines and Optimising the safe and rational use of medicines.** It follows the structure of the Road map document adopted on 16 December 2010 in order to address the drivers for change under these areas.

Implementing the recently adopted pharmacovigilance legislation and the upcoming falsified medicines legislation has important consequences on both the core and strategic activities of the Agency. While the majority of the activities under the new legislative provisions fall under the strategic areas outlined in the Road map, it must be stressed that the document is not intended to provide all details.

In the area of veterinary medicines the European Commission has initiated an impact assessment of the current regulatory framework to evaluate if changes are required to adapt the requirements to the

[1] Although the majority of objectives are common to both sectors, veterinary specific activities have been identified under each sub-heading. Unless there is a particular focus on specific types of medicinal product (e.g., generic, herbal or non-prescription, orphan or medicines for paediatric use), activities should be considered as applying to all products within the Agency's remit

[2] From Road map to 2015: 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.

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specific needs of this sector, particularly in view of ongoing problems with availability. The outcome of this impact assessment has the potential to change the priorities and tasks of the Agency with respect to veterinary medicines over the life span of this implementation plan and it will therefore be necessary to review the relevant sections as the Commission's review progresses. Similarly the potential impacts of proposed legislative changes in areas such as 'information to patients' , revision of the clinical trials directive and the planned recast of the medical devices legislation have not been addressed.

Prioritisation through adoption of annual work programmes

Implementation will follow a gradual approach which will be further elaborated in annual work programmes. Those activities identified as priorities will continue to be pursued; other activities will be progressed in line with the priority determination and resource allocation that takes place as part of the Agency's normal planning cycle. These are identified in the annex to this document, grouped according to the three strategic areas outlined in the Road map.

Taking into account uncertainties with respect to resources, other external factors such as additional legislative developments, the activities outlined will be subject to annual adoption in the work programme, and subsequent monitoring and review. The road map identifies the impact/result indicators which will be used for this monitoring. These are considered as success factors against which the delivery of the road map will be measured at the end of the period. Road map topics will be designated as such in the work programmes.

Dealing with resource constraints in the context of implementation of the road map

It must be emphasised, that, as the Agency is currently in a phase of zero-growth and due to economic pressures across the entire EU regulatory network, a number of aspirations in the Road map cannot be addressed with current resources available. Efforts will nonetheless continue to be made to improve efficiency and achieve resource savings.

To achieve this, the Agency has launched an 'operational excellence' initiative across its business activities. This initiative addresses the Agency's need to further strengthen its operations and respond to the changing environment in which it operates. It aims to reduce the complexity of the administrative burden, to support further efficiency improvements and encompasses a revised approach to business operations, ICT governance and the management of information held by the Agency.

The 'operational excellence' initiative is intended to meet demands for:

- Saving resources without compromising on quality
- Reengineering processes and reallocating resources to deliver on core activities
- Improving efficiency to better handle workload
- Demonstrating European best practice.

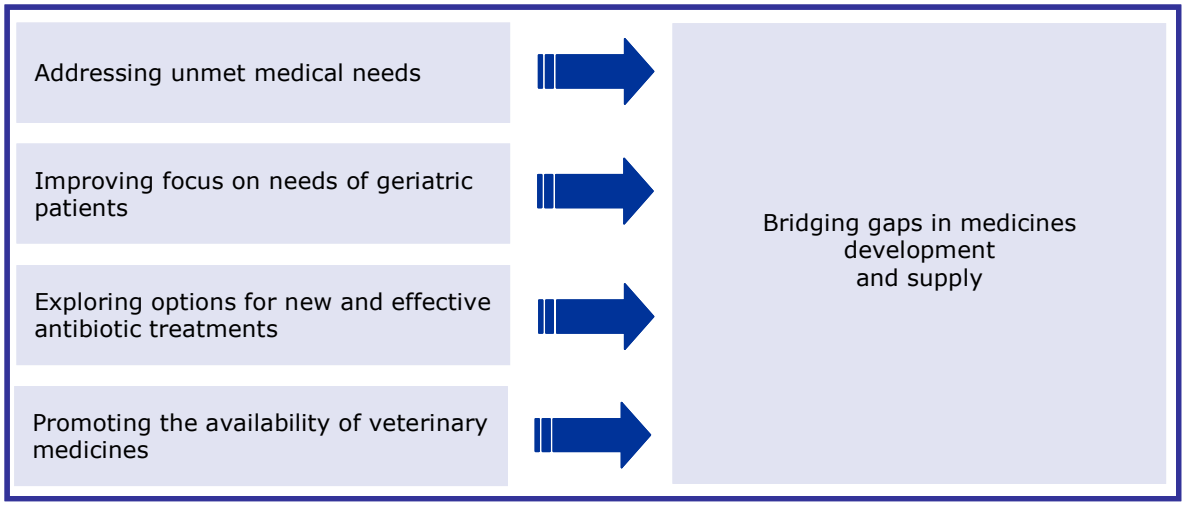
It is important to stress that the success of all of the Agency's activities to implement the Road Map are dependent on the continuing support from the EU regulatory network and that the activities outlined complement those outlined in the Heads of Medicines Agency's strategic plan.

1. Strategic Area 1: Addressing public-health needs

To address current and anticipated public-health needs over the next five years, the Agency will focus on activities relating to addressing gaps in medicines development, responding to new and emerging science and putting in place the necessary preparedness mechanisms to respond to emerging health threats.

1.1. Gaps in medicine development

Three main 'gaps' in drug development have been identified; neglected and rare diseases, specific activities relating to aging populations and the need to address the pipeline gap for new antibiotics. On the veterinary side activities will focus measures to increase the availability of all types of veterinary medicines.



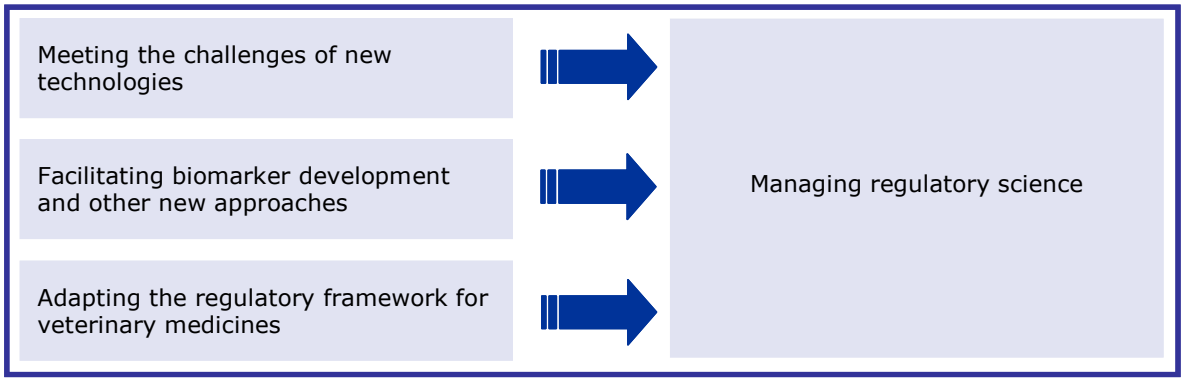
Priority Activities

- Fostering cooperation with the Commission to ensure greater input into the research agenda in these areas taking into account the objectives outlined in the Europe 2020 strategy[3] (ONGOING)
- Developing an EMA geriatric medicines strategy to address challenges stemming from demographic changes such as a population ageing (COMPLETED)
- Providing support to the European Commission to promote the availability of medicines for veterinary use in general, and in particular those indicated for minor use and minor species (MUMS/limited markets) (ONGOING)

1.2. New and emerging science

The focus of efforts to address the challenges of new and emerging science will include efforts to enhance liaison between approaches to drug and diagnostic development, facilitation of biomarkers and the science supporting the development of more personalised medicines, as well as specific activities aimed at adapting the regulatory framework for veterinary medicines.

[3] Europe 2020: A European strategy for smart, sustainable and inclusive growth COM (2010)2020

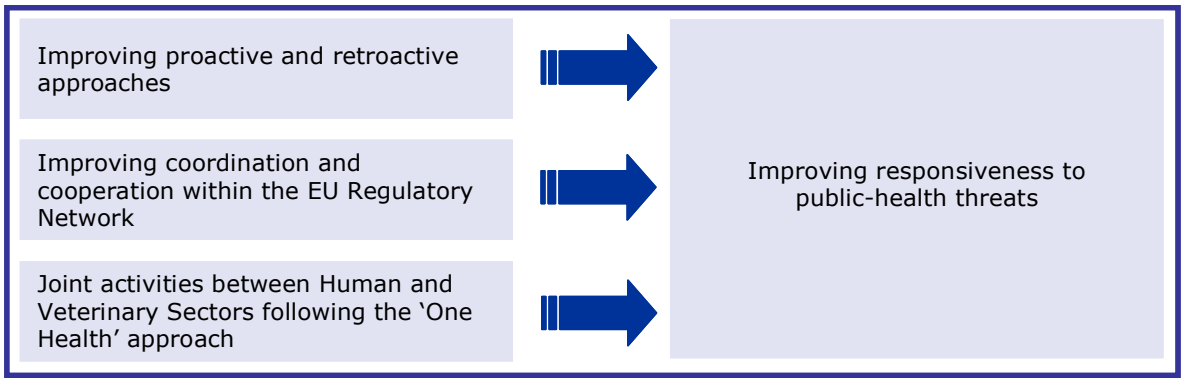


Priority Activities

- Consolidating and streamlining the consultation and interactions with notified bodies for medical devices for the evaluation of combined ATMPs and ancillary substances (ONGOING)
- Adapting existing scientific and regulatory guidelines in order to ensure that criteria for regulation of established medicines do not create a barrier to the development of new approaches such as stem cell technology, regenerative and personalised medicines (ONGOING)
- Qualification of novel methodologies as support to the Innovative Medicines Initiative (IMI) and Critical Path frameworks, in association with regulatory partners such as the US FDA (ONGOING)

1.3. Public-health threats

The Agency will aim to improve its responsiveness to public-health threats through proactive and retroactive approaches and through efforts to improve coordination and cooperation within the EU regulatory network. Coordination between activities in the human and veterinary areas remains essential to support the 'One Health' concept whereby promotion of health in animals promotes health in humans[4].



Priority Activities

- Building on experience with influenza pandemic preparedness to assist the Commission in the development of a coordinated strategy with European partners to ensure a quick and coordinated European response to any specific European health threat and accelerated decision making (ONGOING)

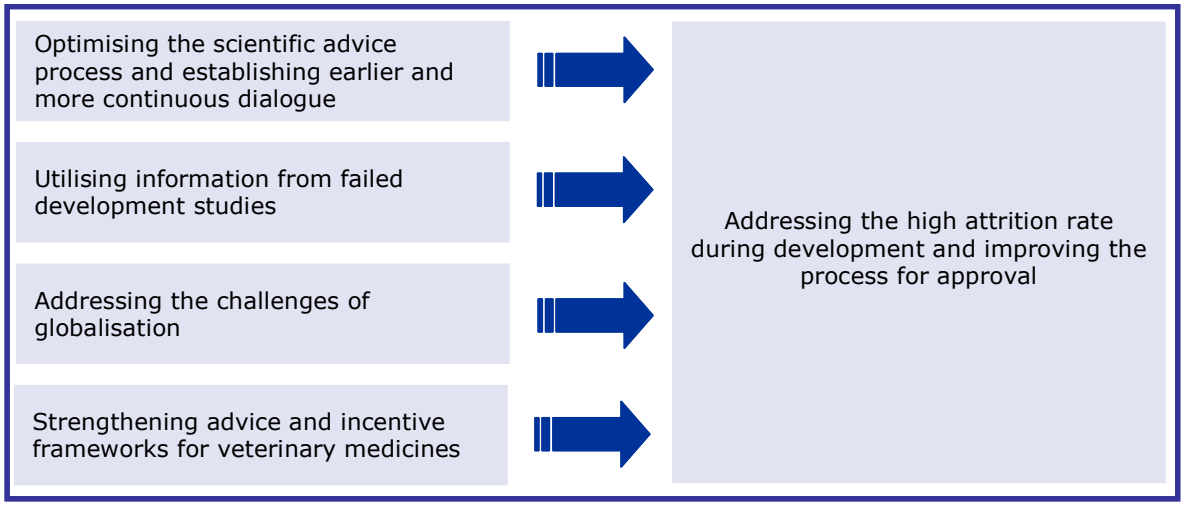
[4] http://www.onehealthinitiative.com

- Improving communication between regulatory bodies and public-health bodies to ensure consistency of messages and mutual understanding of respective roles (PLANNED)
- Intensifying work on a European and international perspective to minimise the risk of antimicrobial resistance (AMR) arising from the use of both human and veterinary medicines within the framework of Community and international activities including the Transatlantic Taskforce on AMR established based on conclusions of the 2009 EU-US summit (ONGOING)
- Developing the European Surveillance of Veterinary Antimicrobials project from a pilot into an operational system to collate, analyse and report on sales and use of veterinary antimicrobials in order to assist with risk assessment and risk management of antimicrobial resistance at EU level (TO BE PROGRESSED IN THE CONTEXT OF THE REVIEW OF THE VETERINARY MEDICINES LEGISLATION)

2. Strategic Area 2: Facilitating Access to Medicines

To address the high attrition rate the Agency will focus on activities relating to the medicine development process, benefit-risk assessment and relative effectiveness assessment. The three areas are addressed separately whilst acknowledging their interdependency.

2.1. Medicines-development process, early assessment and continuing dialogue



Priority activities

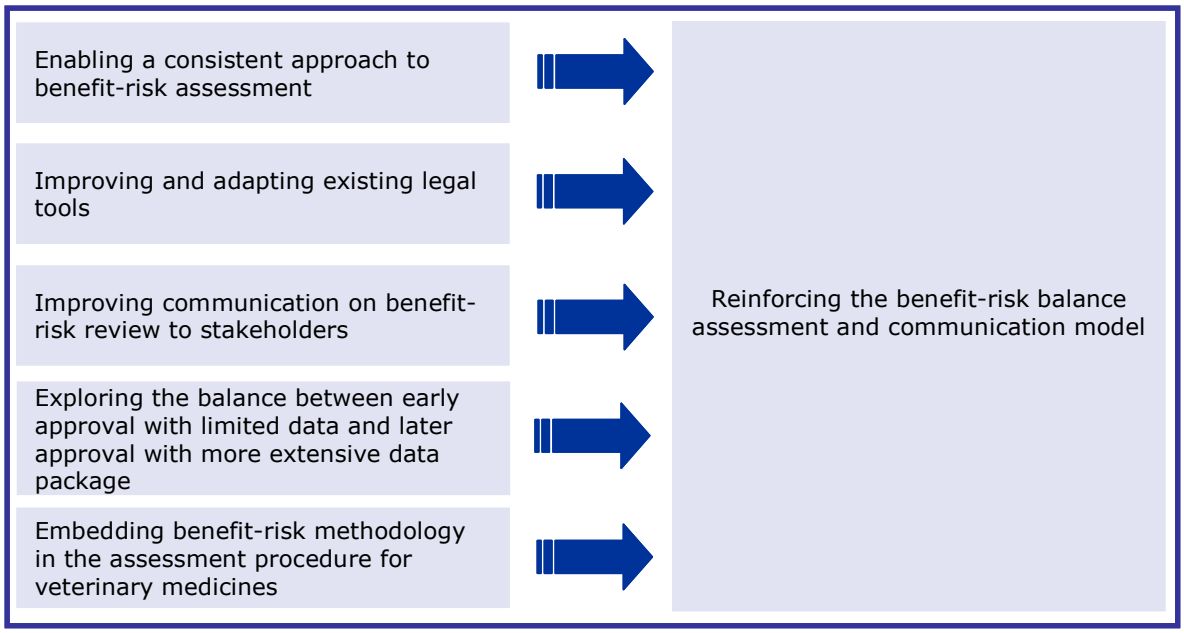
- Updating process for guideline development to improve planning and clarify interactions with stakeholders (academia/learned societies/patient organisations) in the process as well as establish prioritisation. Consider more use of adapted comment periods and second consultation rounds (e.g after major modifications) when appropriate (ONGOING)
- Reinforcing support offered to Advanced therapy, SME, and orphan applications in the period between scientific advice and initial application for marketing authorisation (PLANNED)
- Promoting a global approach to quality of Active Pharmaceutical Ingredients, Finished Products and the integrity of the supply chain through developing contacts with the main countries where

manufacture takes place, promoting ICH and VICH principles and assisting with training, capacity building and networking with a view towards more risk based and synergistic approaches and less duplication of international effort (TO BE PROGRESSED IN THE CONTEXT OF THE IMPLEMENTATION OF THE FALSIFIED MEDICINES LEGISLATION)

- Preventing the circulation of falsified medicines through measures designed to protect the legitimate supply chain as described in the falsified medicines legislation (TO BE PROGRESSED IN THE CONTEXT OF THE IMPLEMENTATION OF THE FALSIFIED MEDICINES LEGISLATION)
- Addressing the growing numbers of patients recruited to clinical trials in countries outside the EU through the activities described in the Agency's draft reflection paper and within the framework of the review of the clinical trial legislation, with particular focus on ethical approaches, transparency of review and international collaboration. International collaboration aspects include the need to support training and capacity building (ONGOING)
- Conducting an annual review of measures to support veterinary medicines for MUMS/limited markets. Proactive follow up at pre-submission stage and encouraging follow-up scientific advice procedures where necessary (ONGOING)

2.2. Benefit-risk assessment and communication

The activities that will be undertaken to reinforce the benefit-risk balance assessment and communication model will focus on improving consistency and communication and exploring how existing legal tools can be adapted to improve knowledge and decision making on the benefits and risks of medicines.



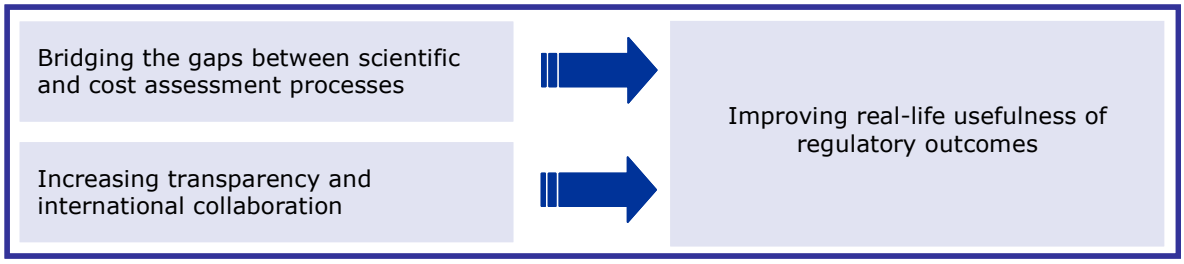
Priority activities

- Continuing to work on the development of more quantitative tools aimed at improving the consistency of the benefit-risk assessment process (ONGOING)
- Continuing to improve the quality and the regulatory consistency of the outcome of the scientific review (ONGOING)

- Strengthening the consistency of the scientific assessment related to changes to the marketing authorisation with particular relevance for the benefit-risk assessment throughout the product life-cycle (ONGOING)
- Strengthening the monitoring of the benefit-risk balance of medicines through the development of a set of innovative tools and methods to collect data from consumers, proactively detect signals and improve the design and conduct of pharmacoepidemiological studies (PLANNED)
- Improving the formulation (wording), implementation and monitoring of post-authorisation commitments for marketing authorisations (ONGOING)
- Analysing the CHMP's approach to access of non-prescription medicines and to "switching" from prescription to non-prescription status in the centralised procedure and taking remedial action, where necessary (PLANNED)
- Adapting the structure and content of the European Public Assessment Report and use the new website tools to improve communication of the decisions on the benefit-risk of authorised medicines to stakeholders including patients, the scientific community and health technology assessment bodies putting more emphasis on the quantitative aspects of the benefit-risk assessment (ONGOING)
- Increasing the involvement of patients, academia and health care professionals in the scientific work of the Agency to ensure that these stakeholder views are taken into account in benefit-risk decision making (ONGOING)
- Assessing in the veterinary area, the usefulness of benefit-risk methodology in terms of promoting availability of veterinary medicines when applied to medicines for emergency diseases and limited markets (TO BE PROGRESSED IN THE CONTEXT OF THE REVIEW OF THE VETERINARY MEDICINES LEGISLATION)

2.3. *Facilitation of the relative-effectiveness assessment of medicines for human use*

Efforts to facilitate relative effectiveness assessment will focus on increasing the role of the Agency as an information provider and on greater collaboration with health technology assessment processes.



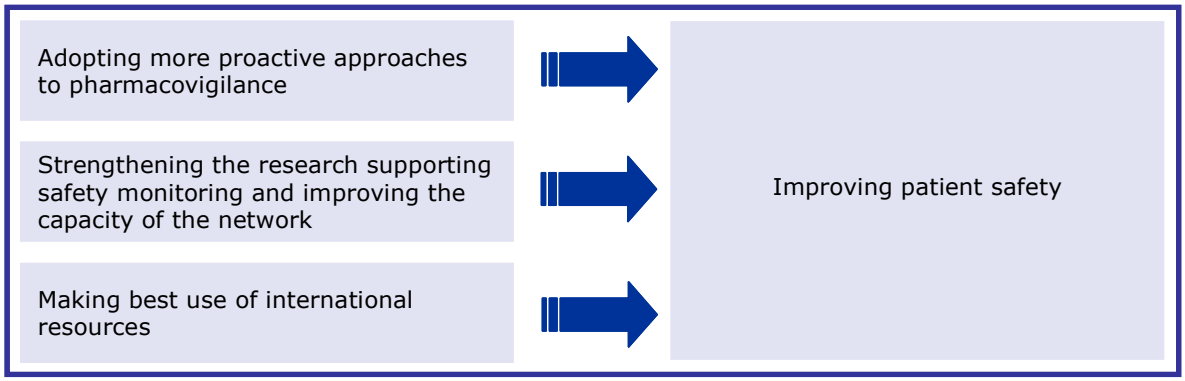
Priority activities

- Increasing mutual understanding of the respective roles of HTAs and pharmaceutical regulators and the impacts of decisions such as choice of clinical endpoints, efficacy versus effectiveness, and relative efficacy versus placebo controlled studies (ONGOING)
- Increasing engagement with HTA bodies from early medicine development throughout the medicine's lifecycle including participation in scientific advice discussions (ONGOING)

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

The Agency's initiatives in this field will focus on enhancing patient and animal safety by avoiding unnecessary risks, strengthening the evidence base to enable better decision making, and improving communication and information tools for stakeholders. In the area of medicines for human use, many of the actions are those required as a consequence of the new pharmacovigilance legislation.

3.1. Patient Safety



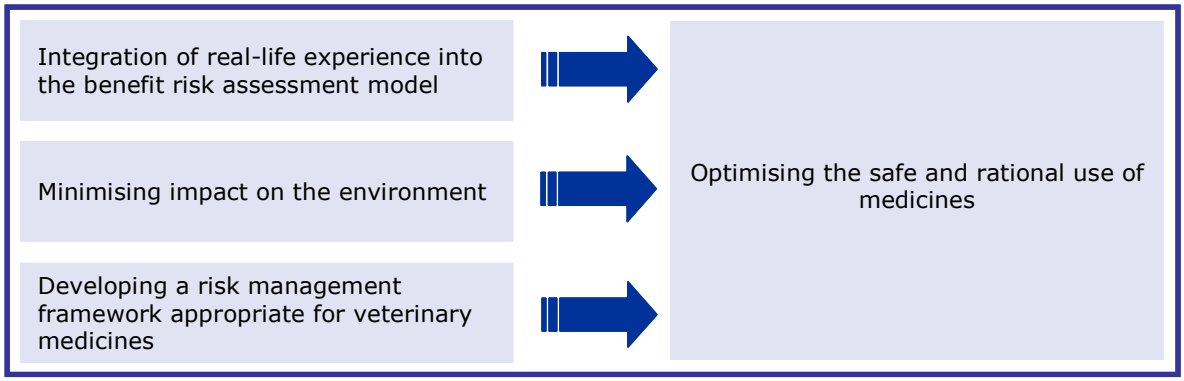
Priority activities

- Implementing the new pharmacovigilance legislation in the areas of Periodic Safety Update reporting, non-interventional post-authorisation safety studies, terminologies needed to support pharmacovigilance, ADR reports collection and data management, ADR data provision, signal detection, prioritisation and evaluation, the new Scientific Committee (PRAC), robust decision-making, referral procedures for pharmacovigilance, communication and transparency, pharmacovigilance inspections and risk management (TO BE PROGRESSED IN THE CONTEXT OF THE IMPLEMENTATION OF THE PHARMACOVIGILANCE LEGISLATION)
- Supporting the conduct of pharmacovigilance through maintaining and strengthening the EudraVigilance system (TO BE PROGRESSED IN THE CONTEXT OF THE IMPLEMENTATION OF THE PHARMACOVIGILANCE LEGISLATION)
- Supporting ENCePP as a functional network of centres for the conduct of multi-centre, independent, post-authorisation studies. Reviewing the ENCePP study concept based on acquired experience, guidance in methodological standards in pharmacoepidemiology, facilitating conduct of multinational studies, consistent interpretation of the definition of non-interventional study, further development of ENCePP databases and interfacing with the new pharmacovigilance legislation, HTA and the Enpr-EMA network (ONGOING)
- Improving processes for managing Risk management plans (RMPs) including through the outcome of the Review and Learning project, peer review mechanisms, guidance and SOP documents, review of the risk minimisation toolbox (ONGOING)
- Enabling the application of best evidence to support decision making post-authorisation (ONGOING)

- Identifying research topics for which funding is needed and strengthening research in the areas of signal detection, pharmacoepidemiology and supporting benefit-risk decision and translating research funding into implementation of process (ONGOING)
- Working with the IMI Joint Undertaking to ensure the research agenda addresses important public-health needs as identified by the EMA (ONGOING)
- Collaborating on international standardisation including ICSRs, IDMP, Risk management, Electronic PSURS and formats for clinical trials (TO BE PROGRESSED IN THE CONTEXT OF THE IMPLEMENTATION OF THE PHARMACOVIGILANCE LEGISLATION)

3.2. Post-authorisation follow-up

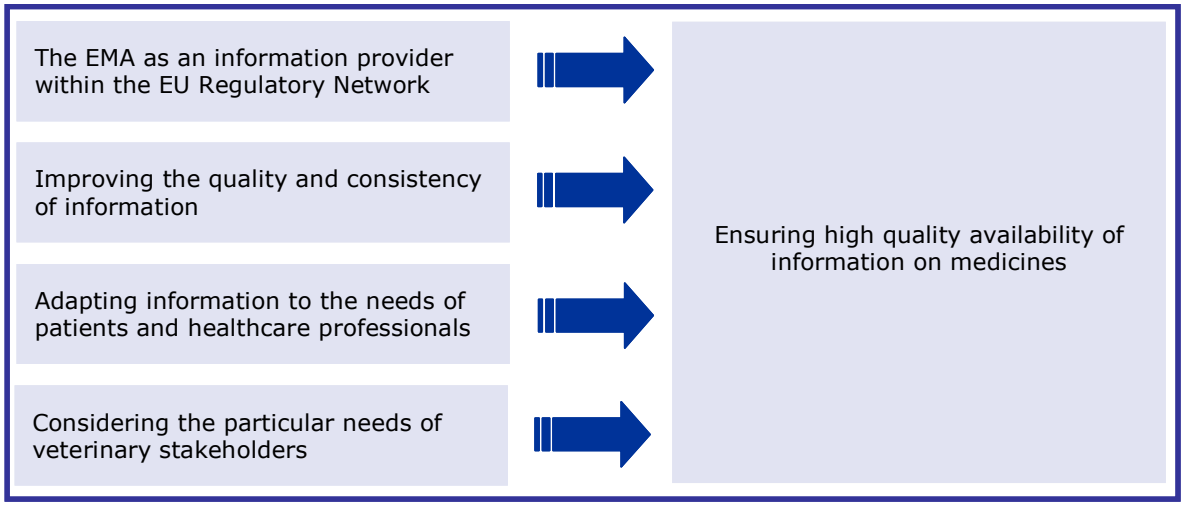
Optimising the safe and rational use of medicines will require greater emphasis on the collection of data in 'real-life' situations, and better management of risks, including risks to the environment. Activities that are not already covered under area 3.1 are identified here. Activities relating to minimising impact on the environment are addressed under section 4.



Priority activities

- Increasing contribution from patients and healthcare professionals on assessment of benefit-risk, particularly by obtaining information on the use of medicines in real life (ONGOING)
- The development of an approach to pharmacovigilance and the introduction of a framework for post-authorisation risk management that is adapted to the needs, expectations and resources of the veterinary sector. (TO BE PROGRESSED IN THE CONTEXT OF THE REVIEW OF THE VETERINARY MEDICINES LEGISLATION)

3.3. Authoritative source of information



Priority activities

- Strengthening the EMA's collaboration with the EU national regulatory agencies and decision makers in the area of provision of information as well as developing an appropriate model and structure for this in collaboration with the EU regulatory network (see also activities under strategic area 1), improving communication with the various stakeholders). This will be achieved through the development of a communication strategy and a transparency policy to address the growing need for greater transparency. (ONGOING)
- Better communication to HCPs and patients on the reasons what the medicinal product is not indicated for use outside the approved indications (PLANNED)

Annex 1: Listing of additional EMA activities which support Road map objectives

Selected activities from this list will be progressed in line with the priority determination and resource allocation that takes place as part of the Agency's normal planning cycle

Strategic Area 1: Addressing public-health needs

Addressing unmet medical needs

Analysing the reasons why there continue to be gaps in orphan medicines and neglected disease areas, report on this analysis and explore methods to encourage development, in cooperation with DG Research and international partners. This work will also cover the area of advanced therapy medicines and specific needs of SMEs.

Analysing the reasons why specific types of medicines (orphan, ATMPs) fail to progress to applications for marketing authorisation in order to propose possible remedial measures

Considering the specific difficulties faced by SMEs and academic sponsors

Considering the relative merits of existing incentives schemes (orphans/paediatric/SME), and regulatory pathways (accelerated assessment, Article 58 opinions) to stimulate development of medicines to treat neglected diseases etc.

Initiating international collaboration to consider what regulators can contribute to stimulate medicines development in areas of unmet medical need or neglected diseases. This will include collaboration through existing bilateral and multilateral arrangements and in cooperation with WHO

Supporting the expansion of Enpr-EMA, the European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population

Conducting a mapping exercise to identify disease areas where additional medicines are needed

Improving focus on needs of geriatric patients

Implementing more detailed assessment of clinical data relating to geriatric populations and reflection of this in the assessment report

Considering the need to involve older patients in clinical trials, impacts of polypharmacy, sources of ADRs

Exploring options for new and effective antibiotic treatments

Reviewing existing options to promote development of new antibiotics to treat multi-resistant bacteria including adaptation of clinical guidance documents, consideration of the balance between the amount of prior data needed with enhancing post-marketing surveillance, use of orphan legislation, etc.

Contributing to European and transatlantic activities to address the need for novel treatments for TB and to streamline their development

Strategic Area 1: Addressing public-health needs

Developing a position on the development of new veterinary antimicrobials that takes into account both the interests of animal health and the need to preserve the efficacy of certain critically important antimicrobials for human use

Promoting the availability of veterinary medicines

Facilitating the authorisation of vaccines against epizootic diseases as part of the EMA input into the Community Animal Health Strategy

Providing assistance with the development of novel tools for disease control and ensure best use of existing tools (such as revised MRL regulation) to promote authorisation of new medicines and retain existing medicines on the market

Considering, as part of the review of legislation in the veterinary sector, the feasibility of the Agency assisting with authorisation of veterinary medicines intended for less developed countries in a procedure analogous to the Art 58 procedure for human medicines operated with WHO

Meeting the challenges of new technologies

Establishing better links between diagnostic and medicine regulation: in order to, inter alia enable the development of personalised medicine and stratified medicine, borderline and integrated products.

Enhanced collaboration on Borderline discussions with EC Borderline and Classification Medical Devices Expert Group and its related subgroups

Facilitating biomarker development and other new approaches

Providing regulatory and scientific support to the Innovative Medicines Initiative (IMI) to facilitate calls for research in areas such as life-cycle genomics biomarkers

Reviewing the impact of genomics in personalised medicines evaluated in Agency’s procedures.

Reinforcing European and International collaboration on nanotechnologies in life sciences to encourage greater understanding and synergies across disciplines, taking into account the conclusions of the specific international workshop organised by the EMA in Sept 2010 and the need to promote Agency and EU regulatory network competence development through specific training activities

Adapting the regulatory framework for veterinary medicines

Providing input into the revision of the veterinary legislation to facilitate the development of novel veterinary medicines and/or to enable possibilities to adapt human use products for veterinary use

Adapting existing scientific and regulatory guidelines in order to ensure that criteria for regulation of established veterinary medicines do not create a barrier to the development of new approaches, and create new guidelines as appropriate

Strategic Area 1: Addressing public-health needs

Working with all stakeholders as part of the legislative review process to define the optimal role for the Agency in any revised structure for the EU regulatory network

Working with the network to develop a strategy for progressive harmonisation of existing products that minimises the need for referral to CVMP and ensures that issues are prioritised on the basis of public and animal health

Improving proactive and retroactive approaches (to public health threats)

Collaborating within the EU regulatory network and associated institutions to identify possible public-health threats including challenges to key treatment supply

Contributing to simulation activities to facilitate preparation and conducting lessons learnt exercise after each simulation or major event.

Joint Activities between Human and Veterinary sectors

Improving the linkages between the protection and improvement of animal health and the protection and improvement of human health, particularly in the area of zoonotic and emerging diseases, antimicrobial resistance, and ensuring the safety of substances of animal origin used in the production of human and veterinary medicines

Ensuring the safety and continuity of supply of medicines for human and veterinary use, and particularly raw materials, arising as a results of threats to the supply chain

Strategic Area 2: Facilitating Access to Medicines

Optimising the scientific advice process and establishing earlier and more continuous dialogue

Reviewing existing arrangements with FDA and other international partners with the aim of promoting parallel scientific advice and in the context of other international collaboration at the scientific advice phase

Involving the FDA in the development and discussion of 'model / template' Paediatric Investigation Plans

Coordinating and interacting with ethics committees to ensure smooth authorisation of PIP studies

Reviewing the procedure for centralised initial applications to include early dialogue with Rapporteur and EMA and to define roles and responsibilities in the early phase exploring the possibility of earlier appointment/continuous rapporteurship on a voluntary basis

Improving communication between the Clinical trial sponsors and the EU regulatory network taking into account the outcome of the revision of the Clinical trial legislation

Strategic Area 2: Facilitating Access to Medicines

Introducing a process for access and exchange of information with member states on national and centralised scientific advice.

Analysing the current process of interactions between EMA/CHMP and applicant/MAH during the life-cycle of the Product, exploring ways to improve efficiency

Increasing the integration of post-authorisation medicine development in the Agency's scientific advice framework

Strengthening engagement with the pharmaceutical industry, the European Commission, EDQM and the ECVAM to promote the 3Rs principles

Utilising information from failed development studies

Analysing and exploring the reasons for failed development and how the learning process can be used to influence future regulatory decisions. Exploring incentives to make information from failed studies available, collaboration with sponsors about possible publication and investigation of ongoing initiatives, e.g. applicability of 'patent pooling' initiatives

Creating a platform for dialogue with DG Research to raise awareness of this topic and facilitate inclusion on the research agenda (see also priority activity on fostering communication with the Commission in section 1.1)

Addressing the challenges of globalisation

Promoting EU scientific approaches and ICH and VICH principles to regulators outside the regions involved in these activities

Promoting information and work sharing as well as networking concepts with a view towards encouraging a global approach to regulatory activities such as paediatric development, conduct of clinical trials, manufacture and pharmacovigilance.

Strengthening advice and incentive frameworks for veterinary medicines

Maintaining the current, increased level of uptake of the scientific advice procedure in the veterinary sector through promotion of the concept and potential benefits at pre-submission meetings with applicants and external conferences

Identifying the reasons why intended products for which scientific advice was requested, fail to progress to applications for marketing authorisation in order to propose possible improvements

Implementing as necessary improvements to the content and procedure for scientific advice to increase its perceived and actual usefulness

Promoting early dialogue with sponsors to facilitate understanding of regulatory and scientific challenges

Making better use of specialised expertise during the assessment phase

Strategic Area 2: Facilitating Access to Medicines

Monitoring the developments in the human sector regarding the possibilities of establishing an overarching regulatory process from inception to application and assess relevance for veterinary medicines

Strengthening engagement with the pharmaceutical industry, the European Commission, EDQM and the ECVAM to promote the 3Rs principles throughout regulatory procedure for veterinary medicines (vet specific activity)

Enabling a consistent approach to benefit-risk assessment

Performing a retrospective analysis of selected divergent decisions taken by the Agency and non-EU Regulatory authorities, in particular US FDA to better understand the reasons behind differences in benefit-risk decisions and assess the potential for greater alignment

Improving consistency in the assessment of identical applications for generic products between procedures at Agency level and at decentralised / national level. Implement improved peer review process for generic marketing authorisation applications.

Improving and adapting existing legal tools

Reviewing conditional marketing authorisation to ensure criteria are complied with in the context of a broader concept of early access to medicines

Developing a pilot project on orphan medicines to explore how to better communicate and justify significant benefit decisions reached by the Committee for Orphan Medicinal Products

Responding to actions arising from the end of the transition period with respect to traditional herbal medicinal products

Enhancing cooperation between the Agency and EFSA in the area of health claims and clarification of the borderline with medical devices

Improving communication on benefit-risk review to stakeholders

Considering the use of additional communication tools, such as scientific articles and other forms of interactions to increase awareness and understanding of benefit-risk decisions of individual medicines by the scientific and academic community

Reviewing and implementing the recommendations of the recently published report reviewing case studies on stakeholders' expectations regarding benefit-risk communication

Performing stakeholder analysis and reviewing target audience (setting up priorities). Adapting and designing communication tools as per reviewed target audience.

Strengthening the robustness of the scientific review through the use of more statistical expertise

Initiating discussion involving patient groups and health technology assessment bodies aimed at exploring how to ensure patient values are taken into account in benefit-risk assessments

Strategic Area 2: Facilitating Access to Medicines

Exploring the balance between early approval with limited data and later approval with more extensive data package

Considering the merits and mechanics of an optional approach to early authorisation of medicines in a restricted population e.g. based on early information from good responders. Exploring the broader applicability of 'staggered' approvals and preparing guidance on the applicability of such approaches.

Embedding benefit-risk methodology in the assessment procedure for veterinary medicines

More clearly embedding the benefit-risk methodology in the assessment procedure and better communicating to the Agency's stakeholders, and the provision of training within the EU regulatory network

Reviewing the CVMP benefit-risk recommendations in light of experience gained

Exploring the concept of conditional marketing authorisation for veterinary medicines

Considering the need for development of a specific benefit-risk framework for authorisation of veterinary antimicrobials

Bridging the gaps between scientific and cost assessment processes

Exploring possibilities for collaboration on clinical and methodological guidelines with a view to facilitate study designs that can generate data relevant for both regulatory and health technology assessments

Considering the needs of both Regulators and HTA bodies in the determination of what data should be collected during the post-authorisation phase, including the need for additional effectiveness data to be collected. Encouraging the use of the scientific advice procedure to achieve this.

Increasing transparency and international collaboration

Contributing to international activities involving both HTA bodies and international pharmaceutical Regulators.

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

Adopting more proactive approaches to pharmacovigilance

Considering the impact of risk minimisation measures on the work of health care professionals

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

Making best use of international resources in the safety area

Working with ENCePP (EMA) and Sentinel (FDA) and DSEN (Health Canada) initiatives to ensure a synergistic approach

Developing international cooperation on pharmacovigilance inspection to improve supervision and inspection in a global context.

Integration of real-life experience into the benefit-risk assessment model

Increasing the collection of information from 'real-life' use of the medicine, including off-label use through work within the ENCePP framework and the use of in-house data sources in order to better integrate the assessment of benefits and risks

Minimising impact on the environment

Initiating a cross-Agency discussion to update the Agency's strategy on potential risks to the environment of medicines for human use taking into account the experience gained from veterinary medicines

Contributing to workshops organised by the European Commission, the IMI and EUFEPS addressing the potential for risks to the environment and consideration of relevant outcomes

Considering the particular risks of nanomedicines on the environment

Developing a risk management framework appropriate for veterinary medicines

Consulting with stakeholders on appropriate risk management framework

Exploring the possibility to licence medicines earlier, balanced by increasing post-marketing requirements

Reviewing developments and the outcome of European Commission funded research projects in the field of environmental risk assessment of veterinary medicines

The EMA as an information provider within the EU Regulatory Network

Strengthening the interactions described above involving patients and healthcare professionals' organisations to build up a network of excellence at EU level

Improving the quality and consistency of information

Supporting appropriate prescribing patterns of medicines consistent with the authorised conditions, including links with e-prescribing to ensure the best information is available at the point of patient care

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

Further emphasising the need for balanced benefit-risk communication including quantitative elements (see also activity area 'improving communication of benefit-risk review to stakeholders'
Providing stakeholders with consistent, high-quality, targeted and accessible information on medicines and Agency outputs within the framework of a new policy on transparency.
Encouraging the provision of relevant data on the safe use of medicines in pregnancy
Considering the particular needs of veterinary stakeholders
Understanding the particular requirements of veterinary stakeholders and targeting delivery of information appropriately
Outcomes research
Analysing impact of PIP Decisions (including appropriate implementation of paediatric information) on Marketing Authorisations
Analysing the impact of regulatory decisions on public health through studies which address actual versus intended use and the effectiveness and feasibility of risk minimisation measures
Monitoring the use of authorised medicines, in close collaboration with HCPs, patient organisations and academia.
Considering how public-health outcomes from drug treatment can be assessed in order to provide input into regulatory policy decision-making.
Conducting a study on outcome assessment making use of the ENCePP network
Developing proposals for outcomes research in the field of veterinary medicines and obtain necessary resource to deliver them

Annex 2: List of abbreviations used in this document

Abbreviation	Full Text
3R	Refinement, Reduction and Replacement
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
ATMP	Advanced Therapy Medicinal Product
CHMP	Committee for Medicinal Products for Human Use
CVMP	Committee for Medicinal Products for Veterinary Use
DG Research	Directorate General Research of the European Commission
DSEN	Drug Safety and Effectiveness Network
EC	European Commission
ECVAM	European Centre for the Validation of Alternative Methods
EDQM	European Directorate for the Quality of Medicines and Healthcare
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
Enpr-EMA	European Paediatric Research Network at the EMA
EU	European Union
EUFEPS	European Federation for Pharmaceutical Sciences
FDA / US FDA	Food and Drug Administration
HCP	Health Care Professional
HTA	Heath Technology Assessment
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICT	Information and Communication Technology
IMI	Innovative Medicines Initiative
MAH	Marketing Authorisation Holder
MRL	Maximum Residue Limit
MUMS	Minor Uses and Minor Species
PIP	Paediatric Investigation Plan
PRAC	Pharmacovigilance and Risk Assessment Committee
RMP	Risk Management Plan
SME	Small and Medium-sized Enterprise
SOP	Standard Operating Procedure
TB	Tuberculosis
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products
WHO	World Health Organization