EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Multiannual work programme to 2020

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Introduction

The European Medicines Agency (EMA) and national competent authorities (NCAs) have developed a common strategy[1] to guide the work of the European Union (EU) medicines regulatory network over 2016-2020. As part of this strategy, major drivers and themes for the work and contribution of the network were identified and common multiannual objectives were agreed. With the strategy being a high-level overarching document, separate multiannual work plans were foreseen, to provide the detail of how the strategy will be taken forward within the remit of each of the components of the European network.

In addition, Article 32 of Financial Regulation requires the Agency to develop a multiannual programme that sets out the overall strategic programming, including objectives, expected results and performance indicators, as well as resource programming, including multi-annual budget and staff.

The Agency's multiannual work programme (MAWP) builds on the network strategy and outlines the main initiatives and activities that the Agency will undertake in the coming years, to support achievement of common goals.

The MAWP reflects the structure of the network strategy and follows the principles used in the Heads of Medicines Agencies (HMA) multiannual work programme. The MAWP is structured into four themes, each outlining four strategic objectives. The main areas of work are identified for each strategic objective, and, for each of these areas, key medium-term objectives and initiatives supporting the achievement of these objectives are identified. Performance indicators are included for each initiative, to allow its progress and success to be monitored.

Medium-term objectives and initiatives will be further mapped and detailed in annual work programmes, describing the specific steps to implement the initiatives and achieve medium-term and strategic objectives.

As required by the Financial Regulation, the MAWP, along with the annual work programme, will form the Agency's 'programming document', providing both a medium-term overview of the main activities in the coming years, as well as a detailed plan for the next year.

The MAWP is envisaged to be a rolling document, and as such, it will be reviewed annually to reflect on the key actions and initiatives, remove completed ones and include new ones that may arise as time passes.

It must be noted that, while this MAWP describes many of the key initiatives and areas of work for the coming years, it does not cover the full spectrum of work undertaken by the Agency, or the routine day-to-day activities that must continue.

[1] 'EU Medicines Agencies Network Strategy to 2020' (EMA/MB/151414/2015).

Theme 1: Contributing to human health

Objective 1: Focus on key public-health priorities, including availability of medicines and antimicrobial resistance

Area: Antimicrobial resistance

Antimicrobial resistance (AMR) remains a growing issue for both humans and animals. The World Health Organization (WHO) highlights AMR as a global health crisis of similar importance to infectious-disease pandemics. Therefore, efforts to combat AMR will remain high on the Agency's agenda and will include, among others, providing the necessary support to the European Commission action plan and to transatlantic and WHO initiatives, and balancing the need to assure the continued availability of antimicrobials in veterinary medicine with the need to minimise the risk to man from their use in animals.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Promote responsible use of antibiotics in human and veterinary medicine adopting a 'One Health' perspective*	Establish and run cross-Agency task force on antimicrobial resistance	2015	2016	Critical/ urgent	- task force established and running - proposals given/implemented for EMA activities to address antimicrobial resistance
Contribute to European and international initiatives and collaborations in the area of AMR	Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	2016	2018	High	- number and proportion of TATFAR actions implemented (where EMA has a role) - level of completion of the actions
	Contribute to implementation of the next phase of the EC Action Plan on AMR, the WHO Global action Plan and other action plans such as the "G8"	2016	2018	High	- actual contribution to WHO - completion level and/or rate of implementation of actions in the action plan(s)

* Specific initiatives in the veterinary domain are covered under Theme 2: Objective 4.

Area:	Public-health needs and priorities

Changes in the world's demographic composition draw increasing attention to the older population, their health needs and polypharmacy. New and redefined diseases, such as dementia, are becoming an increasing public-health burden. Increasing focus is placed on medicines for pregnant women and for children, and tackling rare diseases remains one of the key priorities for regulators worldwide. Ensuring the needs of these and other specific populations are met and these groups have timely access to appropriately developed medicines, together with appropriate information to support their use, will therefore remain one the Agency's focus areas.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Ensure needs of specific populations are met, including elderly, children, patients with rare diseases and others	Contribute to Global Action Against Dementia (GAAD)	2015	2017	High	- implementation of the actions in the GAAD - increased number of new medicines for dementia
	Implement the geriatrics strategy	2011	2019	Medium	- level of strategy implementation - proportion of actions implemented - deliverables completed (guidelines, pilot outcomes, GVP module)
	Support innovation, early dialogue and research for paediatric medicines	2007	2019	Medium	- increase in paediatric medicines under development (number of early interactions, advice requests) - increase in early paediatric interaction meetings / pre-submission meetings / PRIME involvement / scientific workshops supporting innovation in paediatric medicines - increase in clinical trials and participants under 18 years old
	Develop GVP module to enhance drug safety in pregnancy	2015	2017	High	- GVP module on medicines in pregnancy
	Strengthen scientific evaluation of orphan designation criteria by COMP at the time of MAA	2015	2018	High	- reduction of appeal procedures overturning original opinion

Area:	**Public-health emergencies**

With population movement across the globe continuously increasing the risk of spreading infectious diseases and globalising previously local or regional diseases, the ability to react fast and in a flexible manner is imperative to limiting and containing emerging public-health threats. Public-health emergencies such as pandemic influenza, the recent Ebola epidemic and the current Zika virus outbreak further highlight the importance of ensuring faster patient access to medicines on the market, while maintaining the quality of scientific assessments. EMA will therefore seek to improve its crisis-response mechanisms and flexibility for a quick response in public-health emergency cases.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Enhance ability to respond quickly to public-health emergencies	Facilitate early introduction of appropriate treatments or preventive measures	2015	2019	High	- time between starting point (e.g. application/request for advice) and EMA response (e.g. approval of medicine/SA letter)
	Improve Health Threats plan and update post-health-threat activity completion (e.g. Ebola, Zika etc.)	2015	2016	Medium	- action plan developed and process for rapid answers set up - number of 'lessons' implemented from the 'lessons learned' - rate of completion of post-health-threat activities

Area:	Supply issues and availability of new and well-established medicines

The EU medicines regulatory network is increasingly confronted with supply challenges and shortages, caused by manufacturing non-compliance, falsified or stolen medicines, or a number of other factors. Working closely with partners and stakeholders, implementing initiatives to minimise disruptions caused by manufacturing issues or quality defects, and supporting additional measures that can address the wider aspects of availability will be key to ensuring the availability of new and well-established medicines.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Minimise risk and impact of shortages due to manufacturing problems and quality defects	Implement revised action plan regarding medicinal product supply shortages caused by manufacturing/good manufacturing practice compliance problems, including - harmonised definition (criteria) of shortages - develop metrics for shortages - best practices on communication of shortages - review impact of implementation of tools developed by industry	2017	2019	High	- implementation of the action plan: level of completion of initiatives and proportion of initiatives implemented
	Develop formal collaboration with WHO in the area of supply disruptions	2017	2019	Medium	- formal agreement with WHO - number of cases worked in collaboration
	Support to the European Observatory on the supply of medical radioisotopes	2017	2019	High	- timely input provided to facilitate implementation by the regulatory network of the transition from the use of highly enriched uranium to low enriched uranium in the production of radiopharmaceuticals
	Consolidate information on compliance issues and quality defects	2017	2019	Medium	- system of warning letters in case of GMP non-compliance issues implemented - improvements implemented in the

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
					coordination/handling of quality defects across the network
Address the threat posed by illegal medicines supply chains	Continue to support the implementation of the Falsified Medicines Directive	2011	2019	High	- number of cases supported/coordinated by EMA in relation to falsified medicines in the supply chain
	Streamline process for reporting of suspected falsified medicines in the supply chain by MAHs	2011	2019	High	- implementation of the revised form for reporting quality defects and suspected falsified medicines
	Strengthen communication within the network, including with WGEO	2014	2019	High	- timely sharing of relevant information related to illegal supply chain as it is notified to EMA
	Review collaboration with EDQM in the framework of the sampling and testing programme to include increased number of APIs and parallel distribution medicinal products	2016	2018	High	- criteria for inclusion of APIs and parallel distribution medicinal products in the sampling and testing programme agreed and reflected in new contract with EDQM
Facilitate/support availability of already approved medicines	Support and contribute to Member States' efforts in addressing issues that limit access to already authorised medicines	2016	2020	Medium	*To be confirmed, based on the reflection paper (to be finalised in 2016)*

Objective 2: Ensure timely access to new beneficial and safe medicines for patients

Area: Early access to medicines

The ever-increasing expectations of patients and healthcare professionals to have promising medicines available at the earliest appropriate opportunity, in combination with the continuous need for flexible and fast reaction to arising public-health threats, require exploring flexible licencing pathways and a lifespan approach to medicines. At the same time, regulators must balance the drive for earlier access to new medicines with the need for more information on the quality, safety and efficacy of medicines. Therefore, EMA will explore ways to reduce the time-to-patient of medicines while maintaining high focus on quality and safety aspects, including post-authorisation monitoring.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Reduce time–to-patient of novel medicines through optimised use of existing and new assessment approaches within existing regulatory frameworks	Integrate 'adaptive pathways' concept into formal EMA scientific advice procedures	2014	2018	Medium	- increase in number of adaptive pathways products in scientific advice - increase in number of adaptive pathways products approved for marketing authorisation
	Provide reinforced regulatory and scientific advice for priority medicines (PRIME)	2014	2017	Critical/ urgent	- number/increase in PRIME products that received scientific advice - time from request to final response – compared with other products and with previous period
	Develop/enhance collaboration with HTAN, EUnetHTA, HTA/pricing and reimbursement bodies, including in the area of parallel scientific advice	2010	2019	High	- increase in parallel scientific advice - number of HTA bodies involved
Support effective and efficient conduct of pharmacovigilance	Implement planned access and analysis of real-world data to support adaptive pathways	2016	2020	High	- availability and use of tools and processes for analysing real-world data
	Conduct planned surveillance using patient registries to support adaptive pathways	2016	2019	High	- patient registries actually used for novel medicines

Area:	Benefit-risk assessment

Patients are the ultimate beneficiaries of medicines, and meeting their needs is a key aspect of medicines development and assessment. A multitude of other stakeholders are also increasingly involved in the regulatory processes from the early stages of development through to patients accessing and using the medicines. The Agency continuously works to improve these interactions and stakeholder involvement, including incorporating patients' views and values in the scientific review process and assessment of medicines throughout their lifecycle.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Increase involvement of stakeholders in relevant regulatory activities	Capture and incorporate patients' values and preferences into the scientific review process, in particular in benefit-risk evaluation	2016	2019	High	- processes to capture such values and preferences developed and implemented - increased number of cases where patient and healthcare professional input is incorporated in the scientific review - number of patients involved in benefit-risk evaluation - outcomes of AddValue project

Objective 3: Support patient-focused innovation and contribute to a vibrant life-sciences sector in Europe

Area: Clinical trials

Increasing globalisation in the pharmaceutical industry and the complex regulatory environment has led to a slowdown of innovation and clinical trials activity in Europe. To create a more favourable environment, a new Clinical Trials Regulation was published in May 2014. The Regulation becoming applicable is subject to full functionality of the IT systems underpinning it. Therefore, the Agency's main focus will be on delivering the necessary systems and updating relevant processes to ensure successful implementation of the Regulation and, thus, an improved regulatory environment in Europe.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Implement the Clinical Trials Regulation	Deliver the required IT tools to allow implementation of the Clinical Trials Regulation	2014	2018	Critical/ urgent	- availability of functional IT tools/systems
	Update guidelines and inspection-related procedures in accordance with the new legal requirements	2014	2018	High	- level of completion or availability of updated guidelines/processes

Area: Innovation

The pharmaceutical industry is evolving, with an increasing number of small or medium-sized enterprises undertaking the early stages of new medicines development. Ensuring more prospective medicines reach their patients therefore depends on improved interaction with, and adequate support to, SMEs, academia and others that are driving innovation. The Agency will focus on reviewing and improving the support measures and regulatory environment, as well as undertaking activities to facilitate translating innovation into medicines that reach patients.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Facilitate translating innovation into medicinal products	Streamline interaction with academia	2016	2019	Medium	- implemented framework for collaboration with academia - increased number of interactions with academia

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
	Strengthen collaboration with HTAN, EUnetHTA, HTA/pricing and reimbursement bodies to optimise relative timing and content of dossiers for medicines assessment by regulators, and appraisal by downstream decision makers	2015	2019	Medium	- report on cases of divergence between MAA and a sample of HTA bodies during the reporting period - number of cases where EUnetHTA relative efficacy assessment was facilitated following regulatory assessment
	Identify areas in need of further science and innovation support for medicines development, in collaboration with the network, and communicate these to funding bodies	Continuous	Continuous	High	- number of research areas/opportunities identified
	Explore opportunities to reduce regulatory and administrative burden	2016	2020	Medium	- number of opportunities identified and implemented
Provide adequate regulatory support to innovation stemming from SMEs and academia	Review existing support measures and explore additional supportive measures to incentivise innovation by SMEs	2016	2020	High	- increasing use of the available support measures/incentives
	Involve academia in early dialogue procedures (ITF, Innovation network, SA, Paediatric procedures, PRIME, orphan designation)	2016	2017	High	- increase in the number of early dialogue procedures involving academia

Objective 4: Strengthen regulatory capability and transparency

Area: Regulatory capability

Advancements in science and technology are redefining the scientific basis of disease, expanding the possibilities for medicines development and use, and increasing demands on regulatory advice and assessment. Emerging new technologies, personalised medicines, new advanced therapies, combination and borderline products all contribute to the increasing complexity of medicines. The availability of sustainable, high-quality scientific and regulatory expertise will be a critical success factor in addressing progress in regulatory science. Therefore, strengthening capacity and capability development across the network to adequately assess and monitor these new medicines will remain an important part of the Agency's agenda.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Strengthen pharmacovigilance capability across the network	Implement necessary processes to ensure capacity and capability to manage signals submitted by the pharmaceutical industry	2016	2018	High	- implementation of required processes
	Ensure EU network is ready for the new EudraVigilance functionalities, including centralised reporting and the new data format	2016	2018	High	- number of NCAs/MAHs trained on new functionalities

Area:	Transparency

Technological developments, including electronic health records and social media developments, provide increasing opportunities to collect vast amounts of data relevant for regulatory activities, such as post-authorisation monitoring. Similarly, increased access to data from clinical trials could further improve regulatory decision-making and benefit-risk assessment. Exploring these opportunities to increase access to data will be a focus area for the Agency.

At the same time, modern technology and media have increased dramatically the quantity and speed of providing and consuming information, and changed the patterns of information consumption, thus raising also stakeholder expectations for high levels of transparency and demand for more and better information. To address this, efforts to increase transparency of the Agency's work and decision-making will continue.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Increase access to data for delivery of regulatory activities	Take forward discussion on making available individual patient data from clinical trials	2016	2018	Medium	- draft reflection paper prepared and endorsed by the Management Board
	Explore the potential use of real-world databases, electronic healthcare records and 'big data'	2016	2020	High	- number of new data sources used in regulatory activities/decision-making
Increase transparency of the work of the network	Implement clinical data policy and provisions of the Clinical Trials Regulation regarding the transparency and availability of clinical trial data	2014	2019	Critical/ urgent	- availability of clinical trial data/information
	Improve provision of information to patients and prescribers	2011	2017	High	- better information to patients
	Increase transparency on the work done during authorisation procedures to assess and manage risks to the environment arising from the use of medicines	2015	2019	Medium	- level of acceptance/implementation of new benefit-risk template in assessment report

Theme 2: Contributing to animal health and human health in relation to veterinary medicines

Objective 1: Increase availability of veterinary medicines and promote development of innovative medicines and new technologies

Area: Availability of veterinary medicines

Ensuring adequate availability of a wide range of high-quality, safe and effective veterinary medicines and vaccines remains the highest priority for regulators within the European Union. Lack of availability is particularly acute for products for minor use in major species or for use in minor species (MUMS). The small size of the market exacerbates the availability issue, not only in terms of developing new medicines, but also regarding maintaining existing medicines on the market. Therefore, the Agency's efforts will be focused on facilitating development and access to the market for MUMS products and veterinary vaccines, as well as working with the NCAs to help limit the attrition of existing products.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Provide support and incentives for development of new medicines for MUMS/limited markets	Provide a clear framework to industry on the classification and incentives for authorisation of products indicated for MUMS/limited markets	2015	2017	High	- increased number/proportion of MUMS marketing-authorisation applications and MUMS products on the market - publication of the revised MUMS/limited markets guidelines
Support development and availability of veterinary vaccines	Identify and implement EMA contribution to the EU Network Strategy to 2020 in the area of promoting availability of vaccines within the EU	2016	2020	High	- increased number of pre-submission requests and submissions of MAAs for vaccines in general and those against transboundary diseases in particular
Explore ways to limit attrition of existing products	Develop with the network a strategy and action plan to support retention on the market of long-used veterinary antimicrobials	2016	2017	Medium	- final strategy and action plan for retention of long-used antimicrobials adopted and published

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Explore new ways for specific sectors to improve availability	Provide CVMP feedback on gap analysis from the FishMed Plus coalition on availability of fish medicines	2016	2020	Medium	- regulatory activities initiated to address identified gaps in the availability of fish medicines

Area: Innovation

A wide range of technologies that are new to veterinary medicine are increasingly being developed; novel therapies previously seen only in the human domain are also making their way into veterinary medicine, presenting new challenges for regulators. Ensuring adequate guidance and support will be a prerequisite for facilitating innovation and, consequently, improved availability of new veterinary medicines.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Promote innovation and use of new approaches in the development of veterinary medicines	Evaluate the impact of measures recently put in place to support innovation (ADVENT, ITF) and implement improvements in measures to support innovation	2016	2019	High	- increasing number of applications in novel therapies - report on impact of measures to promote innovation published
	Develop and implement regulatory guidance in priority areas for technologies that are new to veterinary medicine (including cell-based therapies and monoclonal antibodies for veterinary use)	2015	2019	High	- increased number of applications for innovative medicines - draft guidance on areas of cell-based therapies and monoclonal antibodies published

Area:	Maximum residue limits

Safeguarding human health through extrapolating maximum residue levels of veterinary medicines for food-producing animals of all species continues to be one of the key tasks of the Agency.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	Review the approach on genotoxic impurities in veterinary medicinal products	2014	2016	High	- first draft of guideline on genotoxic impurities in veterinary medicines published
	Finalise, in collaboration with ECHA and EC, the procedure for the establishment of MRLs for biocidal substances used in animal husbandry included in the 10-year review programme (long-used substances)	2015	2017	High	- role of EMA confirmed with the European Commission for establishment of MRLs for biocidal substances
	Provide technical support to the European Commission in drafting implementing acts specified in Regulation 470/2009	2016	2017	High	- recommendations and implementing acts sent to the EC

Objective 2: Promote 'better regulation'

Area: Legislative framework

The new legislative framework aims to increase availability of veterinary medicines, reduce the administrative burden on the industry and regulators, improve the functioning of the internal market for veterinary medicines throughout Europe, and minimise risks to human and animal health that may arise from the use of antimicrobials in veterinary medicine.

The discussions leading to the revision of the EU veterinary medicines legislation are expected to continue in the next years, with the legislation becoming applicable no sooner than 2019. Until then, the Agency's focus will be on preparing for the revised legislation while ensuring the most effective application of the current legislative framework.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Plan for and implement the revised veterinary legislation	Provide necessary advice to the European Commission during the co-decision process for the new veterinary legislation	2014	2019	High	- advice provided to the European Commission on request in a timely and accurate manner
	Put in place the revised processes and IT systems envisaged in the revised legislation	2015	2019	Critical/ urgent	- IT systems and processes implemented

Area:	Veterinary pharmacovigilance

Ensuring the safety and benefit-risk balance of veterinary medicines is just as important as it is for human medicines, considering also their potential impact of human health. The Agency will work to support efficient and effective conduct of veterinary pharmacovigilance by optimising the relevant processes and strengthening pharmacovigilance reporting.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Support efficient and effective conduct of pharmacovigilance	Publish information to the general public on the surveillance of centrally authorised products on the market	2016	2020	High	- annual pharmacovigilance bulletin published
	Strengthen signal-detection for veterinary medicines by developing an approach for ensuring quality control and verification of product data in the EU database of veterinary medicines, and linking these data to adverse event information in the EudraVigilance veterinary data warehouse	2016	2019	High	- VICH-compliant database fully operational
	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species	2016	2017	Low	- increase in reporting of adverse reactions in food-producing species, following the publication of the revised reflection paper

Area:	Quality of scientific output

The changing scene of medicines development and increasing use of new technologies will require new approaches and state-of-the-art guidance to ensure high quality of medicines' assessment and monitoring. The increasing transparency and availability of information, combined with the growing health consciousness of society, leads to more intense scrutiny of all aspects of the work of the Agency by its stakeholders and the community as a whole. Providing consistent, high-quality outputs not only strengthens the trust in and reliance on the European assessment and output, but also contributes to operational efficiency and cost-effectiveness. Therefore, the Agency will continue its efforts to strengthen the quality of scientific review processes and outputs.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Provide high-quality and consistent scientific outputs of the EMA	Finalise the development and promote the uptake of the revised guideline, procedures and templates for CVMP assessment reports	2016	2018	Medium	- templates for assessors finalised - high-quality assessment reports received
Ensure efficient operation of procedures within the Veterinary Medicines Division	Review operational procedures within the Veterinary Medicines Division	2016	2017	High	- improved performance metrics introduced, demonstrating an improvement in performance

Objective 3: Improve functioning of the single market for veterinary medicines within the EU

Activities under this strategic objective are led by the EU medicines regulatory network, mainly through CMDh/CMDv, hence no specific activities initiated by EMA are identified at this time. Several activities identified throughout this work programme will contribute to the effective functioning of the single market (e.g. training and processing of referrals).

Objective 4: Focus on key public- and animal-health priorities, including antimicrobial resistance

Area: Antimicrobial resistance

Antimicrobial resistance (AMR) remains a growing issue for both humans and animals. The World Health Organization highlights AMR as a global health crisis of similar importance to infectious-disease pandemics. Therefore, efforts to combat AMR will remain high on the Agency's agenda and will include, among others, providing the necessary support to the European Commission action plan and to transatlantic and WHO initiatives, and balancing the need to assure the continued availability of antimicrobials in veterinary medicine with the need to minimise the risk to man from their use in animals.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	Engage with the EC and Member States to identify and, where possible, prioritise the referral of antimicrobials and other classes of products for which the conditions of use need to be both harmonised and aligned with the principles of prudent and responsible use, including in relation to environmental issues	2010	2019	Critical/ urgent	- agreed list of priority and antimicrobial substances for referral to CVMP
	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine	2010	Continuous	High	- publish the outcome in the ESVAC annual report

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
	Draft and validate methodology to measure the use of antimicrobials in poultry (2016) and cattle (2017)	2016	2017	High	- methodology approved by the steering group
	Produce a reflection paper on aminoglycosides (consultation 2016) and extended-spectrum penicillins (consultation 2017)	2015	2018	High	- draft reflection paper published for consultation
	Deliver a joint EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species	2015	2016	High	- joint EMA-EFSA opinion sent to EC

Area: Risk to the environment

The growing environmental consciousness in society brings increased focus on the impact medicines have on the environment throughout their lifecycle, including development, use and disposal. The use of medicines, both human and veterinary, to ensure the health of patients and animals must be balanced to maintain a sustainable ecosystem. The Agency will therefore work to manage and minimise risks to the environment from the use of medicines.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Effectively manage risks to the environment arising from the use of veterinary medicines	Develop a strategic approach to persistent bioaccumulative and toxic substances within the authorisation procedure for veterinary medicinal products	2014	2017	Medium	- first draft of document published for consultation/adoption
	Develop a guideline on risk assessment of veterinary medicinal products in groundwater	2013	2018	High	- finalised guideline adopted by CVMP

Theme 3: Optimising the operation of the network

Objective 1: Reinforce the scientific and regulatory capacity and capability of the network

Area: Regulatory capability and capacity

Advances in science and technology are redefining the scientific basis of disease, expanding the possibilities for medicines development and use, and increasing demands on regulatory advice and assessment. Emerging new technologies, personalised medicines, new advanced therapies, and combination and borderline products all contribute to the increasing complexity of medicines. The availability of sustainable, high-quality scientific and regulatory expertise will be a critical success factor in addressing the progress in regulatory science and delivering high-quality outputs of scientific review processes. Therefore, identifying any current and future gaps in scientific and regulatory expertise, and strengthening capacity and capability development across the network to adequately assess and monitor medicines, will remain an important part of the Agency's agenda.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Ensure 'fit-for-purpose' scientific capability of the network	Conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in human medicines, and identify gaps in expertise	2016	Continuous	High	- inventory of needs available - mapping of expertise versus needs available
	Deliver curricula for competence development on the basis of the identified needs	2016	2017	Medium	- action plan available - number of curricula drafted
	Develop a catalogue of training material through the EU Network Training Centre	2016	2019	Medium	- training material catalogue developed
	Provide continuous training through the EU Network Training Centre in accordance with an agreed action plan	2014	Continuous	Medium	- training programme available and implemented - number of training sessions provided - number of experts trained, including in specific (gap) areas

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Ensure optimal organisation of the available expertise within the network for services provided to EMA	Monitor and improve implementation of the multinational assessment team (MNAT) approach pre-authorisation	2016	2020	Medium	- increase in the number of MNAT procedures - implementation level of the identified improvements
	Implement the multinational assessment team approach post-authorisation in a phased approach	2016	2019	Medium	- increase in the number of MNAT procedures - implementation level of the identified improvements
	Enhance outreach for academic expertise for services provided to EMA, in particular as regards innovation of medicines	2017	2019	Medium	- implementation of the framework of interaction with academia

Area: Scientific and regulatory expertise

The availability of sustainable, high-quality scientific and regulatory expertise is a critical success factor in addressing the changing scene of medicines development and the progress in regulatory science; securing the best-possible expertise to regulate medicines is becoming increasingly important to ensure the quality, safety and efficacy of medicines. At the same time, considering the close connections and collaborations of various stakeholders (e.g. academia and industry), ensuring independence and impartiality of the experts involved in regulatory work is imperative to ensure objective assessments and decisions on medicines. Therefore, the Agency will continue to improve its independence policies, to ensure an optimal balance between the expertise available and the independence of experts.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Strike an optimal balance between ensuring impartiality/independence of experts and securing the best possible scientific expertise	Undertake annual review of the EMA independence policies to identify room for improvement to strike such balance	2016	2020	Medium	- annual review of all policies prepared and discussed by the Management Board - agreed improvements implemented

Objective 2: Strive for operational excellence

Area: Sustainability of the regulatory system

Efficiency is the key to sustainable delivery of regulatory activities, and to coping with increasing responsibilities, volumes and complexity of procedures and activities. Continued economic pressures on Member States and regulatory authorities translate into expectations to deliver more with fewer resources.
To further increase efficiencies, optimise operations and ensure long-term sustainability of the Agency and the network, EMA will continue to improve its internal processes, support the work and efficiency efforts of the national authorities, and explore opportunities to further optimise the current regulatory framework.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	Undertake a continuous review and improvement of the centralised procedural management	2016	2020	High	- processes maintained /updated using an agreed methodology - key interfaces with network and industry enhanced (as demonstrated using surveys, workshops, etc.) - increased efficiency of the processes
	Undertake a continuous review and improvement of the EMA support to scientific committees/working parties/expert groups	2016	2020	High	- increased productivity of the committees - optimised product support and guideline generation activities, following revision of the working party utilisation
	Undertake a revision of the operation of the EU pharmacovigilance system for human medicines	2017	2020	High	- process improvements/efficiency gains implemented in the areas of ADR reporting, signal management and incident management
	Improve the efficiency of EMA corporate support activities	2016	2017	Medium	- integrated planning and reporting system introduced
	Ensure EMA has the right capabilities to deliver its mission	2016	2020	High	- mapping of future needs versus current internal expertise completed - targeted recruitment undertaken

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
	Analyse experience with the current legal provisions to identify gaps and provide subsequent input to the EC for any review of current legislation	2017	2020	Medium	- number of analyses conducted - number of contributions to the EC made
	Participate in the BEMA exercise as per the agreed BEMA cycle	2016	2020	Medium	- participation undertaken as per the agreed BEMA cycle - review of quality-management framework undertaken and resulting actions implemented
	Provide regular training to BEMA assessors	2016	2020	Medium	- number of assessors trained within a BEMA cycle - number of training sessions provided
Achieve a sustainable financing model for the network	Complete the data-gathering initiative	2015	2016	High	- data-gathering initiative conducted as per the action plan
	Contribute to external evaluation of the current fee regulation	2016	2017	High	- contribution available as per the agreed action plan
Strive for adequate and inter-operable IT services	Deliver IT solutions in accordance with the Information Management Strategy aligned with the EU Telematics Strategy	2016	2020	High	- IT systems/solutions delivered and in operation
	Establish and improve EMA information services	2016	2020	High	- information services operated with processes that are monitored and continuously improved
	Share information on medicines within the network and with stakeholders	2016	2020	High	- access provided to clinical data - European Medicines Web Portal operational - improved provision of data and analytical capability

Area:	**Quality of scientific outputs**

The changing scene of medicines development and increasing use of new technologies will require new approaches and state-of-the-art guidance to ensure high-quality assessment and monitoring of medicines. The increased transparency and availability of information, combined with the growing health consciousness of society, leads to more intense scrutiny of all aspects of the work of the Agency by stakeholders and the community as a whole. Providing consistent, high-quality outputs not only strengthens the trust in and reliance on the European assessment and output, but also contributes to the operational efficiency and cost-effectiveness. Therefore, the Agency will continue its efforts to strengthen the quality of scientific review processes and outputs.

Medium-term objective	**Initiative(s)**	**Start**	**End**	**Priority**	**Performance indicator(s)**
Strengthen the quality of the scientific review processes	Achieve common standards of scientific quality across the network	2016	2018	High	- availability of improved templates and a guideline for completing the templates - availability of accepted standards against which the quality of outputs can be measured - AddValue project delivery
	Develop and maintain state-of-the-art scientific guidelines	2016	2019	High	- revised procedure and harmonised standards for guideline development and revision - number of new/revised guidelines
	Improve the benefit-risk methodology and expand it to post-authorisation updates	2016	2017	High	- AddValue project delivery

Objective 3: Ensure effective communication of and within the network

Area: Building / maintaining trust of civil society

A key prerequisite for efficient operation of the network is an effective and collaborative communication approach. Improved communication of the remit of the medicines regulators and the work done (and planned) to protect and improve public health, as well as explaining the decisions taken, will lead to a more knowledgeable society and help build and maintain public trust in the work undertaken by regulators. Launching necessary communication initiatives to support achievement of the goals outlined in the network strategy will be one of the focus areas of the Agency.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Run necessary communication initiatives to support achieving strategic goals	Develop and implement a five-year EMA communication strategy	2016	2020	High	- framework strategy for external communication approved and implemented, supported by annual communication plans
	Implement an Agency-wide structure for public hearings	2016	2020	High	- public hearings for safety-related referrals implemented and lessons learned incorporated
	Upgrade the EMA corporate website	2016	2020	High	- EMA corporate website upgraded
	Develop and implement a social media strategy	2016	2020	High	- implementation level of the approved strategy
	Expand the range of digital and multimedia communication tools	2016	2020	High	- increased production of new communication tools is measured and reported

Area:	Cross-EU communication about medicines

Modern technology and media have changed the patterns, volume and speed of providing and consuming information, including instant availability of information on medicines and health-related topics, thus continuously raising stakeholder desire and expectation to have information available at their convenience. Improved content and availability of information will contribute to a more informed and knowledgeable society, and, as a result, a better and more appropriate use of medicines. In addition, the multinational and multilingual nature of the EU regulatory system requires a strong, coordinated approach within the network to achieve effective and consistent communication to EU citizens on important issues about medicines. Therefore, the Agency, working with the national authorities, will focus on improving the information on medicines and engaging the most appropriate and efficient means to deliver high-quality and reliable information to various audiences across the EU.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Ensure effective and consistent communication about medicines	Review and improve as needed the information on medicines for stakeholders, in particular information for patients and healthcare professionals	2016	2020	High	- all information for patients systematically user-tested - simplification of EMA information to patients and healthcare professionals agreed and implemented
	Capture communication needs and expectations of partners and stakeholders	2016	2020	High	- biennial perception survey implemented and analysed
	Explore additional ways to assess the impact of EMA communications	2016	2020	High	- dedicated workshop with HCIN planned and organised
	Advance the development of the European Medicines Web Portal	2016	2020	High	- European Medicines Web Portal launched

Area:	Health emergencies and emerging events communication

Timely, consistent and effective responses and communication are all the more important in cases of public-health emergencies or emerging events, such as safety concerns or quality defects that put into question the positive benefit-risk balance of authorised medicines. The Agency will work to improve communication on health emergencies, providing, in collaboration with the Member States, consistent and coordinated messages to stakeholders across Europe, and ensuring that the Agency's outputs are usable, authoritative and reliable.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Improve communication on health emergencies	Improve coordination of communication on emergency health threats across the network	2016	2020	High	- crisis communication strategy endorsed and implemented - report on coordination of safety announcements finalised and improvements implemented

Objective 4: Strengthen links with other authorities and with stakeholders

Area: Collaboration with partners

To deliver high-quality outputs and ensure a consistent approach and aligned opinions on specific topics, the Agency works closely with a number of other EU organisations and agencies, including EDQM, ECDC, EFSA, ECHA and others. Scientific questions, such as those regarding antimicrobial resistance or vaccine effectiveness monitoring, require multidisciplinary inputs. Continuously striving to achieve efficiency improvements and deliver quality results with limited resources also contributes to increased interest among all EU agencies to cooperate and share best practices, thus building on each other's strengths and improving own performance. Collaboration with partners is integral to the Agency delivering on its mission, hence it will continue to work on strengthening and expanding its collaboration with partners in areas of common interest.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Increase collaboration with other EU decentralised agencies	Establish a framework for monitoring the safety and effectiveness of vaccines, in collaboration with ECDC and the Member States	2017	2019	High	- availability and implementation of framework - number of benefit-risk profile updates achieved - final output from ADVANCE project - final proposals to the EC
	Strengthen cooperation with other EU agencies in areas of common interest, taking into account memoranda of understanding where they exist	2016	2020	Medium	- mapping of areas of common interest completed - existing memoranda of understanding reviewed and updated, taking into account such mapping exercise
Strengthen collaboration with EDQM	Extend the scope of collaboration in the area of sampling and testing as part of the renewal of the contract	2017	2018	Medium	- extended scope achieved and implemented - number of medicinal products/APIs included in the sampling and testing programme

Area:	Collaboration with stakeholders

The process of regulating medicines is becoming increasingly complex, with a multitude of stakeholders involved from the early stages of medicines development through to patients accessing and using the medicines. Increasing stakeholder demands for transparency and more and better information on the regulatory processes and decisions further emphasise the need to interact with and involve stakeholders in the relevant regulatory processes in the best ways possible, including aspects such as considering their needs and preferences in the assessment processes, and obtaining their input regarding opportunities to optimise the regulatory framework. The Agency will therefore focus on improving its understanding of stakeholders' needs and expectations, and improving its interactions with different stakeholder groups.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Increase collaboration with civil-society representatives	Involve patients, HCPs and academia more, to further integrate clinical practice and real-life experience of disease and its management along a medicine's lifecycle	2016	2020	High	- increase in number of patients, HCPs and academia involved in EMA activities - frameworks for interaction with patients and HCPs and/or action plans revised, taking into account experience gained - framework for collaboration with academia implemented
	Increase engagement with GPs, thus fostering interaction with primary care	2016	2019	Medium	- virtual expert group with GPs created - number and implementation level of joint recommendations between EMA/UEMO/EFPC/WONCA for GPs' involvement in EMA activities
Streamline interactions with corporate stakeholders	Formalise and structure interactions with pharmaceutical industry associations	2016	2020	High	- framework for interaction with corporate stakeholders implemented

Theme 4: Contributing to the global regulatory environment

Objective 1: Assure product, supply chain and data integrity

Area: Supply chain and data integrity

Globalisation of pharmaceutical activities results in an increasing number of manufacturing and clinical-trial activities being conducted outside the EU. This, coupled with the increasing complexity of international supply chains, presents challenges to ensure adherence to the required clinical-trial and manufacturing standards, to ensure data integrity, and to manage risks of errors and counterfeits or product diversion. To ensure medicines developed outside the EU adhere to EU requirements, it is imperative to work in collaboration with other regulators, to make sure all steps in the manufacturing and supply chains are adequately controlled and monitored, and ensure integrity of the data on which the regulatory decisions on medicines are based.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Ensure adequate control and monitoring through all stages of the manufacturing and supply chain	Increase information-sharing between regulators responsible for oversight of different stages of manufacturing	Continuous	Continuous	High	- timely sharing of relevant information related to GMP inspections, quality defects and shortages
Improve knowledge and understanding of data integrity, and implications for regulatory decision-making	Develop guidance on data integrity in collaboration with PIC/s	2017	2018	High	- draft guidance published
	Develop communication and training in collaboration with the FDA	2016	2018	High	- communication material developed - one joint training session per year delivered
Ensure quality of medicines wherever they are manufactured	Develop a procedure to facilitate populating the EudraGMDP Planning module	2016	2017	High	- information on planned GMP inspections systematically introduced in the EudraGMDP planning module by inspectorates
	Develop a procedure for the coordination of inspections in third countries, to make best use of network resources	2017	2019	Medium	- increased coverage of GMP inspections in third countries, using fewer network resources
	Implement a risk-based approach to PMF inspections	2012	2018	Medium	- implementation level of the risk-based approach to PMF inspections

Objective 2: Convergence of global standards and contribution to international fora

Area: Harmonisation of international standards and approaches

Differing requirements, standards and approaches used in the assessment and regulation of medicines around the world make it harder for regulators to ensure that medicines development activities performed elsewhere (e.g. clinical trials, manufacturing) comply with the requirements of the particular region/regulator. These differences also make it harder for industry, as they need to comply with varying requirements to obtain marketing authorisation in different parts of the world. Aligning these requirements and harmonising the standards of regulatory activities would not only help ensure adherence to the required (EU) standards and safeguard the quality of medicines, regardless of where they are tested/manufactured, but also allow for greater reliance on the work done by other regulators, thus improving the efficiency of the use of global regulatory resources. The Agency will therefore continue to work with other regulators on improving the uptake and application of harmonised standards in various aspects of human and veterinary medicines regulatory work.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	Develop (through relevant inspector working groups) and apply an integrated and consistent approach to cooperation with key authorities (such as China and India)	Continuous	Continuous	High	- Network approach to inspections and training collaboration agreed, with particular focus on China and India - agreed procedures for cooperation
	Invite non-EU regulators to relevant training activities and to observe GCP and GMP inspections	Continuous	Continuous	High	- increase in number of non-EU inspectors participating in relevant training activities - increase in number of non-EU observers participating in inspections
	Leverage the technical, procedural and scientific advancements resulting from the EU pharmaceutical legislation to improve convergence with other regions	2017	2019	High	- systematic reporting to WHO of EU ADR reports and use of EU pharmacovigilance products by non-EU regulators, such as medical literature monitoring and on single assessment periodic safety update reports
Facilitate effective information-sharing by using international electronic standards	Implement first iteration of international electronic standards within the EU, and extend to non-EU countries	2012	2019	High	- implementation plan agreed - increase in the number of international partners using the standards

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Promote uptake of harmonised standards for veterinary medicines at international level	Consider international scientific approaches for the establishment of MRLs for harmonisation purposes	2016	2019	Medium	- a report on the outcome of discussions with Codex Alimentarius presented to the CVMP
	Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries	2016	2019	Medium	- EU systems and approach presented at international training events

Area: Compliance with global standards

Global standards covering various aspects of the work of any organisation are used around the world, to improve the efficiency and effectiveness of the operations and work done, as well as to increase the ability to compare and assure the quality of operations, and collaborate in the global environment. Along with its contribution to harmonising global standards for medicines regulation, the Agency works continuously to ensure compliance with other global standards (such as corporate quality, environment, etc.), to improve its performance and efficiency of operations.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Contributing to European and international initiatives and collaborations regarding environmental friendliness	Implement a structured approach to environmental management, with objective-setting and monitoring, with a target to reduce the carbon footprint of the Agency's activities	2016	2017	Medium	- registration to EMAS, eco-friendly management system

Area: International cooperation mechanisms

The increasingly global nature of medicines development, their use and consequently their regulation further highlights the importance of collaboration among regulators, to ensure the quality of medicines regardless of where they are developed and manufactured. A number of international fora are working to increase alignment of requirements and improve the application of consistent standards throughout the development, assessment and monitoring phases for medicines. The Agency's continued active participation in these fora is not only crucial to contribute to global convergence of standards and approaches, but also provides opportunities to help define the future shape of international collaboration.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Ensure appropriate representation in relevant fora, to ensure convergence of standards	Implement mechanisms to ensure representative and consistent representation of the network in international fora, and to provide feedback to the network, including ICH, VICH, WHO, OIE, IRCH and PIC/S, ICMRA, IPRF, IGDRP	2017	2019	Medium	- mechanism to ensure participation and feedback through pharmaceutical committee and HMA agreed

Area: Use of animals in medicines development

Following the ban of animal testing for cosmetics in July 2012, and the introduction of the new Animal Welfare Directive (2010/63/EU), the pharmaceutical industry is facing high pressure to take animal welfare aspects into account in the development of pharmaceuticals. EMA, as the EU regulator, has a key role to play in advocating for minimised use of animals in medicines R&D, and in ensuring that alternatives to the testing of medicines in animals are used wherever possible. International collaboration is one of the most effective ways to minimise the use of animals in the regulation of medicines, and the Agency will continue to work to ensure increasing compliance with and application of the '3R' (replacement, reduction, refinement) principles.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Minimise use of animals in medicines research and development activities	Contribute to the development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch-testing of veterinary vaccines and other relevant areas	2014	2020	Medium	- completed guidelines on applying 3R

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
	Improve the guidance available on regulatory acceptance of 3R principles in testing approaches	2014	2017	Medium	- availability of up-to-date guidance

Objective 3: Ensure best use of resources by promoting mutual reliance and work-sharing

Area: Efficient use of global resources

Faced with ever-increasing economic pressures and limited resources to deliver their mission, regulators worldwide are increasingly recognising the potential and the need to create synergies, share best practices, avoid duplications and use global regulatory resources more effectively. Increased collaboration and greater reliance on the work done by other regulators will expand the capacity of regulators and help alleviate the pressures on resources, improve efficiency of global regulatory work, and contribute to reducing the regulatory burden on the industry. Expanding work-sharing and mutual-reliance initiatives, and increasing reliance on European assessments and outputs, will be the focus of the Agency's work in this area.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Expand work-sharing and mutual-reliance initiatives	Support the Commission with the establishment of a Mutual Recognition Agreement with the US	2016	2018	High	- principles of mutual recognition agreed and implemented for certain group of medicines
	Increase information-sharing between regulators responsible for the conduct of clinical trials and pharmacovigilance activities	Continuous	Continuous	High	- GCP initiative with PMDA established - pharmacovigilance inspection initiative with FDA established
Increase reliance of other regulators on European assessments and outputs	Extend cooperation on the evaluation of generic medicines, to promote leveraging regulatory authorities' collective resources	2017	2019	Medium	- document on good-reliance practices
	Improve existing mechanisms for sharing and exchanging information with other regulators on products throughout their lifecycle	2017	2019	Medium	- agreement on template for sharing confidential information
	Explore opportunities to leverage resources in other areas and increase reliance of other regulators on European assessments and outputs	2017	2019	Medium	- number of areas identified where reliance on European assessments can be increased

Objective 4: Support training and capacity-building, and promote the EU regulatory model

Area: Training and capacity-building for non-EU regulators

The European regulatory system is becoming recognised as a model to follow, and non-EU regulators are increasingly looking to the network for support and capacity-building. They are also considering it as a model for their regional harmonisation initiatives. This is an opportunity to build global regulatory capacity and capability, simultaneously contributing to the harmonisation of standards and approaches, thus ensuring the quality of medicines wherever they are developed or assessed.

Medium-term objective	Initiative(s)	Start	End	Priority	Performance indicator(s)
Support capacity-building of non-EU regulators	Organise regular training courses for GXP inspectors, with participation of non-EU regulators	Continuous	Continuous	High	- number of training sessions organised with non-EU regulator participation - number of non-EU regulators' representatives trained
	Extend the Network Training Centre to involve non-EU regulators	2016	2018	Medium	- increased number of participants from developing countries / non-EU regulators

Annex: Terms and abbreviations

Term / abbreviation	Definition
3Rs	'3R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
ADR	adverse drug reaction
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	ad hoc expert group on veterinary novel therapies
AMR	antimicrobial resistance
API	active pharmaceutical ingredient
BEMA	benchmarking of European medicines agencies
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
COMP	Committee for Orphan Medicinal Products
Commission	European Commission
CVMP	Committee for Medicinal Products for Veterinary Use
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EDQM	European Directorate for the Quality of Medicines and Healthcare
EFPC	European Forum for Primary Care
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMAS	EU Eco-Management and Audit Scheme
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and distribution practice
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUnetHTA	European network for health-technology assessment
FDA	United States Food and Drug Administration
G8	'Group of eight' highly industrialised nations: France, Germany, Italy, the United Kingdom, Japan, the United States, Canada and Russia
GAAD	Global Action Against Dementia
GCP	good clinical practice
GMDP	good manufacturing and distribution practice
GMP	good manufacturing practice
GP	general practitioner
GVP	good pharmacovigilance practice
GXP	good practice (e.g. laboratory, clinical, manufacturing, etc.)
HCIN	Heads of Communication and Information Network of EU agencies
HCP	healthcare professional
HMA	Heads of Medicines Agencies
HTA	Health-technology assessment
HTAN	Health-technology assessment network
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
IGDRP	International Generic Drug Regulators Programme
IPRF	International Pharmaceutical Regulators Forum
IRCH	International Regulatory Cooperation for Herbal Medicines
IT	information technology

Term / abbreviation	Definition
ITF	Innovation Task Force
MAA	marketing-authorisation application
MAH	marketing-authorisation holder
MAWP	multiannual work programme
Member State (MS)	Member State of the European Union
MNAT	multinational assessment team
MRL	maximum residue limit
MUMS	minor use, minor species
NCA	national competent authority
Network	European medicines regulatory network
NTC	EU Network Training Centre
OIE	World Organisation for Animal Health
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	plasma master file
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public-health potential
R&D	research and development
SA	scientific advice
SME	small or medium-sized enterprise
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
UEMO	European Union of General Practitioners
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WGEO	Working group of enforcement officers at HMA
WHO	World Health Organization
WONCA	World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (short name is World Organization of Family Doctors)