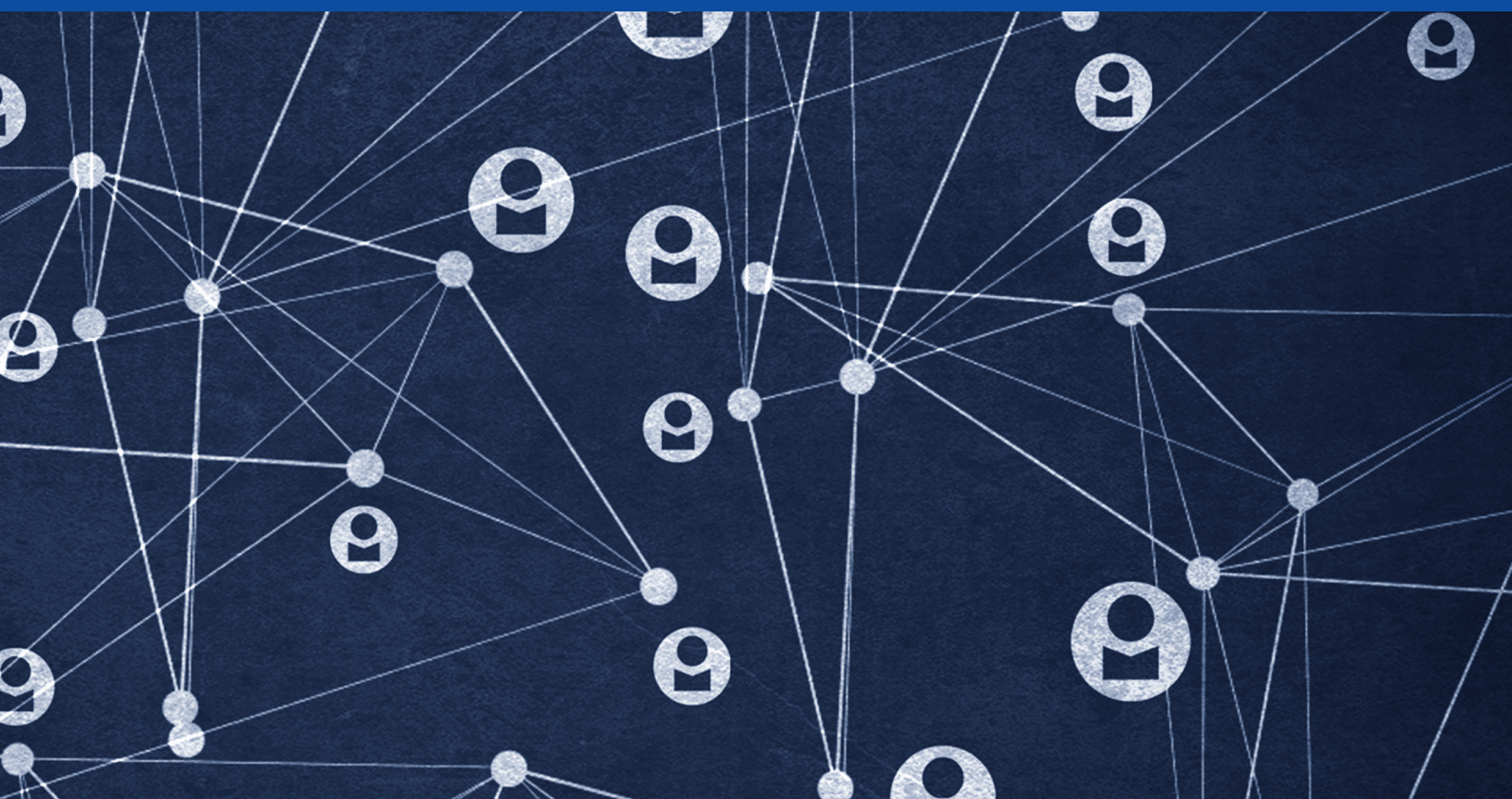




EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# European medicines agencies network strategy to 2025

Protecting public health at a time of rapid change



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# 1. Introduction: a Network strategy for a rapidly evolving healthcare environment

The European medicines regulatory network (EMRN) represents a unique response to the challenge of regulating human and veterinary medicines across a diverse group of countries. It includes the national competent authorities (NCAs) of the 27 EU Member States plus those of Iceland, Liechtenstein and Norway, who are responsible for medicines regulation at national level and also come together under the aegis of the Heads of Medicines Agencies (HMA) and the centralised regulator and coordinating body, the European Medicines Agency (EMA), within whose scientific committees sit representatives of those countries. The European Commission provides EU legal and supervisory authority to the Network's decisions.

These bodies have access to the knowledge of thousands of experts in multiple scientific and therapeutic fields and must work closely with stakeholder groups including patients and healthcare and veterinary professionals, health technology assessment bodies and payers, and the pharmaceutical industry and global regulators. Their duty is to ensure that patients, animals and the wider society have access to safe, high-quality and effective medicines, and so protect public and animal health, and the environment.

By working together under a common and agreed set of regulations and laws, and sharing resources, knowledge and expertise to maximise efficiency, they have created one of the world's leading systems for regulating medicines.

Such a complex enterprise inevitably requires detailed planning and coordination. While this is built into the Network's systems on a day-to-day, month-to-month level, it is also necessary to think about the longer-term direction of the Network and how we respond to the clinical, scientific/technological and social challenges it faces.

These challenges have never been greater. Developments in basic science, in medicine, in information technology and data analytics

in particular, continue to pour forth at an astonishing rate. As well as ensuring access to essential older medicines, the Network must have the capacity and knowledge to regulate new types of medicine, making them available to patients with unmet needs while continuing to ensure that any risks are outweighed overall by the benefits. Globally, all societies must respond to environmental and climate change, address sustainability, and cope with the societal impacts of the so-called 4th industrial revolution. In this light, economic and political challenges also continue to face the EU and the wider EEA, not least the many challenges posed by the global supply chains and just-in-time manufacturing processes on which modern society depends. These include dependency on manufacturing capacity and APIs/starting materials sourced from third countries and the need for increased preparedness for emerging health threats.

The dangers of emerging health threats have been made particularly evident by the COVID-19 pandemic. As we have lived and worked through this situation, it has directly demonstrated the very real impact that such threats can have on society worldwide. Learning from this experience presents an opportunity to shape the future role of medicines regulation nationally and at the EU level, and enhance the partnership approaches that we need to ensure that we are proactively positioned to deal with similar emergencies.

On the broadest level the challenges we face go well beyond the remit of medicines regulation, and will need to be addressed by the EU and its Member States as a whole and individually: the EU's forthcoming Pharmaceutical Strategy for Europe will shape the policies to do this for human medicines, thus setting the direction for the Network's response, and will continue to do so beyond the period covered by this strategy. In addition, other strategic initiatives are taking place at EU level to respond to the

global challenges already referenced. However, more specific strategic planning on the part of the EMA and HMA is needed to ensure that the Network is ready to play its part and implement the actions needed to protect public and animal health going forwards, hence the present document.

In the veterinary medicine area, the Network is fully committed to the practical implementation of the Veterinary Regulation ([Regulation \(EU\) 2019/6](#)), which will provide the means to address many of the issues raised in the strategy below. However, the future will also be shaped, inter alia, by the EU environmental strategy ([European Green Deal](#)) which is currently under discussion and which aims to improve public and animal health and the environment by a range of proposed measures, including significant reduction in use of chemicals in agriculture and of sales of antimicrobials for farmed animals and in aquaculture by 2030, and by the [EU Farm-to-Fork Strategy](#) as well as following up on the [European Union Strategic Approach to Pharmaceuticals in the Environment](#).

As the society that the Network serves continues to change and develop, we must also change and develop so that we can continue our mission successfully, with the most efficient use of the resources and knowledge available to us. This will rely in particular on increased use of digital technology in our processes, to ensure that data is standardised, maintained consistently across the EMRN and used intelligently. The Network should thus become a reference source for trusted data, able to reduce administrative effort, respond to challenges in a timely fashion and increase efficiency.

In 2015, the HMA and EMA came together to look ahead and develop an overarching European Medicines Agencies [Network strategy](#) for the coming 5 years, building on previous HMA strategy documents and EMA road maps. This strategy addressed 4 key priority areas (supporting development and availability of medicines for human health; increasing availability of veterinary medicines and reducing the risks of veterinary antimicrobial use; optimising the operation of the Network itself;

and continuing to develop resource sharing and regulatory convergence at the global level) and was developed in consultation with stakeholder groups.

Building on the success of this previous strategy and the work carried out under its auspices, HMA and EMA are now planning for the next 5 years, in the shape of the proposals included in this document. These high-level goals and supporting recommendations will shape and feed into the detailed workplans of the Network's members in the coming years. As it strives to implement these, the Network will always attempt to follow its broad **guiding principles** of *trustworthiness, acting transparently, communicating clearly*, ensuring the highest *ethical standards*, and supporting environmental sustainability through reduced use of resources, emissions, degradation and pollution related to pharmaceuticals. It will be able to rely on the solid foundation of existing work in areas such as patient engagement, pharmacovigilance and medicines for special populations such as paediatric patients.

The Network recognises the need for change – more, it is eager to change, in order to fulfil its mission ever better. However, it cannot do this alone, and the strategy emphasises the importance of international collaboration and of communication and the need to engage ever more fully with our stakeholders and partners. This means sharing our respective views of the challenges ahead; showing that, even when methods and approaches change, ensuring the quality, safety and efficacy of marketed medicines remains our goal; demonstrating how the steps in the strategy will support improvements across the life cycle of a medicine; and inspiring a vision of a medicines regulatory system able to meet the challenges of the 21st century and provide EU patients with the medicines they deserve while continuing to protect them from unsafe and ineffective medicines.





## 2. Scope of the document

### What does the strategy cover?

This document outlines six strategic focus areas for the joint Network strategy to 2025:

- ▶ Availability and accessibility of medicines
- ▶ Data analytics, digital tools and digital transformation
- ▶ Innovation
- ▶ Antimicrobial resistance and other emerging health threats
- ▶ Supply chain challenges
- ▶ Sustainability of the Network and operational excellence

Each of these is addressed in more detail below, with a discussion of the main challenges of each as the Network sees them, an identification of topic-related goals for each area, and, in Annex 1 of this document, proposals for high-level objectives that might form the starting point of actions to address these goals. It should be emphasised that some focus areas are by their nature more specific whereas others are broader themes that touch many areas– thus, the level of granularity in the discussions below inevitably varies somewhat, but in all cases the goals and objectives identified have been designed to lead to detailed and concrete actions which EMA and the NCAs will develop in their multi-annual work plans.

Some of these detailed actions will be largely or entirely the business of the national competent authorities, others will be primarily an EMA responsibility, while in many cases the work will be shared and collaborative. Having a joint strategy enables all three situations to be addressed in a coordinated and consistent way.

The strategy takes into account the European Commission's priorities for health and will be aligned with its broader Pharmaceutical Strategy for Europe, as already mentioned, and the actions in the Network strategy will seek to provide synergies with actions developed under the Pharmaceutical Strategy where their subject matter overlaps. Wherever matters of policy or potential legislative change for human medicines

are referred to in this document these should be understood as identifying issues that could inform the broader Pharmaceutical Strategy, where the ultimate responsibility for such matters will lie.

As noted throughout the document, many of the lessons learned from the COVID-19 pandemic will be strategic considerations in the coming years, and will be sustained by the measures expected to be launched as part of the EU's 'EU4Health', and 'rescEU' programmes, including building a strategic pharmaceutical reserve of critical medicines, and encouraging API production in Europe. An Information Management Principles document will take into account Network business needs for digital transformation, allowing development of a roadmap and consideration of how these can be applied at Network and national level.

## How was the strategy developed?

- ▶ During meetings in 2019, HMA members came to a consensus on 6 key focus areas for the new strategy and produced a concept paper discussing the challenges and how the Network might address them. This was then shared with EMA for reflection.
- ▶ EMA and HMA created joint working teams to address each of the focus areas, clarifying the scope and developing more formalised goals with supporting recommendations for action. These teams consulted external experts and partners as necessary and developed their proposals with an eye to alignment with other strategic considerations such as the EU Telematics roadmap and the priorities of the present European Commission.
- ▶ The conclusions of the 6 teams were distilled into a draft working strategy.
- ▶ An early engagement phase with stakeholders was organised within the limitations imposed by the COVID-19 pandemic; an early discussion with patient, consumer and healthcare professional organisations ([PCWP/HCPWP](#)) and a written consultation with industry, academia and vet stakeholders

helped to capture initial views. The document was then subject to a 2-month public consultation during the summer of 2020.

- ▶ The extensive and helpful feedback from the public consultation, which successfully captured input from a full range of stakeholder groups, was carefully analysed and reviewed in order to refine and finalise the strategy. More detail on the comments received and the Network's analysis of them is available in a separate report.
- ▶ Publication of the final strategy took place in the final quarter of 2020.

### 3. Strategic focus areas

The six strategic focus areas identified by the Network are discussed in more detail below. Inevitably, any such division of the issues is somewhat artificial, and some common and overlapping issues arise repeatedly under multiple themes, including the need for **pandemic preparedness** emphasised by COVID-19 and the more insidious effects of **antimicrobial resistance**; the **impacts of innovation, digitalisation and big data** and the **need to ensure that the Network has the necessary competencies** to deal with them; the need for further, increased

**collaboration and engagement with our stakeholders and downstream decision makers such as HTA bodies and payers** (particularly in explaining, preparing for, resourcing and managing a **shift to more post-licensing evidence generation** as the regulatory system evolves); the need to prepare adequately for the **implementation of new legislation**; an increased **focus on the supply chain, particularly to minimise shortages**, and on **environmental issues**; and a recognition of the importance of good **communication and transparency**.

#### 3.1. Availability and accessibility of medicines

##### Strategic goals

Based on its environmental analysis of the strategic area and the identified challenges, the Network has laid down two main goals to be achieved within the strategy period:

1. Strengthen the availability of medicines to protect the health of European citizens and animals, via:
  - ▶ efficient and targeted regulatory measures, made possible through an in-depth understanding the root causes of unavailability of patented and off-patent products (e.g. low volume products such as paediatrics);
  - ▶ identification of possible challenges in implementing legislation, removal of national barriers, increased coordination of the EMRN, sharing and implementation of best practices including by the stakeholders and increased transparency are the essential steps towards this goal.
2. Optimise the path from development, evaluation through to access for medicines through collaboration between medicines regulators and other decision makers in the areas of:
  - ▶ evidence planning, including post-licensing evidence;
  - ▶ engagement in review of evidence and methodologies, respecting remits of the various players;
  - ▶ collaboration on horizon scanning.

As a result of this work, medicines that address unmet medical needs should have broader and earlier access coverage.

*Recommended high-level objectives to support these goals are given in the [table in Annex 1](#).*

Lack of availability of medicines in the EU/EEA, either because medicines are authorised but not marketed or no longer marketed, or due to supply disruptions, has been recognised by the HMA and EMA as an area of great concern

posing threats to patient and animal health, animal disease control programs and sustainable livestock production.

This part of the strategy concentrates on availability and accessibility issues from the perspective of supply disruption/shortages [availability] and commercialisation/downstream decision making together with therapeutic challenges in small markets [accessibility]. Ongoing implementation of the veterinary medicines regulation ([Regulation \(EU\) 2019/6](#)) will provide new measures to increase the availability of veterinary medicines such as stimulation of the development of innovative veterinary medicines, including products for limited markets, and to improve the functioning of the internal market for veterinary medicines, not least by publishing information on the availability of veterinary medicines, not least by publishing information on the availability of veterinary medicines in the Union database on veterinary medicinal products (Union Product Database or UPD). Although not outlined in this strategy, it is expected that initiatives to address specific problems of availability of veterinary medicines, including vaccines, will continue as necessary, even beyond the requirements of the veterinary medicines regulation. Many of the principles and learnings presented here from the perspective of human medicines, may also be applicable to the veterinary situation and will be built upon under this strategy.

The causes of availability and accessibility issues of human and veterinary medicines are multifactorial and the solutions require actions at different levels involving all stakeholders.

The broader policy issues will therefore form an important part of the Commission's Pharmaceutical Strategy for Europe. It is important to differentiate shortages caused by safety, efficacy or quality/supply chain issues from availability issues for commercial reasons, where political engagement may be necessary. Commercial strategies, and pricing and reimbursement (P&R) considerations are major reasons for non-marketing of new medicines. Robust actions at EU level are necessary in order to adequately address the resultant health inequality and to ensure that all patients

and animals across the EU can have access to medicines they need. Better understanding of the multifactorial causes and solutions is a precondition for an effective solution to the availability and accessibility of medicines. At the same time, it should be recognised that there might be unintended consequences: strengthening regulation of the supply chain, for example, may potentially come at the cost of reduced affordability, and would need therefore to be seen in a broader context than the regulatory remit.

Medicine regulatory authorities are only one of the many concerned players and operational measures taken by regulators cannot address all issues or solve all situations. Any strategy should therefore strengthen partnerships with other actors and stakeholders including HTAs and payers, political authorities and international initiatives and organisations such as the OECD. The proposed EU Regulation on HTA, currently under the co-decision process, could provide an important instrument to address several of the objectives and planned actions of this strategic area in relation to collaboration with HTA bodies. In terms of engagement with payers it is recognised that their heterogeneous nature and varying responsibilities across the national healthcare systems in European Member States lead to more diversity in the areas for collaboration with regulators.

### **Supply disruptions/shortages (availability)**

**Increased collaboration and sharing of data** about products and their availability within the EU is key to address shortages<sup>1</sup>. Medicine shortages are usually not isolated or limited to one market and cannot be solved through national measures alone. Thus, there is a need for coordinated action at EU level to ensure effective measures and to avoid duplication of efforts. In addition, unilateral measures taken to address issues in one country, such as imposing medicines stockpiling and restricting export, can exacerbate shortages in other Member States. Therefore, there is an opportunity for a

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<sup>1</sup> A shortage of a medicinal product occurs when supply does not meet demand at a national level. [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf)



pan-European solution to the issue, which is a priority for the current Commission.

Lessons learned from the COVID-19 crisis, including the potential impact of repurposing medicines to treat a pandemic on their availability for their previously authorised uses, will need to be taken into account (see also section 3.5.). Matching supply data and forecast demand data of medicinal products at a network level by collecting information from various data sources (consumption data, e-prescription data, distribution data) will help prevent shortages in crisis situations, and more broadly, where repurposing of is considered outside crisis situations to support affordability of medicines.

Investigation into the **factors causing medicine shortages** is essential as a first step to identify measures that may prevent shortages. In addition, there is a need to better understand the supply chain and different roles the various stakeholders play (MAHs, manufacturers, wholesalers, parallel distributors/importers, pharmacists, health care and veterinary professionals and patients). A particular focus on solutions for the generics/off patent segment is required since this is where most shortage situations are observed. This includes understanding how current regulatory requirements fail to encourage MAHs' oversight of the complex manufacturing and distribution chains and how regulatory costs impact on low-priced generics and older medicines vis-à-vis new pharmaceuticals. The system should also be as flexible as possible to facilitate access to smaller players such as SMEs and start-ups.

Other initiatives aimed at reducing barriers to national access or distribution may further improve the European or multi-national market for medicinal products. **Electronic product information (ePI)** is one such initiative and should be considered as a way to facilitate marketing of medicines in all Member States and redistribution of medicines available in other Member states to countries experiencing shortages or where medicines are not marketed.

**Increased transparency** on the marketing status of centrally authorised medicines would give Member States insight on what is marketed

in neighbouring countries. Marketing status data is to be included in the SPOR programme, facilitating its re-use and supporting greater transparency. This in turn should facilitate a more effective negotiation of pricing and reimbursement with MAHs. This information could also increase societal pressure on companies to place their products on the market since health care professionals and patients across the EU can see first-hand if a medicinal product is commercialised in their country, though in itself this would not guarantee marketing or accessibility. This information would also be very useful for HTA bodies. The Union Product Database would also provide information on the annual volume of sales and information on the availability for each veterinary medicinal product in each relevant Member State.

There is also a need for increased transparency in the manufacturing and distribution chains. The growing outsourcing/off-shoring trends throughout the manufacturing chain and the complex distribution environment pose a challenge to the quality and availability of medicines. Increased transparency would allow regulators to better monitor the supply chain and anticipate potential issues with the supply of critical products. In turn, manufacturers may come to better understand regulators' expectations around transparency related to the monitoring of the supply chain. This would complement measures at other levels to ensure traceability and oversight in the supply chain (see section 3.5.).

Good **communication** on these complex issues with patients, patient representatives and health care professionals is essential. The network should develop effective coordination and communication to foster trust and increase the chances of successful handling of a crisis.

### **Commercialisation/down-stream decision making (accessibility)**

In order for European patients to gain access to best therapeutic options and innovative medicines, the Network needs to act at various points in the medicine lifecycle.

As part of the development of a broader EU model of horizon scanning (see [3.3.](#)) it should play an active role in collaboration on **horizon scanning activities** such as the International Horizon Scanning Initiative (IHSI) for the benefit of the Network and HTA bodies/payers. It should also establish closer collaboration with HTA bodies during the **scientific advice procedures**, building on EMA/EUNetHTA cooperation, to ensure relevant evidence regarding relative effectiveness is available to support timely national decision making by HTAs/payers.

Increasing complexity and diversity of evidence means that further work is needed on how best to document and clearly **communicate the regulatory assessment** and the quality and robustness of the scientific evidence supporting the marketing authorisation. This improved communication and transparency should include highlighting the inherent risks of over- or underestimation of the real benefits and risks of a treatment, particularly when there are limitations and resulting uncertainties (e.g. orphan medicines, conditional marketing authorisations).

There is also a need to continue to collaborate with HTA bodies, and where appropriate, payers, on **pre-planning and generation of post-licensing evidence**. Such generation of evidence is largely only possible if products are reimbursed and used. It is important to ensure that all post-licensing evidence is made available to the regulatory network to facilitate timely follow-up of benefit-risk by regulators, including where payers enter into 'managed entry' or 'pay-for-performance' agreements. Such collaboration is also integrated with the Network's response to innovation (see also section [3.3.](#)).

Another aim is to develop better **metrics** as basis for cross-country comparison of accessibility by patients, including the impact of early access schemes. Metrics on accessibility should be developed in collaboration with other stakeholders and harmonised between Member States.

## Challenges

The challenges in this area include:

- ▶ the **complexity of the root causes** of shortages and the **role played by different stakeholder groups**. This includes the need to understand
  - » how the intricacies of the **regulatory environment** itself (both at EU level and nationally) contribute to the problem, and looking at ways to address this
  - » the risks the growing **outsourcing trends** throughout the manufacturing chain (including for APIs and raw materials) and the **complex distribution environment** pose to the quality and availability of medicines (see also section [3.5.](#)).
- ▶ managing **resource impact of shortages on the Network** itself, in order to properly handle the increasing number of supply disruptions faced by NCAs on a daily basis.
- ▶ preventing the **erosion of public trust** caused by regular shortages and the inequality in healthcare across the EU due to non-availability of medicines in Member States
- ▶ finding the best way to **improve collaboration with HTA bodies and payers** in order to ensure that we establish agreement on development plans that can deliver "universal clinical evidence" and provide coherent and consistent advice to developers, managing the shift to increasing post-licensing evidence generation in a mutually acceptable way (see also section [3.3.](#)). While this should support better and more evidence-based prioritisation of innovative medicinal products within limited budgets it is recognised that any strategic response might have other consequences (e.g. potential impact of reimbursement approaches on commercial decisions on marketing).

- ▶ ensuring a better alignment of the national **implementation of compassionate use** programmes in order to avoid competition with clinical trials, promote equity in access for patients during late stage development and improved utilisation of data from such programmes to support later decision making.
- ▶ how best to further **improve communication and transparency** about the evidence supporting regulatory decisions and the evaluation process, and on the marketing status of medicines

## Interdependencies

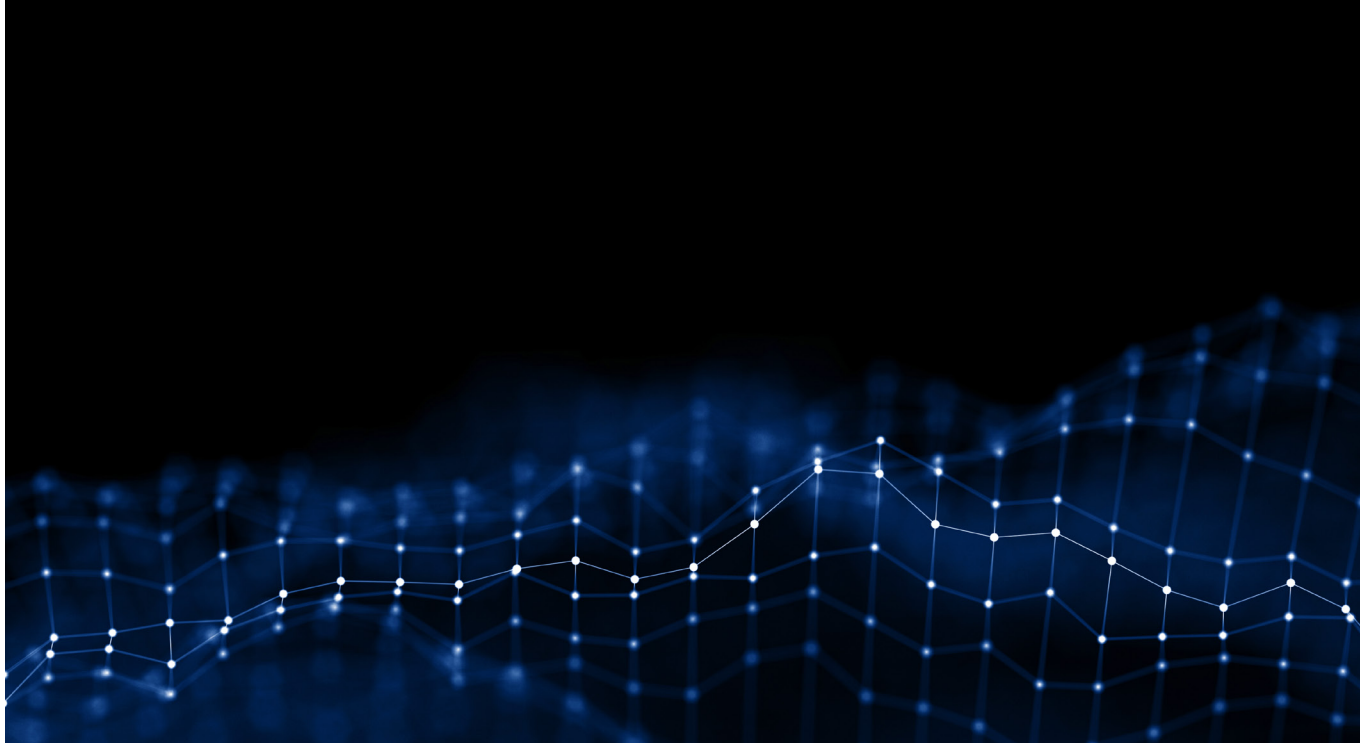
In its planning, the Network will take into account a number of existing initiatives, including:

- ▶ [Work programme](#) of the HMA/EMA Task Force on Availability of Authorised Medicines.
- ▶ EMA/EUnetHTA work plan: <https://www.ema.europa.eu/en/documents/other/ema-eunetha-three-year-work-plan-2017-2020-en.pdf>
- ▶ HTA Network reflection paper: [https://ec.europa.eu/health/sites/health/files/technology\\_assessment/docs/ev\\_20161110\\_co06\\_en.pdf](https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co06_en.pdf)
- ▶ EC proposal for a regulation on HTA: [https://ec.europa.eu/health/sites/health/files/technology\\_assessment/docs/com2018\\_51\\_en.pdf](https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51_en.pdf)
- ▶ International Horizon Scanning Initiative: <https://ihsi-health.org/>
- ▶ OECD activities with regard to access to medicines: <https://www.oecd.org/health/health-systems/pharmaceuticals.htm>
- ▶ Ongoing work on data standardisation and development of master data, e.g. implementation of international data standards like ISO IDMP across Europe and progress in implementing usage of SPOR throughout the Network, thus uniquely

identifying products and manufacturers and allowing data to be re-used for multiple purposes

- ▶ Implementation of the veterinary medicines regulation, [Regulation \(EU\) 2019/6](#), and its associated actions for improving accessibility of veterinary medicines and identifying veterinary medicines through a Union product database

The issues raised in this focus area are intimately connected to those related to globalisation and supply chain challenges (3.5.) and sustainability and operational excellence of the Network (3.6.) in particular. Those elements of the innovation focus area (3.3.) that relate to collaboration on post-licensing evidence generation will also be key.



## 3.2. Data analytics, digital tools and digital transformation

### Strategic goals

Based on its environmental analysis of the strategic area (including the goal of creating a European Health Data Space set out in the European Strategy for Data), as well as the identified challenges, the Network has laid down four main goals to be achieved within the strategy period:

1. Enable access to and analysis of routine healthcare data, analysis of individual patient data from clinical trials, and promote standardisation of targeted data
2. Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics
3. Promote dynamic regulation and policy learning within the current regulatory framework
4. Ensure that data security and ethical considerations are embedded in the governance of data within the Network

*Recommended high-level objectives to support these goals are given in the [table in Annex 1](#).*

The convergence of new treatments, treatment modalities, diagnostics, medical devices, wearables, sensors and connected health is generating enormous amounts of data and more and more routine healthcare data is captured in electronic format. With easy access to ever greater computational power and development of advanced analytics including machine learning, the digital wave is already impacting the medicines development process and healthcare systems. Principal sources of real-world data include electronic health records,

claims data and data from registries. The use of **real-world data** to generate evidence for regulatory decision-making is already a reality and there is increasing interest in using big data and advanced analytics as a complementary source of evidence. The work at EU level on a European Health Data Space (EHDS) recognises the benefits of better access to such data to support public health and its use in the regulation of medicines and the strategy should be seen within this broader context. Thus, the Network aims to contribute to the development



of EHDS and to grasp the opportunities that the EHDS will bring in leveraging health data from across the EU for better regulatory decisions and better health promotion and protection.

In turn, this is promoting an increasing emphasis on post-approval activities using real world data. Clinical trials remain the foundational method of establishing the safety and effectiveness of medicines during the pre-authorisation phase. However, they do not fully reflect the real world, resulting in gaps between regulatory dossiers and subsequent clinical evidence needed by downstream stakeholders including HTAs, payers and ultimately clinicians and patients, which digital techniques have the potential to address. The Network is thus seeing evidence from real-world, patient-level data proposed as a way of complementing clinical trials and filling evidence gaps that cannot be addressed through trials and this is reflected during discussions on medicines development, at marketing authorisation application and extensively in the post-authorisation phase.

Pre-authorisation, there is particular interest in real-world data as a complement to clinical trials for medicines to treat rare diseases, where a comparative randomised trial may be very difficult to perform. Real-world data may also support evidence on the natural history of the disease being treated and on populations beyond those represented in clinical trials. In the post-authorisation phase real-world data has an established place in the monitoring of product safety and there is interest in complementing this by monitoring product effectiveness in the authorised indication and monitoring performance in populations not studied pre-authorisation.

By viewing real-world data as complementary to clinical trials data the Network Strategy aims to benefit patients through better decisions based on more comprehensive evidence. The aim is that the planned generation of evidence from complementary sources can support decision-making not only by regulators, but also by HTA bodies and beyond. The Network is focused on ensuring appropriate data ethics, data privacy and thus having clear guidelines for collecting and storing data at patient level.

Experimental evidence and data analysis techniques can be used to evaluate the impact of healthcare policy decisions and establish a feedback mechanism which can enable formulation and implementation of effective healthcare policies. This has been highlighted as one of the lessons learned from the COVID-19 pandemic, in which rapid collection and analysis of data to support communication and healthcare decisions by the Member States has been of vital importance.

Looking ahead, further development of analytical capabilities within the Network must include seamless integration of pharmacokinetic/pharmacodynamic model-based development of medicines with new data analytical methodologies. Regulators must be able to provide scientific advice as well as apply modelling/simulation analyses on applicant data during assessment. Modelling and simulation are already pivotal in developing medicines, but it will require further capability building within the Network to utilise its potential, including enabling better inclusion of subgroup perspectives such as paediatric, pregnant women etc.

To adapt to the industry and other stakeholders' ever-increasing use of **data and process analytics** and new **digital tools**, and to fully deliver our public and animal health mandate, we need to be able to utilise all available data and tools to generate evidence for better and more efficient regulatory and clinical decision making. Without this we risk a situation where the Network neither possesses the technology to receive and interpret such data, nor the competences or regulatory setting and procedures required to address developments in this field. This would curtail the Network's collaboration with third countries and other external stakeholders. Furthermore, the Network would not be able to reap the benefits of the transformation such as utilising artificial intelligence and reducing time spent on regulatory and scientific evaluation of marketing authorisation applications or related activities. Ultimately the EU could become an unattractive region for the global life science industry and innovative therapies and technology would not reach EU patients in due time.

This means we must ensure that the agencies of the Network continuously adapt to the rapid global evolution of digital healthcare systems so they can cope with the increased use of Big Data, including real-world data, advanced analytical platforms and new digital tools, and make best use of them themselves. It also emphasises the need for access to routine healthcare data and the requirement to promote standardisation of data reflected in the EC's policy on Open Data and the Public Sector Information (PSI) Directive. Thus, the Network will strive to enhance the level of standardisation of real-world data during the strategy period, wherever meaningful and feasible.

The Network will need to collaborate with key external stakeholders to ensure that it can access and make use of the necessary competencies and capabilities. Hence, it is key for the successful implementation of the strategy that the Network establishes collaborations with external stakeholders including patients, academia, NGOs and industry, and with other regulatory authorities (e.g. US FDA, PMDA) engaged in Big Data initiatives.

In addition to the important contribution of healthcare data to the generation of evidence for regulatory decision-making, it is of utmost importance that the Network makes an appropriate **digital transformation** to modernise its own processes and create a supporting digital infrastructure. This implies a new way of leading and executing our work, with optimisation and automation of many of the Network's processes, and use of AI and digital tools in new ways to achieve our goals. This undertaking will constitute a fundamental transformation of the regulatory Network in line with disruptions seen in other sectors of society, e.g. the emergence of Uber, streaming services like Netflix and HBO and AirBnB that have completely transformed the market for transport, video renting and hospitality respectively. In the Network context, one can envision the use of patient level data in authorisation processes and 3D printed medicines as results of the digital transformation. This will require adequate resourcing, training and acquisition of new skills across the Network, further development of

our existing sharing of best practices (including learning from experiences in other sectors), and ways to enlist external support as required. Initially, the use of patient level data will be implemented in Clusters of Excellence and expanded to the rest of the Network as the use of the data in question matures.

An important first step towards building sustainable capability and capacity within the Network is to map the main shortcomings of the Network and build a strategy and roadmap towards an ideal state of operation (see also the strategic elements referred to in sections [3.1](#) and [3.6](#)). It will be crucial that the potential impacts of ongoing legislative and business initiatives are understood and planned for.

The convergence of medicines and medical devices means that the authorities within the respective fields cannot do the mapping by themselves. It should be a joint effort by these authorities together with the HTA bodies – at both national and European level.

As the Network continues to evolve, it will need to take into account the **diverse level of digitalisation** across the EU Member States as well as ensuring a more comprehensive digital interface to **optimise interaction** with our stakeholders, and EU citizens more widely. An important aim will be to provide fully digitalised deliverables (e.g. ePI, SPOR and IRIS) from the Network's own operations that can be used by others to promote a better use of medicines.

Providing digital support for **veterinary medicines**, for which the systems have historically been less well developed and resourced than for human medicines, will also be an important component of the strategy, and digitalisation of the relevant processes will be a significant element of the work to implement the veterinary medicines regulation, [Regulation \(EU\) 2019/6](#). Although the use of Big Data in veterinary medicine applications is not common, at least at present, the new legislation allows for the potential importance of Big Data, AI and block chain employment in pharmacovigilance, in the detection and reduction of antimicrobial resistance and in the monitoring of environmental impact. Thus,

the four strategic goals of this section of the strategy apply as appropriate to both veterinary and human medicines.

## Challenges

The challenges the Network faces in making such a transformation include in particular:

- ▶ the **sheer increased volume and complexity of data** ('Big Data')
- ▶ a **lack of regulatory standards, guidance and validation** for the use of patient-level healthcare data, artificial intelligence (AI) and machine learning
- ▶ a somewhat **static regulatory process** that is ill-adapted to an increasingly dynamic environment in which technology and science, particularly in areas such as use of device data, real world data, adaptive algorithms etc., are developing faster than current regulations / guidelines
- ▶ a **lack of technological capability and capacity** (hardware and software) within the Network to analyse patient-level healthcare data (including applicant's clinical data sets, images etc.) and support digital transformation
- ▶ a **lack of required personnel and competences** within the Network for driving digital transformation, in areas such as AI/ machine learning, assessment of advanced analytics, digital leadership, data and computer scientists. This could be developed in collaboration with the EU NTC
- ▶ the **need to maintain public and stakeholder trust**; data and new technology must be used not only in accordance with legal requirements such as data protection legislation but also in line with societal values, ensuring a high level of data ethics within the Network via secure data management and high data ethical standards. Thus, openness, access to data and transparency regarding study results, statistical methodology and algorithms are key elements in the strategy.

In addition, we must be aware that digital transformation will bring changes in the inter-dependencies between the Network and external stakeholders, including HTA bodies, authorities working with medical devices and training organisations

- ▶ some stakeholders view **healthcare data as a commercial commodity** and this risks limiting the public and animal health benefits of real-world and big data. The Network should collaborate to promote access to, and analysis of, healthcare data where this is in the interest of European patients and of animal welfare. Access to and analysis of healthcare data should be facilitated through the development of the European Health Data Space
- ▶ the need for mechanisms to ensure better access to, and wider sharing and re-use of, existing data and decisions in order to achieve more consistent regulatory outputs; this might include better access to electronic health records, claims data, patient registries and other data sources (taking into account issues that may be raised by GDPR requirements, which have to be applied in a uniform manner within the Network), moves to ensure interoperability of existing data sets on an international level, combining data to address specific validation needs of medicines agencies and appropriate infrastructure for access to and exchange of data, all of which could potentially form part of the work to create a European Health Data Space.

## Interdependencies

The Network and its partners have already made considerable steps to understand some of the issues related to this theme and a number of existing initiatives will be taken into account in planning. These include:

- ▶ The [ten prioritised recommendations](#) of the [Big Data Task Force](#)
- ▶ Priority areas in the [EMA Regulatory Science Strategy](#), notably on use of real world evidence

- ▶ The Commission’s initiatives relating to [digital transformation of health and care in the Digital Single Market](#), the activities of the [high-level expert group on AI](#) and the [European Health Data Space](#); in particular the [communication on the European Strategy for Data](#), adopted in February 2020, which refers specifically to the activities of health sector regulators including medicine agencies
- ▶ Work to implement the veterinary medicines regulation, [Regulation \(EU\) 2019/6](#), in relation to pharmacoepidemiology, signal detection and AMR, which will benefit significantly from use of Big Data and AI
- ▶ Implementation of international data standards like [ISO IDMP](#) across Europe and progress in implementing usage of SPOR throughout the Network; initiatives on e-submission and development of the clinical trial information system (CTIS) are also relevant
- ▶ The goals and objectives of the strategy should be mapped to the existing Telematics Application Landscape and Lifecycle Model in order to divine where investments in existing capabilities might be needed and where entirely new capabilities are required, ensuring that we promote re-use and long-lived capabilities/platforms

As with the wider digital transformation of society, digital transformation implies big changes to the way that the Network functions. As noted in the Introduction to this document, it will affect and underpin many of the initiatives reflected in other themes within this strategy, for example ePI and availability metrics ([3.1.](#)), many aspects of dealing with innovation ([3.3.](#)), and regulatory optimisation and moves to improve the sustainability of the Network and operational excellence ([3.6.](#)).





### 3.3. Innovation

#### Strategic goals

Based on its environmental analysis of the strategic area and the identified challenges, the Network has laid down four main goals to be achieved within the strategy period:

1. Catalyse the integration of science and technology in medicines development and ensure that the Network has sufficient competences to support innovators in various phases of medicines development.
2. Foster collaborative evidence generation – improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTAs, and pricing and reimbursement authorities.
3. Enable and leverage research and innovation in regulatory science.
4. Enhance collaboration with other stakeholders including medical device experts, notified bodies, SMEs and research/academic groups.

*Recommended high-level objectives to support these goals are given in the [table](#) in Annex 1.*

Advances from transformational research in biomedical science are bringing new treatment opportunities, and innovation throughout the lifecycle of medicines, at an ever-increasing pace. Editing of the genetic code and functions of cells has already brought new and effective treatments against cancer and other major diseases, while developments in Advanced Therapy Medicinal Products (ATMPs) also offer opportunities to address unmet medical needs. Biomarkers identified from genomic, proteomic, metabolic and microbiomic data, as well as clinical and imaging data, offer the possibility

to tailor treatments at a personalised level in a more targeted way (precision medicine). Such innovations may require novel manufacturing technologies and delivery approaches including nanotechnology, 3D printing, decentralised in-situ manufacturing and greater use of medical device/medicinal product combinations and related diagnostics.

Appropriate engagement with patients will be needed during product development and throughout the lifecycle to ensure a patient-centred focus while protecting public health and

availability of medicines. Capacity building and development of expertise at regulatory and HTA agencies is needed to cope with the increasing number of ATMPs seeking approval; knowledge sharing with international partners will be helpful in this regard. In the field of biosimilars, it is expected that regulators support and enhance the stepwise development of these products and further clarify the concept.

The increasing incorporation of digital tools, data standardisation and the consequent ability for improved evidence generation throughout the lifecycle of a medicine also offers an opportunity to better capture patient preferences during the evaluation process and make clinical development and regulation more cost-effective. On the veterinary side, alternative methods of evidence generation, for example through farm management systems, offer similar opportunities.

As with the digital arena (see [3.2.](#) above) regulators need to adapt and evolve so they can support such innovative approaches to data generation, developing the requisite competences for this quickly evolving environment. This is made more acute by social and economic change: globalisation continues to make the surveillance of good practice related to drug development very challenging, greater environmental concerns remind us of the need for regulators to pay more attention to the international environmental impact of pharmaceuticals, and an aging population in EU countries emphasises the need for clinical studies in the elderly population. Initiatives in special/vulnerable populations, such as geriatric or paediatric populations, should continue to be sought.

Regulatory science must advance in tandem with transformational research which significantly shifts existing scientific and treatment paradigms. The ultimate public and animal health aim will be to ensure that regulatory science remains at the cutting edge so that the EMRN can continue to assess innovations rigorously and efficiently and deliver its fundamental mission of protecting human and animal health and facilitating the availability of medicines to patients and animals. One

relevant consideration will be how innovative developments on the human side could be best harnessed for veterinary medicines.

Sharing best practice globally will also mean that the knowledge and expertise of the Network can contribute to public health on a wider stage. For unexpected emerging health threats (global crisis, epidemics, pandemics), it is crucial to seek early international collaboration and engagement, as has been shown by the COVID-19 pandemic. The pandemic has also emphasised the importance of a coordinated approach in obtaining robust data over a short period of time. Small, competing clinical trials are unlikely to be helpful in such a situation and there is a clear need to promote large, multicentre and whenever possible multinational clinical trials with a shared protocol and standard, so that robust evidence is available to decision makers. Developing large EU investigator networks and investing in the public infrastructure to support such networks and trials ought to be a focus going forward.

An aim of particular interest for this strategy period is development of EU **horizon scanning capability** so regulators can become aware of innovation earlier and address questions from innovators at a much earlier stage, so as to help developers avoid major regulatory problems. Such horizon scanning activities should also consider synergies with other initiatives (see section [3.1.](#)). A common model for horizon scanning is under development in the EU-Innovation Network and should be prioritised; global collaboration with other agencies is also needed. It is recognized that the different actors involved (regulators, HTA bodies, price and reimbursement authorities) may differ in the nature and timing of their information needs, so good communication is essential to ensure these needs continue to be met for all parties.

Other focus areas include:

- ▶ **how to classify complex, borderline medicines** and identify mechanisms to establish more convergence about borderline decisions at the strategy stage. All relevant stakeholders (NCAs, medical device authorities, EMA, European Commission and

industry associations) must be involved; establishing an **integrated evaluation pathway** for the assessment of medical devices, in vitro diagnostics and borderline products for which specific expertise and collaboration between regulators is key

- ▶ developing **consistency and convergence in scientific advice** between national authorities, and exploring further synergies with HTA bodies and payers (building on the success of parallel scientific advice procedures);
- ▶ **supporting innovation and digitalisation in clinical trials** by strengthening the Network's expertise in handling more complex designs, including the use of data analytics and real-world data. Such innovation should go in parallel with a common regulatory framework and harmonisation within the EU/EEA; digital tools such as the clinical trial information system (CTIS) and SPOR, and introduction of electronic submission and assessment processes will be important here but alignment on application of GMO requirements in the EU would also be required;
- ▶ working to **evolve the marketing authorisation paradigm** to a more dynamic model, in which authorities will be able to re-use data and use data analytical capabilities not only to validate the applicant's analysis at the time of assessment and initial benefit-risk analysis but repeat this at predefined time intervals post-approval;
- ▶ leveraging **collaborations on regulatory science with academia and SMEs**, involving them in discussions about where research resources should be focused and engaging with academics and industry-based researchers involved in medicine development to guide them through the regulatory pathway. As an example, early development of ATMPs usually takes place in academia making regulatory advice at an early stage necessary. Relevant training in areas of innovation must be developed in close collaboration with these groups;

- ▶ supporting the repurposing of existing medicines for new indications in areas of unmet medical need (see also availability, under section [3.1.](#)).
- ▶ collaboration between regulators and other stakeholders such as policy makers, developers, academia, industry and National Immunization Technical Advisory Groups (NITAGs) may help accelerate the complex and challenging development, approval and post-marketing monitoring of the next generation of innovative vaccines including those for pandemics such as COVID-19.
- ▶ contributing to the development of regulatory and scientific guidelines to facilitate new innovative treatment options and cope with emerging challenges;
- ▶ encouraging and prioritising the appropriate use of novel pre-clinical models, notably those adhering to the 3Rs, and making developers aware of their acceptability to regulators. Training on these methods might be envisaged.
- ▶ addressing environmental aspects of innovation without jeopardising either support to medicine developers or protection of public health.

The Network should also further strengthen its engagement with public-private partnerships such as Horizon Europe during the strategy period.

All of these focus areas come with associated challenges (see below).

## Challenges

Focusing on the areas of innovation above also foregrounds a number of challenges:

- ▶ as increasingly complex medicines are developed that converge different technologies or apply 'platform technologies' in multiple ways to promote and protect human and animal health, **consistently applied EU-wide rules** on whether a

borderline product should be considered a medicine or a medical device should be an aim during the strategy period, to promote harmonisation in decisions among Member States. Strong alliances with experts from medical device authorities and others (Member States, European Commission, EMA, industry associations) will need to be sought. In addition, a better understanding of medical device regulation and their mechanism of actions by regulators will be helpful.

- ▶ innovations in **patient-centred healthcare**, and **precision/personalised medicine** often do not fit properly into existing regulatory systems. This can range from treatments that target stratified populations (biomarker-led medicine) or different stages of the disease, to the use of individualised treatment such as modified autologous cells. Protecting public health while providing a regulatory environment that can support such steps towards precision medicine is key if EU patients' needs are to be better addressed with new, safe, effective and clinically appropriate treatments.
- ▶ development of innovative and precise medicines, for example with the success of incentives for medicines for rare diseases, has led to more conditional marketing **authorisations based on sometimes very limited evidence**, and this is likely to increase with the trend for more targeted medicines in which new biomarkers result in splitting larger indications into smaller ones. The resultant need for confirmatory evidence about efficacy and safety of such products puts a lot of pressure on **post-licencing evidence generation**, which is needed not only by regulators, but also by HTA bodies and pricing authorities. Meeting the challenge is likely to mean adapting the marketing authorisation system to reflect that the initial marketing authorisation is only the first step in the process of evidence generation about the benefits and risks of the product. It is recognised that this may lead to situations where products are withdrawn from the market because efficacy could not be confirmed by Marketing Authorisation

Holders after initial marketing authorisation was granted.

- ▶ new and **innovative clinical trial designs and methodologies** are already challenging the system. Complex designs such as umbrella trials and basket trials require advanced biostatistical and data analytical understanding and recruitment of patients may also change with the use of new technologies to identify eligible study participants and new ways to capture data during clinical trials. Companion diagnostics are also being developed and there is a need to adapt the Network's IT landscape to handle innovative products including addressing the potential for products developed by or incorporating AI/machine learning. Challenges include **validation** of such devices and tests, **data ethics and GDPR** considerations (see also section [3.2.](#) above). An increased need for interaction with competent authorities for medical devices is also foreseen. The commercialisation of data (a so-called "data market") may be a barrier to regulatory access as noted in the challenges under section [3.2.](#) above. In addition, cybersecurity issues may also emerge.
- ▶ the regulatory system needs rapid **access to appropriate expertise** to ensure adequate, fit-for-purpose and effective regulation and so that the latest scientific and technological knowledge can be built into medicines development where it benefits public health. This requires closer collaboration on an international level with academics, research centres and infrastructures to ensure that such expertise is present in the ongoing dialogue between regulators and developers at all stages of the process. In the absence of the required expertise there will be a need to identify **training needs**.
- ▶ the need for stepwise implementation of a **coherent view of innovation and scientific advice provision**, agreed and built into all pre- and post-approval regulatory activities as well as subsequent HTA and pricing and reimbursement (P&R) decisions for the entire life cycle of medicines.



The proposed EU Regulation on HTA, currently under the co-decision process, could provide an important instrument to implement and address collaboration with HTA bodies.

- ▶ stronger **alliances with relevant regulatory global partners** are needed to work together as we develop our approach and response to the challenges from innovation.
- ▶ innovative products will create new requirements for **storing data and maintaining the data lifecycle** of medicinal products at national and European level.

## Interdependencies

Existing initiatives that need to be taken into account in this area over the strategy period include:

- ▶ the project [STARS](#) (Strengthening Training of Academia in Regulatory Sciences and supporting regulatory scientific advice) supported by the DG Research and Innovation
- ▶ [EMA Regulatory Science Strategy to 2025](#) (plus any related ongoing action plans)
- ▶ [EU Cancer Action Plan](#) (under development)
- ▶ [Horizon Europe](#) and [IMI Research Agendas](#)
- ▶ Ongoing initiatives on horizon scanning such as the common model under development by the [EU-Innovation Network](#) or [TISP project in collaboration with EUNetHTA](#) or collaboration within ICMRA.
- ▶ Repurposing project under the auspices of the [Commission Expert Group on Safe and Timely Access to Medicines for Patients \("STAMP"\)](#)
- ▶ the new [Medical Device Regulation/ In-vitro Diagnostics Regulation \(MDR/IVDR\)](#)
- ▶ [Simultaneous National Scientific Advice project \(SNSA\)](#)

- ▶ Parallel consultation between Regulatory Authorities and [EUNetHTA](#)
- ▶ EU-IN work plan
- ▶ INNO group
- ▶ [Regulation \(EU\) 2019/6](#) on veterinary medicinal products
- ▶ [International collaboration: International Coalition of Medicines Regulatory Authorities \(ICMRA\)](#), among others.
- ▶ [Regulation \(EU\) No 536/2014 on clinical trials on medicinal products for human use](#)
- ▶ [Clinical Trials Facilitation Group \(CTFG\)](#)
- ▶ [European Reference Networks](#)

Again the effects of innovation will be felt in many areas of this strategy, including in particular the sections on data analytics, digital tools and digital transformation (3.2.), globalisation and supply chain challenges (3.5.) and sustainability and operational excellence (3.6.), as well as its impacts on availability (3.1.).



### 3.4. Antimicrobial resistance and other emerging health threats

#### Strategic goals

Based on its environmental analysis of the strategic area and the identified challenges, the Network has laid down six main goals to be achieved within the strategy period:

1. Provide high quality information on antimicrobial consumption and surveillance data on antimicrobial resistance in animals and humans in support of policy development and by ensuring proper implementation of Regulation (EU) 2019/6 on the ground.
2. Contribute to responsible use of antimicrobial agents and effective regulatory antimicrobial stewardship in human and veterinary sectors by putting in place strategies to improve their use by patients, healthcare professionals and national authorities.
3. Ensure regulatory tools are available that guarantee therapeutic options, while minimising impact of antimicrobial resistance on public health and the environment
4. Define pull incentives for new and old antimicrobial agents, including investigating support for new business models and not-for-profit development
5. Foster dialogue with developers of new antimicrobial agents and alternatives to traditional antimicrobials, to streamline their development and provide adequate guidance in both human and veterinary medicine
6. Improve regulatory preparedness for emerging health threats

*Recommended high-level objectives to support these goals are given in the [table](#) in Annex 1.*

In the light of the COVID-19 pandemic and the suffering and disruption it has caused on a global scale, the importance of emerging health threats caused by previously unknown pathogens like SARS-CoV2 has been underlined, and will have an important influence on this strategy and the broader policies within which it

sits. However, while applying the lessons learned from the pandemic it is important not to lose sight of a more insidious health threat, namely that of **antimicrobial resistance** (AMR).

AMR is one of the major global threats to public and animal health. It is considered to currently

cause about 33,000 human deaths per year in the EU alone while global estimates amount to approximately 700,000 human deaths annually. If the emergence and spread of AMR progresses without restraint, the annual number of deaths worldwide is expected to increase to millions, making AMR a more common cause of death than cancer by 2050. AMR carries a heavy economic cost already, amounting to €1.5 billion just in the EU due to health care costs and productivity losses. On a global level, as tuberculosis is the single largest source of AMR, representing one third of the world's AMR burden, it is particularly crucial to address multi-drug resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB).

AMR demands a "One Health Approach", requiring collaborative multidisciplinary efforts involving legislators, regulators, physicians, veterinarians, academia, the pharmaceutical and the food industry as well as the agricultural and, importantly, the environmental sector. In the EU context this is to be developed through close collaboration between the European Commission and relevant EU Agencies within their specific remits.

Increased consumption of antimicrobials leads to increase in antimicrobial resistance. The risk grows higher with misuse of antimicrobials including inappropriate use, dosing errors, duration of administration or excessive use of broad-spectrum antimicrobials. Reduction of antimicrobial use (e.g. by infection prevention, vaccination and promotion of responsible use, ensuring that the appropriate antimicrobial therapy is used and that antimicrobials are only be used in cases where their use is justified) is key to addressing the risks to public and animal health. Also important are efforts to discover and develop new antimicrobial agents and alternative therapeutics. Despite the increase in AMR this latter component is currently rather lacking, with limited engagement from the pharmaceutical industry and the financial failure of some smaller players. New approaches are needed to ensure availability of, and access to, critical antimicrobial agents (including maintaining EU production capacity for older, critical antimicrobials) and the development of alternative preventive and therapeutic approaches.

Beyond AMR, the emergence and re-emergence of infectious diseases requires a global collaboration to develop effective and timely responses. Such health threats will often be best addressed in a One Health approach for which the experiences in addressing AMR provide valuable reference points.

Key areas for the Network in the forthcoming years include encouraging **appropriate use of antimicrobials** (including during pandemics) and supporting adequate stewardship and surveillance of resistance in all Member States as a most urgent measure to addressing antimicrobial resistance in the short term, to preserve efficacy of the currently available medicinal products. This may include

- ▶ continuing to **harmonise and modernise the product information** for longstanding antimicrobials to support appropriate use
- ▶ publishing interpretative **criteria for susceptibility testing** following EUCAST (including VETCAST) deliberations
- ▶ helping to guide therapeutic decision making by **classifying antimicrobials** in consideration of their human and veterinary therapeutic importance and availability of therapeutic alternatives
- ▶ ensuring data quality and standardisation of data relating to availability and consumption of medicines.

Next, it is crucial to further and more effectively **support research** into new antibacterial agents and **incentivise development** of new options, including **therapeutic alternatives to antibiotics**. Regulators cannot tackle the problem alone, but can guide developers on regulatory requirements, including platforms for dialogue such as PRIME and ITF, and supporting development of new veterinary antimicrobials through preliminary risk profiling at the pre-submission stage. Although much of the Network is not directly involved in issues of reimbursement, it should be supportive of **new business models** to incentivise the private sector (while making sure there is no overuse or misuse) by decoupling sales volumes from

return on investment and development of pull incentives for successful products. The potential contribution of not-for-profit organisations should be further investigated.

**Continued collaboration** with other actors and stakeholders will be vital, including with **WHO** to review the pipeline of investigational antibacterial agents and essential “old antibiotics”, with **OIE and FAO** to support responsible and prudent use of antimicrobials in animals and to monitor antimicrobial consumption in animals, with **HTA bodies** to reflect on options for a specific value assessment framework for antibiotics for use in humans, and in various **international forums** to ensure harmonisation, such as the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) and tripartite meetings.

Collaboration and joint planning will also be vital in ensuring that the Network and its partners are as prepared as possible to handle **emerging health threats** and emergencies such as pandemics, as referred to at the start of this section and throughout the strategy. Experiences with COVID-19, Ebola, Zika, SARS/MERS and a decade ago with the influenza pandemic have shown the importance of emergency preparedness and having **public health advice and counter-measures**, in particular vaccines and antivirals, available in a timely manner.

To ensure this, regulatory decisions and pathways for appraisal of medicinal products both in inter-epidemic periods and during outbreaks require continuous refinements of the regulatory science and regulatory tools and procedures. Such health threats may again be best addressed in a One Health approach using global collaboration with other actors and stakeholders to develop an effective and timely response.

Importantly, **new approaches to estimate efficacy** of medicinal products for human use in such a case, via animal models or human challenge models, need to be further explored before outbreaks occur, as do similar models

for medicinal products for veterinary use. Such models must be robust and properly validated. Clinical studies using human challenge models raise the need of agreement around **requirements for clinical trial approval**, in particular minimal requirements of the quality of the challenge material (e.g. level of GMP compliance), and must take into account the [ethical dimension](#) of any approach. The GMO framework would also require a broader agreement with respect to both human challenge studies and testing of vaccines in emergency settings. The route for **use of investigational agents in the context of emergencies** would benefit from a more harmonised approach across the EU together with the possibility of stockpiling relevant medicinal products for use across the Union.

Another area of discussion is around the use of **platform technologies** that could speed up availability of vaccines and biological products in the face of unpredicted emerging pathogens. The extent to which the establishment of a platform technology can alleviate and accelerate regulatory decision needs to be further defined as part of the preparedness activities.

More broadly, regulators should do what they can to **explore alternative approaches** to treatment of infectious diseases and combatting development of resistance, such as bacteriophages, monoclonal antibodies, vaccines for healthcare-associated infections, and combination therapy, including options for veterinary medicine. This may require **development of appropriate regulatory pathways** for, e.g. customised use and use of phage libraries or development of microbiome products. Regulation will also need to support the choice of appropriate therapies in human and veterinary medicines through use of rapid **point of care diagnostics**.

A major tool in tackling these challenges on the veterinary side will be the **implementation of the veterinary medicines regulation**, which will, among other key activities, support the **mandatory and expanded collection of sales and use data** for antimicrobials by animal species, providing information on the use of antimicrobials in animals across



Europe to support Union and national policies. Through the EMA, the Network will also provide **scientific advice** to the Commission in areas such as designation of antimicrobials or groups of antimicrobials as reserved for human use and restrictions to the prescribing cascade for antimicrobials, as well as developing robust scientific **guidelines** to support regulatory decision-making.

In order to address the potential impact of environmental residues of antimicrobial medicines on the emergence and spread of AMR, we will explore the **Environmental Risk Assessment** (ERA) in more depth. Appropriate measures should be also be considered to ensure that environmental aspects of API production are taken into account (see also under section [3.5.](#)).

## Challenges

AMR is addressed by multiple national, European and international strategies following the One Health approach. This complexity, and the requirement of a deep intersectoral collaboration of a broad range of stakeholders, pose significant challenges in developing a strategy for this area:

- ▶ Thus far, the particular involvement of regulators has been limited. Joint efforts of human and veterinary stakeholders have been scarce and often hampered by conflicting sectoral aims. Ambitions and measures on AMR have thus appeared more aspirational than realistic in many instances. The Network **needs to foster multidisciplinary intersectoral cooperation, dialogue between human and veterinary stakeholders and increased involvement of regulators.**
- ▶ National action plans on AMR are tailored to a certain degree to participating stakeholders, regional epidemiological situations and specifics of national surveillance systems of AMR, AMU (antimicrobial use) and antimicrobial sales. **National One Health approaches thus vary**, leading to differences in national implementations of targeted measures (e.g. stewardship programmes and benchmarking). The Network should leverage

national efforts, to foster their harmonisation and to further refine a targeted common European approach to AMR. An increase of cooperation and communication across the Network would also help further streamline activities related to emerging health threats from infectious diseases.

- ▶ Further **international coordination and solidarity** are critical. The Network must build on successful [international initiatives](#) such as the tripartite meeting scheme between the EU, the US and Japan, TATFAR and the Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR). The same need for coordination and solidarity with regard to emerging health threats has been made evident during the COVID-19 pandemic.
- ▶ Regarding the collection, reporting and quality of data on AMR and antimicrobial use in particular, we see **potential to further harmonise, standardise and extend national surveillance** with EMA and NCAs working in close collaboration to analyse and report such data for the veterinary sector.
- ▶ From a regulatory view, **the size of the problem of AMR has often been insufficiently recognised and addressed.** As a Network, we consider the **need to identify current blind spots** as an opportunity for new approaches to address AMR – taking into account the specific nature of anti-infective medicines (antimicrobials, vaccines, alternative therapies, etc.) and their requirements for specific marketing and post-marketing authorisation requirements, prescription status specification and Health Technology Assessment (HTA) compared to conventional medicinal products. **Adequate resources must be provided** for the necessary actions, e.g. for the review of SmPCs of old antibiotics.
- ▶ **Antimicrobials have to be affordable on a sustainable basis** which calls for an optimisation of use, stocks, the supply chain (including risk analyses) and incentives for maintaining manufacturing of old antibiotics together with health care and dispensing

systems that ensure access to antimicrobial medicines and alternatives thereof. The Network must focus on the **end-to-end supply chain** (see also section 3.5.) and on **how to incentivise manufacturing capability** while safeguarding responsible use.

- » Access has to be ensured, while de-linking return on investment from the volume of sales.
  - » The economic case must be made for sustainable research and development of anti-infectives, vaccines, diagnostics and innovative products for humans and animals.
  - » A transparent regulatory framework for alternative preventive and therapeutic approaches such as bacteriophages, peptides, monoclonal antibodies or microbiome products must be developed and put in place.
- ▶ The potential interaction between the problem of AMR and that of pandemic management should be borne in mind: as noted by [WHO](#), it will be essential that antimicrobials are used appropriately in patient management, to avoid exacerbating AMR.
  - ▶ The creation of an entity with a mandate similar to US Biomedical Advanced Research and Development Authority (BARDA), would be a major contribution in better preparing the EU to mitigate the impact of present and future emergencies related to AMR or emerging pathogens, by supporting development of diagnostics, and preventive or therapeutic medical countermeasures especially in the human domain.

## Interdependencies

Major initiatives on pandemic preparedness are being launched or strengthened in the wake of COVID-19 and any actions proposed in this strategy will be aligned. Similarly, a number of initiatives on AMR are already existing and will be taken into account for the development and definition of specific objectives and actions on AMR.

- ▶ The veterinary medicines regulation, [Regulation \(EU\) 2019/6](#), which provides additional tools for regulators.
- ▶ The [European One Health Action Plan](#) and [Council Conclusions on AMR](#), aspects of which have already started being implemented by EMA.
- ▶ The [EMA Regulatory Science Strategy to 2025](#), which includes specific actions on AMR by promoting the responsible use of antimicrobials and their alternatives.
- ▶ Recognising AMR as a global threat, the Network's strategy and actions takes into account guidance and information developed by international organisations, such as UN, WHO, OIE, FAO and OECD. As noted above, the Network will build on the [existing successful international initiatives such as TATFAR and TFAMR](#).
- ▶ The implementation of SMS (standardised substance identification) and the EU-SRS database in Network activities and IT systems.
- ▶ The initiatives on preparing for emerging health threats proposed by the EU under the umbrella of the [EU4Health](#) and [RescEU](#) programmes.
- ▶ EU AMR specific initiatives and programmes like [EU JAMRAI](#) and [EU JPIAMR](#)
- ▶ The 2014 [Review on Antimicrobial Resistance](#) by Jim O'Neill for the UK Prime Minister.
- ▶ The international network [Action on Antibiotic Resistance](#) (ReAct).
- ▶ The [European Union Strategic Approach to Pharmaceuticals in the Environment](#).

Some of the work involved in this strategic area will be closely linked to initiatives in other areas of the strategy, notably in the areas of availability and accessibility (section 3.1.), the use of new data analytics and tools (3.2.), innovation (3.3.) and supply chain challenges (3.5.).



### 3.5. Supply chain challenges

#### Strategic goals

Based on its environmental analysis of the strategic area and the identified challenges, the Network has laid down five main goals to be achieved within the strategy period:

1. Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs) and excipients.
2. Enhance inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing.
3. Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries for medicinal products for human and veterinary use.
4. Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites, to ensure continuity of supply and availability of medicinal products.
5. Analyse the possible implications of new manufacturing technologies and adapt the regulatory framework to accommodate innovation in manufacturing and distribution of medicinal products for human and veterinary use.

*Recommended high-level objectives to support these goals are given in the [table in Annex 1](#).*

Public and animal health protection depends on a continuous strengthening of supply chain security, both to ensure presence and continuity of supply of the high-quality medicinal products that EU citizens expect, and to permit the entry of new products and technologies while ensuring that their manufacture is

carried out and supervised to an appropriate standard. Given the number of actors involved, effective communication and engagement with stakeholders at all levels of the supply chain is essential to achieve this.

Today, the **supply chain** of medicinal products throughout the product lifecycle, from development through to commercial production is **global and increasingly complex**. Active substances and excipients may be manufactured outside the EU (e.g. in China or India), further formulated and packed or repacked in other third countries or within the EU.

Globalised supply chains and markets underline the need for **extended supervisory oversight** of supply chains, especially active substance manufacturing, through international co-operation and collaboration based on existing (such as with EDQM) and new initiatives.

Hence, **inspector capacity building** will be key to any strategy. Within the EU, the complex development, manufacturing and distribution channels continue to require supervision by EU NCAs. Internationally, EU authorities are working with third country authorities either through bilateral or multilateral **international co-operation frameworks** to build confidence and so allow more reliance on each other's supervisory systems. Such initiatives are key to the most efficient use of inspection resources, increasing the breadth of supervision as well as improving the manufacturers' own understanding of their responsibilities. For example, the network should make optimum use of mutual recognition agreements (**MRAs**) through expansion of scope to include more product categories where appropriate or recognition of inspections by MRA partners in third countries where GMP certificates are available from those partners.

Training inspectors and gaining experience with the implementation of the delegated regulation to the **Falsified Medicines Directive** will be important elements in responding to challenges in the security of the supply chain.

Enhancing linkages in medicinal **product and supply chain information** such as records in EudraGMDP, in the SPOR platform, in the Article 57 Database and in the EU product database for veterinary medicines (UPD) as well as in EMVS will provide additional valuable information source for authorities.

The unexpected presence of N-nitrosamine impurities in angiotensin II receptor blockers and other products subsequently identified, has raised concerns about the quality of medicines and the controls applied by API manufacturers, finished product (FP) manufacturers and Marketing Authorisation Holders. The lessons learned may lead to a **more tailored supervision of API manufacturers** through assessment and inspection of their API development and risk management practices in technology transfer. There is an opportunity to **increase routine assessor-inspector joint inspections** within the current framework especially for pre-approval inspections of API facilities and in the context of the implementation of the EU-US MRA. Utilising the different SPOR services will maximise the benefits of such collaboration and contribution of non-EU regulators like FDA.

The current regulatory framework establishes a basis to **reinforce the responsibilities for product quality** and conduct of the actors within the supply chain. The competences between authorities, especially as regards how GDP activities are authorised and supervised locally, are fragmented: there should be consistent and comprehensive implementation of the current GDP principles in all Member States to ensure the integrity of the supply chain. In addition, there could be a **review of current EU GDP guidelines** for human medicines and API's to establish if they remain sufficient to regulate the complex distribution channels in the EU. **Promoting synergies among GDP actors** would support the development of consistent GDP guidance. The harmonisation of GDP guidance would in turn facilitate a coherent approach to the standards and implementation of resource-effective inspection programmes.

In contrast, GMP activities are harmonised at EU and international level but **GMP guidance** also requires work in some areas. The current GMP for ATMPs covers the batch release process in cases of decentralised manufacturing; however, there is no analogous regulatory guidance for other medicinal products including:

- ▶ Gases, e.g. nitric oxide, oxygen;

- ▶ Blood products, e.g. modified platelet rich plasma;
- ▶ Small molecules, e.g. 3D printing.

The lessons learned exercise launched as a result of the nitrosamine incident may lead to further developments in GMP and Quality guidelines aimed at MAH's and reflecting on the importance of thorough development studies and of process and product knowledge and that manufacturers should ensure implementation of advanced quality management systems. One aim would be to increase awareness of the importance of strengthening oversight of the entire supply chain, and extending to the development phases, including clinical and non-clinical testing.

Implementation of the 2019 veterinary medicines regulation will lead to implementing acts for GMP for **veterinary medicines**, GDP for veterinary medicines, and GDP for active substances used as starting materials in veterinary medicinal products. The implementing acts on GDP being developed should reflect the specificities of the veterinary market and be considered for alignment with the guidelines on the human side unless practical needs dictate otherwise. Further guidance will be published 2020-25, especially in relation to GMP -regulated activities such as GMP for veterinary API's (by VICH) and veterinary medicinal products (by the European Commission).

Disruption in pharmaceutical supply chains poses risks to the **continuity of supply and availability of medicinal products**. This has been emphasised by the effects on global supply chains seen in the COVID-19 pandemic.

Asking the manufacturers of the API and finished product (FP) for inclusion of **risk-assessment evaluations** in the application for a marketing authorisation, regarding supply capacity and their respective measures for mitigation of any potential disruption, would strengthen supply chain resilience. Such a risk assessment should include whether to procure the active substance (including intermediates and starting materials of the API) and excipients from different sources and various regions of the world. At

the time of writing, the COVID-19 pandemic has also highlighted that the repurposing of authorised medicinal products to treat a new disease can undermine the market availability of such medicinal products for their authorised indications.

There may be future **developments in the regulatory framework encouraging supply chain resilience** to ensure continuity of supply and availability of medicinal products through measures which favour manufacturing in the EU, in order to decrease the dependency on third countries and promote diversity of suppliers and the EU's strategic autonomy.

Along with the impacts of globalisation, industry is currently experiencing a technological leap that has been termed the 4th industrial revolution or Industry 4.0 (**Pharma 4.0** in the pharmaceutical context). This includes advanced digitalisation within factories, and the combination of Internet technologies and future-oriented technologies in the field of "smart" objects (machines and products).

Technology advances in research and development are producing advances in automation and alternatives to traditional scale manufacturing and purification techniques, leading to smaller batch sizes and faster production times that proponents contend can ultimately be combined in a closed, easy-to-operate, tabletop-sized machine with integrated production and purification that could be used in for example a hospital pharmacy or operating theatre (**decentralised manufacturing**) or even in mobile clinics to provide **customised products** designed to address the needs of an individual patient.

Regulators can help **support a competitive EU-based manufacturing base** able to implement Pharma 4.0 manufacturing models (with all that means to the supply chain) through engagement in ICH and development and implementation of appropriate guidelines, e.g. Q9 (revised), Q12 (new), Q13 (new). There may also be further **developments in GMP and Quality guidelines** aimed at improving quality culture and regulating the new supply chains needed to develop, manufacture and



distribute new types of medicinal products. Future legislative initiatives might also result in changes, particularly at the interfaces between tissues and cells and organs, to the current **framework for Substances of Human Origin (SoHo)** that would affect the way plasma or tissues as a starting material for medicinal products are currently regulated and inspected.

The degree of automation and big data that are foreseen as necessary to support Pharma 4.0 will also mean that the application of Quality Risk Management (QRM) to the **design and validation of computerised systems and data analysis and forecasting methods** will be very important. It will be vital to **equip EU inspectors and assessors with the skills, training and relevant tools** to inspect and assess the new technologies. Considering the emergence of data-driven paradigms, there is a further need to develop EU-level **data integrity guidance** by adaptation of existing published Q&A's into Chapter 4 and Annex 11 of the GMP Guide in collaboration with WHO and PIC/S.

A key element of the new paradigm will be the move from traditional batch-based manufacturing to Continuous Manufacturing (CM). It will be important to **avoid regulatory barriers or lack of harmonisation** between regulators if industry is to innovate and develop in this area.

## Challenges

A number of obvious challenges must be faced if the Network is to secure and protect its supply chains.

- ▶ It seems likely that the **EU will remain dependent on India and China** as major sources of generic medicines, biosimilars and API's. In addition, there are indications that even more third countries could become players in the supply chain. The COVID-19 crisis has illustrated that being dependent only on **production located in specific spots might pose a risk to continuity of supply**. Medicinal products, such as antibiotics and vaccines, are increasingly manufactured outside the EU. Longer supply chains and supply chains relying on single
- or limited source manufacturing and just-in-time production remain vulnerable to disruption. Older niche products that remain important to public health may be vulnerable to **commercial pressures that impact availability** and there will be a need to build the **EU's strategic autonomy**. Repurposing of authorised medicinal products might entail their scarcity for the authorised indications. On the other hand, new treatments to fight epidemics, especially promising ones, might not be promptly available to patients on an equal basis across the different EU regions.
- ▶ Further regulatory measures may be needed to address the **environmental risks** of pharmaceutical emissions from manufacturing and other sources, not only in the EU but in third countries, especially where these may contribute to the spread of **antimicrobial resistance (AMR)** – see also section [3.4](#).
  - ▶ The potential for presence of **falsified medicines** in the supply chain has also been amplified by globalisation leading to a substantial increase in reports in various countries in recent years.
  - ▶ As noted, there is a **need to enhance existing capacity building initiatives** in the EU to support GMP, GCP and GDP inspector capability and capacity. There is also a need to enhance existing capacity building initiatives to support GMP and GCP inspector capability and capacity in third countries.
  - ▶ At the moment, **regulatory barriers** or lack of harmonisation of regulatory approaches is seen as a significant barrier to industry innovation and take up of new models such as continuous manufacturing. In order to enable manufacturers to take up state of the art innovative methods, and to encourage high quality pharmaceutical quality risk management, a better adapted regulatory framework is needed. This will stimulate innovation, attract inward investment and ensure that EU manufacturers remain competitive, although international alignment on these approaches is needed.

- ▶ The implementation of the **veterinary medicines regulation** will lead to new implementing acts for GMP for veterinary medicines, GDP for veterinary medicines, and GDP for active substances. The emergence of **veterinary novel therapies**, veterinary ATMPs and autogenous vaccines has highlighted that the current GMP framework does not provide sufficient guidance in this area and further work is needed.

## Interdependencies

Existing initiatives and programmes with which there are synergies or with which this Strategy will need to be aligned include:

- ▶ Work to extend the [EU-US Mutual Recognition Agreement](#) to the area of veterinary medicines, vaccines and blood and plasma; this will be an important milestone once achieved. More informal and less-resource intensive mutual reliance initiatives may also become more significant in the future to provide more agile and flexible approaches
- ▶ Information sharing initiatives such as the [International API programme](#), the 'Pilot programme for international cooperation in GMP inspection of manufacturers of sterile medicinal products for human use' will continue or start through 2020-2025. Collaboration relies on the existing API programme with more consideration given to collaborative inspection programmes focusing on mapping of "super sites" that require tailored and customised inspection strategies.
- ▶ A lessons learned exercise from the [valsartan case](#), conducted by the European Medicines Network is currently underway and expected to report with recommendations for enhancement of supply chain controls by authorities and MAH's.
- ▶ New regulatory standards underpinning the evolution and implementation of novel manufacturing technologies in the globalised environment in [ICH Guidelines](#) such as Q8, Q9, Q11 and Q12. Collectively these guidelines can provide the basis for the holistic approach of enabling "lab to patient" or even "patient to patient" value chains controlled by the ICH Q10 Pharmaceutical Quality System/PQS.
  - » A revision of ICH Q9 is currently planned and the provision of extensive training materials is envisaged "(with examples) that address the sources of subjectivity and uncertainty in risk assessment, as well as the role of knowledge and the need for consistency" (ICH Q9 Draft New topic proposal).
  - » A new ICH guideline, ICH Q13 'Continuous Manufacturing Of Drug Substances And Drug Products' is intended to provide harmonisation on technical and regulatory aspects unique to CM of drug substances and drug products for small and large molecules.
- ▶ Collaboration on sectoral initiatives (e.g. antibiotics, vaccines, radiopharmaceuticals) with the HMA/EMA [Taskforce on availability of authorised medicines](#) should assist through collaboration with sectoral initiatives, at national and EU level aimed at improving continuity of supply.
- ▶ The [European One Health Action Plan](#) and [Council Conclusions on AMR](#), aspects of which have already started being implemented by EMA and the NCAs, and the veterinary medicines regulation, [Regulation \(EU\) 2019/6](#), which provides additional tools for regulators on antimicrobial resistance.
- ▶ The work of the [EU-Innovation Network](#) (EU-IN), in liaison with other HMA/EMA working groups, focusing on the last step of the supply chain, and taking into account the "connected patient" and the need to have appropriate safeguards in place.
- ▶ Other initiatives, e.g. One-Voice-of-Quality (<https://journal.pda.org/content/73/5/517>)
- ▶ The [European Union Strategic Approach to Pharmaceuticals in the Environment](#).



### 3.6. Sustainability of the Network and operational excellence

#### Strategic goals

Based on its environmental analysis of the strategic area and the identified challenges, the Network has laid down five main goals to be achieved within the strategy period:

1. Reinforce scientific and regulatory capacity and capability of the network
2. Strive for operational excellence, building on the work done in the current strategy
3. Achieve a sustainable financial and governance model for the network
4. Develop a digital strategy to drive digital business transformation
5. Enable quick, consistent and adequate response to public and animal health challenges

*Recommended high-level objectives to support these goals are given in the [table](#) in Annex 1.*

Sustainability of the Network and its competent authorities is key to its continued role in safeguarding public and animal health in the EU. This has to be ensured by adequate resources (financial, expertise, competence, and skills), business processes, IT capabilities, and an efficient governance structure supporting operational excellence.

The Network needs to ensure a framework for continuous optimisation that creates the right environment for change and improvement now and in the future, not only supporting better public health but allowing a vigorous and innovative European research sector to play a full part. For the Network to grow and retain

its role as a major, globally-relevant regulator it must take account of an expected greater focus on integrating sustainability priorities into EU budgets and metrics, the effects of new science and new technology, as well as the challenges of new legislation and the need to manage scarce resources (ensuring an appropriate funding model and recruitment, retention and development of staff with the right competencies) supported by modern IT capabilities focused on digital transformation through simplification of processes and interfaces (see section [3.2.](#)).

Areas that will need consideration during the strategy period include pharmaceutical

policy and regulatory optimisation, financial sustainability and adequate resourcing, issues of trust and communication, IT governance and the legal and legislative frameworks within which the Network operates.

Adequate **pharmaceutical policy design** in line with the Pharmaceutical Strategy for Europe is needed to facilitate availability and the continuous supply of medicines in all EU member states, safeguard the production of sufficient active product ingredients in Europe and break existing silos between medicines and medical devices. It should also strengthen the relevance and consistency of product information for off-patent medicines. It must be combined with **regulatory optimisation** to ensure best use of scarce resources, capacity, expertise and IT capabilities – this includes approaches to work sharing (including ensuring all NCAs contribute to Network operations, for example in multinational assessment teams), data standardisation and avoiding duplication of work as well as ensuring timely availability of the right expertise and competencies within the Network (see also [3.3](#) above). Combining and enriching EMRN internal data with external data sources (logistics information, consumption data, e-prescription data, distribution data) will provide new opportunities for decision makers and will improve business decisions.

The network should address reduction of regulatory burden for both regulatory authorities and for our stakeholders whilst anticipating the consequences of innovation in development of new medicines and meeting stakeholders expectations with regard to off-patent medicines. The HMA/EMA Regulatory Optimisation Group is the primary platform to develop Network thinking on reduction of regulatory burden.

However, optimisation alone is not enough to ensure adequate resourcing, and thus, ultimately, the financial sustainability of the Network. To ensure adequate resourcing of all regulatory activities a proper new fee regulation safeguarding sufficient resources for the regulatory operation of the Network will be key.

The Network's outputs must meet stakeholder expectations if we are to retain and **build**

**trust** and ensure stakeholder and wider public support for our mission. These are not solely confined to the medicines we license and whose safety we monitor, but include at their heart continuous, risk-based **communication** about our role and performance. The perceived relevance, availability, transparency, consistency and quality of the information we supply will continue to be crucial in ensuring trust and support. Communication and collaboration at an **international** level will also continue to be vital to ensure consistent responses and effective use of resources by regulators globally, all of whom face similar challenges.

Such communication also cannot be one-way. **Engaging** and bringing our stakeholders with us on the journey will be vital to the success of any strategy over the next five years. Mutual communication will be key, so that we can understand and incorporate their unique knowledge, and help them to understand how our actions will improve public health.

Throughout this Network strategy document the need for digital transformation and deployment of appropriate IT capabilities has been highlighted. Similar IT contributions can be utilized for various business needs. Dependency on IT services has constantly increased over time, and IT change management and service delivery are also a prerequisite for the sustainability and continuance of the Network. The functioning of the Network will largely depend on the ability to set up adequate and interoperable IT services based on business needs and optimised business processes. Setting up the future IT landscape will support parallel business process developments. This requires appropriate, effective and transparent **prioritisation and governance of IT-related initiatives**. This future governance should enable joint decisions by business and IT based on the priorities, business value, resources and financial implications. This will be supported by improved management of project implementation. Effective governance requires timely involvement of all Network partners and stakeholders in order to deliver the benefits and business value. To manage and deliver the governance framework, an appropriate model for sharing costs, resources



and knowledge is also required. Experience from the past has shown that additional resources are needed to fulfil the necessary tasks to ensure NCA involvement and effective portfolio management.

The key principles elaborated in the strategy can only be further developed if they are supported by a relevant **legal framework**, developed in close collaboration with the European Commission and its new Pharmaceutical Strategy for Europe, so as to ensure early and structural involvement of regulatory authorities. New EU legislation often aims to reduce administrative burden, and any moves in this direction offer an opportunity to improve Network sustainability. In addition, appropriate framing of new legislation can take into account the potential for digitalisation, and thus allow for effective implementation of digital solutions. For all stakeholders to reap the benefits, however, the legislation has to be implemented in a harmonised way; close collaboration in the Network is necessary to achieve this. For future legislation, principles of risk and proportionality are important to ensure that our resources and expertise are used in the areas representing most risk in terms of public and animal health protection.

Among the lessons to be learned from the COVID-19 pandemic is the need for more EU **coordination** during public health emergencies to allow rapid and appropriate responses, and a sustainable and properly resourced Network is obviously central to such concerns. In future crises, ensuring timely approvals of relevant clinical trials and diagnostics, shortage and supply management, and providing a strong and coherent voice both within and beyond the EU will rely on a smoothly functioning and well-coordinated Network, and strengthened access to expertise and scientific leadership, as well as efficient channels of communication and clear delineation of responsibilities between the Network and other relevant stakeholders.

## Challenges

- ▶ An expected greater focus on **integrating sustainability priorities** into EU budgets

and metrics will need to be taken into account in Network planning and may affect **resource allocation**

- ▶ the effects of new science and new technology, as outlined in sections [3.2.](#) and [3.3.](#) in particular, and the need for the requisite expertise and tools to handle them, including the need for suitable IT/telematics capabilities in an environment. It may be impossible to provide a 'one-size-fits-all' model, and the Network may need to consider the possibility of its members moving at different speeds when it comes to IT development and connection.
- ▶ The challenge of **implementing the veterinary medicines and clinical trial regulations** in a consistent and successful way
- ▶ Further develop the telematics governance model to allow prioritisations, portfolio management and budgetary decisions for all information management related initiatives included in the EMRN strategy 2021-2025 and relevant roadmaps
- ▶ the **need to ensure an appropriate funding model** for the Network going forward and support recruitment, retention and development of **staff with the right competencies**
- ▶ ensuring adequate **funding and resources for shared IT initiatives** and agreeing **prioritisation** where IT initiatives compete
- ▶ **addressing the gap** of funding, resources and necessary knowledge and expertise opened by non-legally driven requirements:
  - » legislative requirements (related to SPOR [ISO IDMP], veterinary medicines regulation and CTIS) are progressing but funding and resources remain a challenge
  - » non-legislative requirements (ePI, DARWIN, EU shortages database) must be considered alongside appropriate funding mechanisms, governance to enable prioritisation and delivery



- ▶ **maintaining and increasing public trust and stakeholder engagement** and addressing any concerns that changes to the regulatory system will reduce protection from unsafe or ineffective medicines
- ▶ ensuring **data consistency** across the Network for medicines and other relevant data elements and developing the reputation of the Network as a **reference source for trusted data**
- ▶ the need for mechanisms to ensure **better access** to, and **wider sharing** of, existing data and decisions in order to achieve more consistent regulatory output

## Interdependencies

- ▶ [New fee regulation](#) under evaluation by the European Commission
- ▶ The veterinary medicines regulation, [Regulation \(EU\) 2019/6](#)
- ▶ The clinical trial regulation, [Regulation \(EU\) 536/2014](#)
- ▶ A new [EU Telematics](#) implementation roadmap., 2021-2025
- ▶ Updated EMA 5-year framework strategy for communication and stakeholder engagement (to be finalised in 2020)

Ensuring the sustainability of the Network of course underpins all the other parts of the strategy, since without a sustainable Network the remaining themes cannot be properly addressed. However, those themes also impinge on sustainability in return, and in particular the areas of digital transformation ([3.2.](#)), and innovation ([3.3.](#)) will play a major part in determining the resources available and how they can be deployed.



## 4. Conclusion – putting it into practice

Following its approval by the Management Board of EMA and by the HMA, the strategy will need to be put into practice. **As noted in Section 2, this document is not an explanation of every detail of the work that will be undertaken in the next 5 years.** Instead it provides an overarching structure and direction, and identifies the areas which that work will need to take into account and objectives it will need to aim at. In addition, there will be a need to align with the Pharmaceutical Strategy for Europe and any future initiatives that may arise from it.

The details will be elaborated in specific work plans for EMA and HMA, which will feed into the day to day work of each component of the network. In the interests of transparency, details of workplans and programmes, and annual reports detailing activities are published by EMA on its [website](#), and similarly, annual reports and information on work programmes are available for [HMA](#). Information on work carried out by the NCAs at national level may also be available from their websites.

Consultation with our stakeholders has already allowed us to refine and prioritise our objectives and proposed actions, but in addition to the checkpoints built into workplans and individual project planning, **implementation of the strategy will be monitored.** After 18 months the

Network will carry out a **review**, to see if the goals and objectives remain appropriate and to adjust them if necessary, in the light of the changing environment and our ongoing engagement with stakeholders. The need for the strategy to remain a living document, and to adjust it as the environment changes, is particularly pertinent given that its drafting has taken place while the COVID-19 pandemic was unfolding, and although the pandemic's early lessons have been taken into account as far as possible, further 'lessons-learned' exercises on **pandemic responsiveness** are anticipated within the timeframe of this strategy and will be taken into account in strategic planning.

During implementation it will be essential to ensure that common or shared issues identified in development of the strategy are addressed concomitantly, to provide the most efficient and synergistic solutions and avoid the waste of resources created by silo working.

In developing its strategy, the Network has been very mindful of the need to **collaborate globally** with bodies such as other regulators, industry associations, and international bodies and forums such as ICH. As elements of the strategy come into practice it is expected in turn that these will influence international standards like IDMP and ISO, and help in developing agreed best practice globally.

# Annex 1: Objectives by focus area

The following tables provide proposals for high-level objectives to support and achieve the goals defined for each strategic focus area, which have been reviewed and refined with the aid of public consultation. Each is related to the relevant goal for its area. These objectives will then be made concrete through specific actions to be developed and implemented in the multi-annual work plans of the Network.

## Availability and accessibility of medicines

(for discussion of the goals see [section 3.1](#))

Goal	Objectives
<b>Strengthen the availability of medicines to protect the health of European citizens and animals</b>	<ul style="list-style-type: none"><li>▶ Identify the specific root causes of shortages for medicines for human and veterinary use and develop strategies to improve prevention and management of shortages (a better understanding of the specific causes for shortages of generics/off-patent products versus products still under patent protection is essential). Based on the outcome of this study, help to identify and suggest areas where changes to EU or national legislation could improve supply.</li></ul>
	<ul style="list-style-type: none"><li>▶ Foster the awareness of the public and healthcare professionals on the approval standards, safety, effectiveness and immunogenicity of similar biological products to facilitate the uptake of biosimilars in healthcare systems</li></ul>
	<ul style="list-style-type: none"><li>▶ Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders and international partners</li></ul>
	<ul style="list-style-type: none"><li>▶ EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply. EMA should also coordinate the activities of the EMRN in order to ensure availability of critical medicines in the EU/EEA by supporting increase of production capacity to meet demand.</li></ul>
	<ul style="list-style-type: none"><li>▶ Increase transparency on availability/launch to facilitate targeted regulatory actions and communication with patients, HC professionals and HTA bodies.</li></ul>

Goal	Objectives
<p><b>Optimise the path from development, evaluation through to access for beneficial medicines (innovative and follow-on) through collaboration between medicines regulators and other decision makers</b></p>	<ul style="list-style-type: none"> <li data-bbox="475 199 1406 416">▶ Develop better scientific evidence which serves different decision makers along the decision chain (regulators, HTA bodies, payers), including evidence to support post-licensing follow-up of medicinal products thereby stimulating a life-cycle approach to evidence generation and the possibility to adjust decisions based on new evidence.</li> <hr data-bbox="448 445 1471 450"/> <li data-bbox="475 499 1414 714">▶ Clear and enhanced communication to patients, health care professionals, veterinarians and animal owners as well as downstream decision makers about the regulatory assessment including information gap inherent for medicinal products approved on the basis of limited scientific data and secondary endpoints (e.g. Orphans, limited market veterinary medicinal products)</li> <hr data-bbox="448 743 1471 748"/> <li data-bbox="475 795 1437 898">▶ New metrics for accessibility of medicines that better represents real patient access to newly authorised medicinal products in different markets</li> <hr data-bbox="448 927 1471 931"/> <li data-bbox="475 981 1437 1122">▶ Foster alignment of national implementation of compassionate use programmes in order to promote equity in access for patients during late stage development and improved utilisation of data from such programmes to support later decision making</li> </ul>



# Data analytics, digital tools and digital transformation

(for discussion of the goals, see [section 3.2](#))

Goal	Objectives
<b>Enable access to and analysis of routine healthcare data, analysis of individual patient data from clinical trials, and promote standardisation of targeted data</b>	<ul style="list-style-type: none"><li>▶ Deliver a sustainable platform to access and analyse healthcare data from across the EU (DARWIN EU)</li><li>▶ Pilot the analysis of individual patient data from clinical trials in initial marketing authorisation assessments with a view to a targeted roll out of such analysis.</li><li>▶ Establish collaborations with external stakeholders (including patients, academia, NGOs and industry) and with international regulatory authorities on Big Data initiatives</li><li>▶ Establish EU framework for data quality, discoverability and representativeness, through agreement on meta-data for regulatory purposes, a standardisation roadmap and registers of real-world data sources and of observational studies</li></ul>
<b>Build sustainable capability and capacity within the Network</b>	<ul style="list-style-type: none"><li>▶ Build EU Network capability to analyse Big Data</li><li>▶ Digital transformation of the EU Network’s scientific and regulatory processes to enable use of digital tool and analytics and creation of a supporting digital infrastructure – e.g. to support uptake and review of big data (from eHR, registries, devices, etc.)</li></ul>
<b>Promote dynamic regulation and policy learning within the current regulatory framework</b>	<ul style="list-style-type: none"><li>▶ Modernise the delivery of scientific advice at central and national level by developing Network skills and processes</li></ul>
<b>Ensure that data security and ethical considerations are embedded in the governance of data within the Network</b>	<ul style="list-style-type: none"><li>▶ Ensure data are managed and analysed within a secure and ethical governance framework</li></ul>

# Innovation

(for discussion of the goals, see [section 3.3](#))

Goal	Objectives
<b>Catalyse the integration of science and technology in medicines development and ensure that the network has sufficient competences to support innovators in various phases of medicines development</b>	▶ Support the integration of scientific and technological progress in the development of medicines (e.g. precision medicine, biomarkers, 'omics and ATMPs) and ultimately into patient treatment
	▶ Transform the regulatory framework for veterinary medicines to support innovation and successful implementation of the veterinary medicines regulation
	▶ Implement an EU-level model for efficient, timely and coordinated horizon scanning and priority setting that fulfils the needs of both regulators, HTA-bodies and payers
	▶ Facilitate the implementation of novel manufacturing technologies
<b>Foster collaborative evidence generation, improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTA and pricing and reimbursement authorities</b>	▶ Foster innovation in clinical trials and develop the regulatory framework for emerging clinical data generation
	▶ Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation and invest in special population initiatives
	▶ Develop further the collaboration of various groups involved with scientific advice and/or regulatory guidance
<b>Enable and leverage research and innovation in regulatory science</b>	▶ Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science

Goal	Objectives
<p><b>Enhance collaboration with other stakeholders including medical device experts, notified bodies, SMEs and research/academic groups</b></p>	<ul style="list-style-type: none"> <li data-bbox="480 197 1437 342">▶ Increase collaboration with Medical Device Authorities and Notified Bodies, exchange knowledge and facilitate collaboration and sharing of expertise to ensure effective and appropriate regulation of combination products</li> <hr data-bbox="456 369 1479 371"/> <li data-bbox="480 421 1430 562">▶ Promote early interaction with academia, researchers and SMEs with a view to increasing awareness of regulatory requirements and facilitating the translation of research into authorised medicinal products and ultimately into clinical practice</li> </ul>

## Antimicrobial resistance and other emerging health threats

(for discussion of the goals, see [section 3.4](#))

Goal	Objectives
<b>Provide high quality information on antimicrobial consumption and surveillance data on antimicrobial resistance</b>	<ul style="list-style-type: none"><li>▶ Implement the requirements for the mandatory collection of sales and use data for antimicrobials used in animals, spread knowledge and ensure better access to data in line with the veterinary medicines regulation.</li><li>▶ Foster more robust surveillance systems in the EU for both antimicrobial consumption and emergence of resistance in veterinary and human medicine in order to foster analyses of the potential relationships between antimicrobial consumption and AMR and of co-selection of AMR by use of biocides and feed additives</li></ul>
<b>Contribute to responsible use of antimicrobials and effective regulatory antimicrobial stewardship</b>	<ul style="list-style-type: none"><li>▶ Modernise SmPC of old antibiotics for human and veterinary use,</li><li>▶ Define a roadmap for Point Of Care (POC) diagnostics to support the development of improved diagnostic tests</li></ul>
<b>Ensure regulatory tools are available that guarantee therapeutic options while minimising impact of antimicrobial resistance on public health and the environment</b>	<ul style="list-style-type: none"><li>▶ Promote guidance on antimicrobial use by adaption of existing and creation of new guidelines and finalise the Agency approach to antimicrobial resistance in the environment</li></ul>
<b>Define pull incentives for new and old antimicrobial agents</b>	<ul style="list-style-type: none"><li>▶ Define value of new antimicrobial agents to inform new business models and cooperate on the establishment of new business models, including the exploration of incentives for continuous manufacturing of old antibiotics</li></ul>



Goal	Objectives
<p><b>Foster dialogue with developers of new antimicrobial agents and alternatives to traditional antimicrobials</b></p>	<ul style="list-style-type: none"> <li>▶ Foster development of new antimicrobials, including new antibacterials for human use, define regulatory pathways for phages and other innovative products in human and veterinary medicine and engage with relevant stakeholders to effectively discuss the issue</li> </ul>
<p><b>Improve regulatory preparedness for emerging health threats</b></p>	<ul style="list-style-type: none"> <li>▶ Refine regulatory activities in inter-epidemics periods to increase preparedness and harmonise regulatory framework and approaches for investigation of medicinal products during emergencies</li> </ul>

## Supply chain challenges

(for discussion of the goals, see [section 3.5](#))

Goal	Objectives
<b>Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs) and excipients</b>	<ul style="list-style-type: none"><li>▶ Improve and inter-link information in current/existing databases to provide supply chain compliance overview.</li><li>▶ Tackle falsified medicines; prevent presence of falsified medicines in the supply chain by strengthening inspections of manufacturers' application of safety features and of the repository systems.</li></ul>
<b>Enhance inspector capacity building at EU and international level</b>	<ul style="list-style-type: none"><li>▶ Enhance capacity building of EU inspectors and assessors in order to harmonise approaches to regulatory inspections procedures to address requirements and challenges of APIs, medicinal products, excipients, new technologies and continuous manufacturing</li><li>▶ Promote a more tailored supervision of API manufacturers through assessment and inspection of their API development and risk management practices in technology transfer; increase supervision of sites that produce medicinal products for a significant number of EEA markets or very significant numbers of products, with dedicated cooperative supervision between MS and strategic partners for these sites.</li></ul>
<b>Reinforce the responsibility for product quality by harmonising and reinforcing guidance</b>	<ul style="list-style-type: none"><li>▶ Develop EU level data integrity guidance</li><li>▶ Ensure a stable EU-GMP regulatory framework with predictable outcomes by promoting and improving the understanding of EU GMP requirements and preparedness by third country manufacturers and their supervisory authorities. Foster an environmentally friendly level playing field.</li></ul>

Goal	Objectives
<p><b>Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites</b></p>	<ul style="list-style-type: none"> <li>▶ Enhance the reliability of evidence available to regulators for informing the decision making process on the supply chain and promote supply chain resilience and reliability of supply of APIs and medicinal products.</li> </ul>
<p><b>Analyse the possible implications of new manufacturing technologies and adapt the regulatory framework to accommodate innovation in manufacturing and distribution</b></p>	<ul style="list-style-type: none"> <li>▶ Analyse the regulatory system with respect to new technologies and new tools used in manufacturing, and for supply chain management and control; identify opportunities to improve supply chain resilience.</li> </ul>

## Sustainability of the Network and operational excellence

(for discussion of the goals, see [section 3.6](#))

Goal	Objectives
<b>Reinforce scientific and regulatory capacity and capability of the network</b>	<ul style="list-style-type: none"><li>▶ Ensure 'fit-for-purpose' scientific capability of the Network</li><li>▶ Prepare for and implement the veterinary medicines Regulation</li></ul>
<b>Strive for operational excellence, building on the work done in the current strategy</b>	<ul style="list-style-type: none"><li>▶ Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations</li><li>▶ Introduce governance and IT process improvements to further professionalise prioritising, budgeting, securing, provisioning and running of technology services</li></ul>
<b>Achieve a sustainable financial and governance model for the network</b>	<ul style="list-style-type: none"><li>▶ Contribute to the revision of the current fee regulation, and implement the final solution</li></ul>
<b>Develop a digital strategy to drive digital business transformation</b>	<ul style="list-style-type: none"><li>▶ Establish an IT operating model and services, in support of the digital strategy and digital business transformation</li></ul>
<b>Enable quick, consistent and adequate response to public and animal health challenges</b>	<ul style="list-style-type: none"><li>▶ Build further capacity and capability within the network to support crisis management</li></ul>

## Annex 2: Glossary

<b>3Rs</b>	Principles relating to the use of animals in medicines testing (Refine testing to reduce the harm to the animal, Reduce the numbers of animals wrequired, Replace animal testing wherever and whenever it is possible)
<b>AI</b>	Artificial intelligence
<b>AMR</b>	Antimicrobial resistance
<b>AMU</b>	Antimicrobial use
<b>API</b>	Active pharmaceutical ingredient
<b>Article 57 database</b>	<a href="#">Database of authorised human medicinal products in the EU</a> , maintained by EMA. Marketing authorisation holders are required to submit information on their medicines to the Article 57 database in accordance with Article 57(2) of <a href="#">Regulation (EC) No. 726/2004</a>
<b>ATMP</b>	Advanced therapy medicinal product
<b>BARDA</b>	<a href="#">Biomedical Advanced Research and Development Authority</a> , an office within the US Department of Health & Human Services established to aid in responding to chemical, biological, radiological, and nuclear threats, including emerging infectious diseases
<b>Big Data</b>	extremely large datasets which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations. In general, big data sets require advanced or specialised methods to provide an answer within reliable constraints
<b>CHMP</b>	EMA's Committee for Medicinal Products for Human Use
<b>CMA</b>	Conditional marketing authorisation
<b>Co-selection</b>	Selection of genes for resistance to an antibiotic by exposure to another substance (e.g. a different antibiotic, a heavy metal, feed additive or biocide) because the gene for resistance to the second substance is on the same shared plasmid
<b>COVID-19</b>	A novel coronavirus infection, first noted to affect humans in China in 2019
<b>CTIS</b>	Clinical Trial Information System
<b>CVMP</b>	EMA's Committee for Medicinal Products for Veterinary Use
<b>DARWIN</b>	Data Analysis and Real World Interrogation Network, a proposed EU platform to access and analyse healthcare data from across the European Union



<b>Digital Single Market</b>	A <a href="#">strategy</a> of the European Commission to ensure the best possible access to the online world for individuals and businesses
<b>EC</b>	<a href="#">European Commission</a>
<b>ECDC</b>	The <a href="#">European Centre for Disease Prevention and Control</a>
<b>EEA</b>	The European Economic Area, comprising the EU Member States, Iceland, Liechtenstein and Norway
<b>EFSA</b>	<a href="#">European Food Safety Authority</a>
<b>EMA</b>	<a href="#">European Medicines Agency</a>
<b>EMRN</b>	European Medicines Regulatory Network, the Network
<b>EMVS</b>	The <a href="#">European Medicines Verification System</a> , a system for tackling falsified medicines by supplying unique identifiers that allow verification at all stages of distribution and use
<b>ENCePP</b>	<a href="#">European Network of Centres for Pharmacoepidemiology and Pharmacovigilance</a>
<b>ePI</b>	Electronic product information
<b>ERA</b>	Environmental risk assessment
<b>ESVAC</b>	<a href="#">European Surveillance of Veterinary Antimicrobial Consumption</a> , a project which collects information on how antimicrobial medicines are used in animals across the European Union (EU)
<b>EU</b>	European Union
<b>EUCAST</b>	European Committee on Antimicrobial Susceptibility Testing, an EU Committee to harmonize antimicrobial breakpoints
<b>EudraGDMP</b>	An <a href="#">EU database</a> of GMP and GDP information
<b>EU-Innovation Network, EU-IN</b>	A <a href="#">collaboration</a> between the EU NCAs and EMA, aimed at fostering medicine innovation and early development of new medicines
<b>EUnetHTA</b>	<a href="#">European Network for Health Technology Assessment</a> , a collaboration between HTA bodies across Europe.
<b>EU-NTC</b>	EU Network Training Centre, a centralised resource for training and sharing best practice in the EMRN
<b>EU-PAS</b>	The European Union electronic Register of Post-Authorisation Studies, a publicly available register of non-interventional post-authorisation studies maintained by EMA and hosted by ENCePP

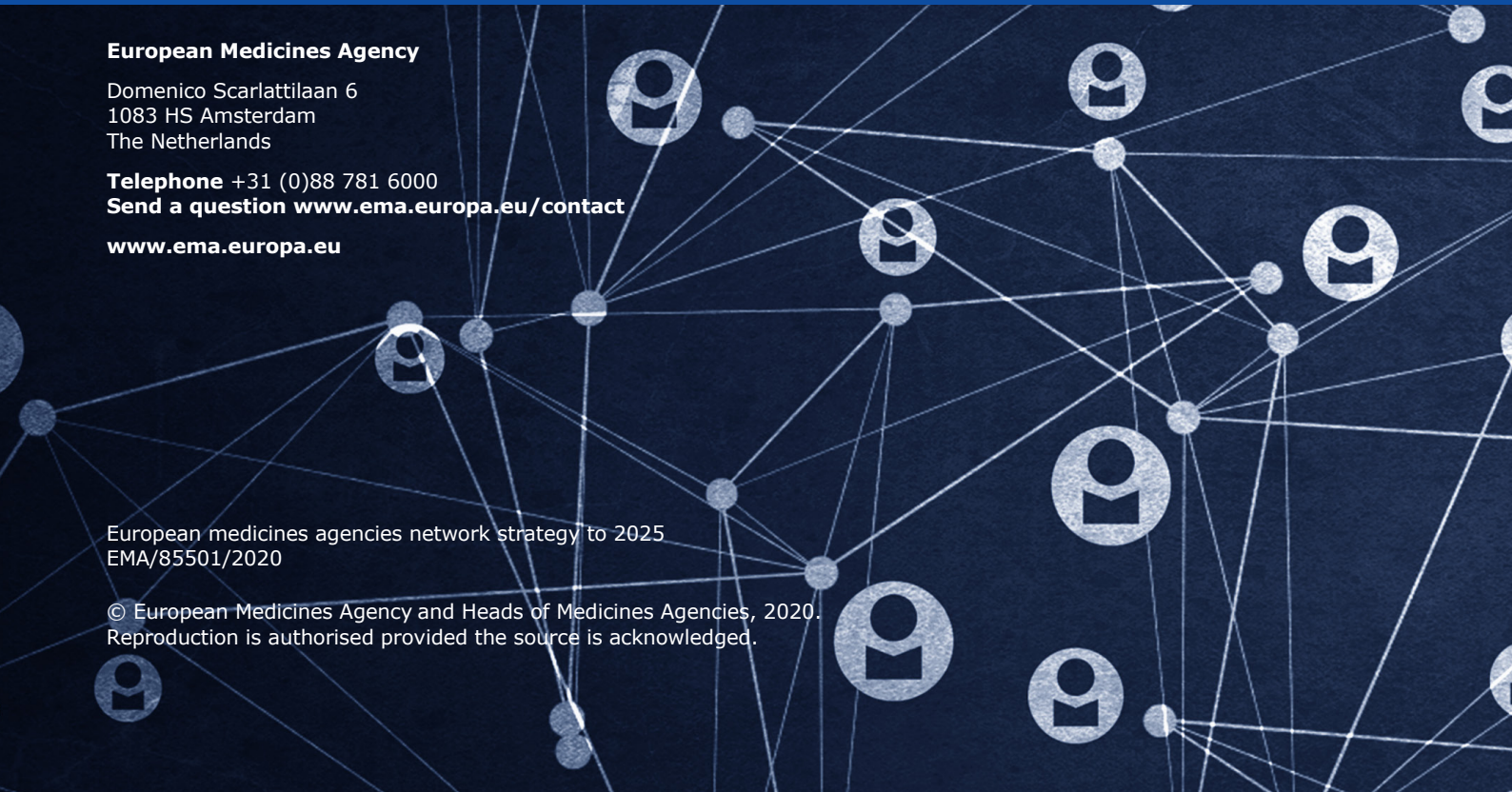
<b>FAIR</b>	Guiding principles for data management and stewardship, that data should be Findable, Accessible, Interoperable and Reusable
<b>FAO</b>	UN Food and Agriculture Organisation
<b>FP</b>	Finished product
<b>GDP</b>	Good distribution practice
<b>GDPR</b>	General Data Protection Regulation
<b>GMO</b>	Genetically modified organism
<b>GMP</b>	Good manufacturing practice
<b>HMA</b>	Heads of Medicines Agencies, a strategic and coordinating body representing the national medicines regulators of the EEA countries
<b>Horizon Europe</b>	The EU's proposed future <a href="#">research and innovation programme</a>
<b>Horizon scanning</b>	Systematic examination of information to identify potential threats, risks, emerging issues and opportunities
<b>HS</b>	Horizon scanning
<b>HTA</b>	Health Technology Assessment (body)
<b>ICH</b>	<a href="#">International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use</a>
<b>ICMRA</b>	<a href="#">International Coalition of Medicines Regulatory Authorities</a>
<b>IDMP</b>	Identification of Medicinal Products, a suite of standards developed by ISO
<b>IMI</b>	<a href="#">Innovative Medicines Initiative</a> , a public-private partnership funding health research and innovation in the EU
<b>IRIS</b>	EMA's online <a href="#">Regulatory and Scientific Information Management Platform</a>
<b>ISO</b>	<a href="#">International Organization for Standardization</a>
<b>ITIL</b>	Information Technology Infrastructure Library, a set of practices for IT service management that focuses on aligning IT services with the needs of business
<b>ITF</b>	<a href="#">Innovation Task Force</a> (EMA)
<b>JIACRA</b>	<a href="#">Joint Inter-agency Antimicrobial Consumption and Resistance Analyses</a> , joint reports of EMA, EFSA and ECDC that analyse data from humans and food-producing animals to better understand the occurrence of antimicrobial resistance across Europe

<b>MAH</b>	Marketing authorisation holder
<b>MDR-TB</b>	Multidrug-resistant tuberculosis, resistant to at least both isoniazid and rifampicin
<b>MERS</b>	Middle-Eastern Respiratory Syndrome, a coronavirus infection
<b>MNAT</b>	Multinational assessment team, a worksharing arrangement in which experts from several EU/EEA countries contribute to a medicine's assessment
<b>MRA</b>	Mutual recognition agreement
<b>NCA</b>	National competent authority, one of the national medicines regulators that form part of the Network
<b>NITAG</b>	National Immunization Technical Advisory Group
<b>OECD</b>	<a href="#">Organisation for Economic Co-operation and Development</a>
<b>OIE</b>	World Organisation for Animal Health
<b>One Health</b>	an <a href="#">approach</a> to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes.
<b>P&amp;R</b>	Pricing and reimbursement
<b>payers</b>	Authorities responsible for P&R decisions at national level
<b>PCWP/ HCPWP</b>	EMA's Patients and Consumers Working Party and Health Care Professionals Working Party
<b>Pharma 4.0</b>	Use of data analytics to optimise use of resources (people, physical systems, and data) in the pharmaceutical industry
<b>PIC/S</b>	<a href="#">Pharmaceutical Inspection Co-operation Scheme</a> , an informal co-operative arrangement for regulators on Good Manufacturing Practice (GMP) of human and veterinary medicines.
<b>PK/PD</b>	Pharmacokinetics and pharmacodynamics
<b>Platform technology</b>	a structure or technology from which various products can emerge without introducing a new process, through recombining different components or functions in various ways
<b>PLEG</b>	Post-launch (post-licensing) evidence generation
<b>POC</b>	Point-of-care (diagnostics)
<b>Post- licensing evidence</b>	Evidence on the efficacy and safety of a medicine produced after regulatory approval and marketing

<b>Precision medicine</b>	An approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle in selecting treatments
<b>PRIME</b>	Priority Medicines Scheme (EMA)
<b>PSI</b>	Public Sector Information (Directive)
<b>Regulatory science</b>	the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine
<b>RWD</b>	Real-world data
<b>SAFe</b>	Scaled Agile Framework, a set of workflow patterns and organisational principles for software development
<b>SARS</b>	Severe Acute Respiratory Syndrome, a coronavirus infection
<b>SAWP</b>	The Scientific Advice Working Party of EMA's CHMP
<b>SDG</b>	Sustainable Development Goal
<b>SmPC</b>	Summary of Product Characteristics, approved EU product information for healthcare professionals
<b>SNSA</b>	Simultaneous National Scientific Advice ( <a href="#">pilot project</a> of the EU Innovation Network)
<b>SPOR</b>	Substance, Product, Organisation and Referential master data, areas of <a href="#">standardised nomenclature to identify medicinal products</a> , as developed by the ISO
<b>STAMP</b>	<a href="#">Expert Group on Safe and Timely Access to Medicines for Patients</a> , a group providing the European Commission with advice and expertise on the implementation of EU pharmaceutical legislation, programmes and policies
<b>STARS</b>	Strengthening Training of Academia in Regulatory Sciences, a project of the European Commission
<b>TATFAR</b>	Transatlantic Task Force on Antimicrobial Resistance
<b>Telematics</b>	The branch of information technology which deals with the long-distance transmission of computerised information
<b>TF</b>	Task force
<b>TISP</b>	<a href="#">Topic Identification, Selection and Prioritisation</a> , part of a collaborative horizon scanning project between EUNetHTA and EMA
<b>TFAMR</b>	Task Force on Antimicrobial Resistance of the Codex Alimentarius

<b>UPD</b>	Union Product Database, a database of information on all authorised veterinary medicines and their availability in EU Member States, mandated by the Veterinary Regulation, <a href="#">Regulation (EU) 2019/6</a>
<b>VETCAST</b>	EUCAST Veterinary Subcommittee
<b>VICH</b>	the <a href="#">International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products</a> , a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration
<b>WHO</b>	World Health Organization
<b>XDR-TB</b>	Extensively drug-resistant tuberculosis, resistant to several lines of treatment as well as isoniazid and rifampicin





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