



Public consultation on European Medicines Agencies Network Strategy to 2025

Fields marked with * are mandatory.



Introduction

The purpose of this public consultation is to seek views from EMA's and HMA's stakeholders, partners and the general public on the proposed joint [European Medicines Agencies Network Strategy to 2025](#) and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, there is an opportunity to help shape the strategy for the coming years, 2021-2025.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic theme areas and goals. We also seek your views on whether the specific underlying objectives proposed are the most appropriate to achieve these goals.

The strategy will be aligned with the broader [Pharmaceutical Strategy for Europe](#) being developed by the European Commission and its actions 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 are referred to, these should be understood as supporting the development and implementation of the broader Pharmaceutical Strategy, where the ultimate responsibility for such matters will lie.

The questionnaire has been launched on 6 July 2020, to enable stakeholder feedback to be collected on the draft network strategy and will remain open throughout the consultation period until **4 September 2020**. In case of any queries, please contact: EMRN2025strategy@ema.europa.eu.

Completing the questionnaire

This questionnaire should be completed once you have read [the draft joint strategy document](#). The survey is divided into a general section on the whole document and then focuses on each strategic theme area. You are invited to complete the sections which are most relevant to your areas of interest.

We thank you for taking the time to provide your input; your responses will help to shape and prioritise the future objectives of the European Medicines Agencies Network.

Data Protection

By participating in this survey, your submission will be assessed by EMA and HMA. EMA collects and stores your personal data for the purpose of this survey. Requests for contributions to be published in an anonymised form, can be sent to the data controller ([S-DataController@ema.europa.eu](mailto:DataController@ema.europa.eu)).

* Name

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Stakeholder Information

* **Question 1: What stakeholder, partner or group do you represent:**

- Individual member of the public
- Patient or Consumer Organisation
- Healthcare professional organisation
- Learned society
- Farming and animal owner organisation
- Academic researcher
- Healthcare professional

- Veterinarian
- European research infrastructure
- Research funder
- Other scientific organisation
- EU Regulatory partner / EU Institution
- Health technology assessment body
- Payer
- Pharmaceutical industry
- Non-EU regulator / Non-EU regulatory body
- Other

*** Please specify:**

Please select one option that best describes your organisation

- Individual company (non-SME)
- Trade association
- SME

*** Name of organisation (if applicable):**

If not applicable, please insert "n/a"

GIRP - European Healthcare Distribution Association

Overall strategy

*** Question 2: Please indicate which area is relevant to your area of interest?**

Please select one or both options, as applicable

- Human
- Veterinary

Question 3: Having read the proposed strategy, how would you rate it in general terms?

Answer the following question on a scale of 1-5, where 5 indicates highly satisfied and 1 highly dissatisfied

	1. Highly Dissatisfied	2. Dissatisfied	3. Neutral	4. Satisfied	5. Highly satisfied
* What are your overall impressions of the EMAN Strategy to 2025?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

*** Question 4: Are there any significant elements missing in this strategy?**

Please note that the strategy aims to focus on major areas of interest for the next five years and it is not intended to cover all activities undertaken by the Network.

- Yes

No

Question 5: The following is to allow more detailed feedback on prioritisation of the joint EMA/HMA goals for each strategic theme, which will also help shape the future application of resources. Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas outside your interest or experience, please leave blank.

Should you wish to comment on any of the goals and their underlying objectives, there is an option to do so.

Strategic Theme area 1: Availability and accessibility of medicines

	Very important	Important	Moderately important	Less important	Not important
1) Strengthen the availability of medicines to protect the health of European citizens, via: efficient and targeted regulatory measures, made possible through an in-depth understanding the root causes of unavailability of patented and off-patent products; identification of possible challenges in implementing legislation, removal of national barriers, increased coordination of the EMRN, sharing and implementation of best practices including stakeholders and increased transparency are the essential steps towards this goal.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>2) Optimise the path from development, evaluation through to access for innovative and beneficial 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.</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Strategic Theme area 2: Data analytics, digital tools and digital transformation

	Very important	Important	Moderately important	Less important	Not important
<p>1) Enable access to and analysis of routine healthcare data and promote standardisation of targeted data</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>2) Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>3) Promote dynamic regulation and policy learning in current regulatory framework</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Ensure that data security and ethical considerations are embedded in the governance of data within the Network	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Map the use and needs of data analytics for veterinary medicines and support a streamlined approach across borders within the EEA	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic Theme area 3: Innovation

	Very important	Important	Moderately important	Less important	Not important
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.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) Enable and leverage research and innovation in regulatory science	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Enhance collaboration with medical device experts, notified bodies and academic groups	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Strategic Theme area 4: Antimicrobial resistance and other emerging health threats

	Very important	Important	Moderately important	Less important	Not important
1) Provide high quality information on antimicrobial consumption and surveillance data on antimicrobial resistance in animals and humans in support of policy development.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Contribute to responsible use of antibacterial 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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) Ensure regulatory tools are available that guarantee therapeutic options (with a focus on veterinary medicines) while minimising impact of antimicrobial resistance on public health and the environment	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Define pull incentives for new and old antibacterial agents, including investigating support for new business models and not-for-profit development	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Foster dialogue with developers of new antibacterial agents and alternatives to traditional antimicrobials, to streamline their development and provide adequate guidance in both human and veterinary medicine	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6) Improve regulatory preparedness for emerging health threats	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic Theme area 5: Supply chain challenges

	Very important	Important	Moderately important	Less important	Not important
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)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Enhance inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3) Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Analyse the possible implications of new manufacturing technologies in order to regulate the new supply chains needed to manufacture and distribute new types of medicinal products for human and veterinary use.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic Theme area 6: Sustainability of the Network and operational excellence

	Very important	Important	Moderately important	Less important	Not important
1) Reinforce scientific and regulatory capacity and capability of the network	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Strive for operational excellence, building on the work done in the current strategy	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3) Achieve a sustainable financial and governance model for the network	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4) Develop a digital strategy to drive digital business transformation	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Enable quick, consistent and adequate response to public and animal health challenges	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic focus areas

* Please indicate which Strategic Theme area(s) you would like provide input

Please select as many choices as applicable.

- 1. Availability and accessibility of medicines
- 2. Data analytics, digital tools and digital transformation
- 3. Innovation
- 4. Antimicrobial resistance and other emerging health threats
- 5. Supply chain challenges
- 6. Sustainability of the Network and operational excellence

Strategic Theme area 1: Availability and accessibility of medicines

Question 6: Do the objectives adequately address the challenges ahead?

- Yes
- No

Comments on objectives of the strategic theme area:

GIRP welcomes the overall goals outlined in this strategic theme area – availability and accessibility of medicines. While progress has been made on trying to map the root causes of medicine shortages and many EU and national developments are being discussed to address the issue, it is critically important that it remains a top priority for the medicine agencies in the coming years.

We would like to congratulate the EMA on establishing a widely recognised and suitable definition for medicine shortages, of which GIRP is highly supportive. GIRP fully supports references to differentiating shortages caused by safety, efficiency or quality/supply chain issues from availability issues for commercial reasons, where political engagement may be necessary. GIRP believes there is still too little data/evidence /transparency on the different root causes of medicine shortages.

Without a proper mapping or understanding of the root causes, it will be impossible to develop effective solutions. Most of the advanced reasons are based on subjective viewpoints and not evidence based. GIRP fully agrees with the need to better understand the multifactorial causes as a pre-condition for an effective solution to availability and accessibility of medicines. A starting point lays with the implementation of EU-wide harmonised categories of root causes in national medicines shortages databases as well as the inclusion of the API in said-databases as crucial for further comparisons and analysis on European level.

GIRP fully supports the argument that increased collaboration and transparency are key to address medicine shortages. There is an urgent need for coordinated action at the EU level to ensure the development of effective solutions and avoid duplication of efforts. A harmonised approach to define the root causes of shortages is required to progress with coordinated actions on European level.

Furthermore, unilateral actions by a Member State, such as export restrictions or stockpiling, can lead to the further escalation of shortages in other Member States. GIRP has often seen parallel trade being touted as one of the main causes of medicine shortages. GIRP's investigation (analysing the cited root cause data from national medicines agencies) into reported root causes of medicine shortages does not yield resounding evidence to support such a claim (e.g. In Spain in 2018, 2% of medicines shortages are cited as being caused by parallel trade and by 2019 the number had dropped to 0.2%). Therefore, export restrictions (to limit parallel trade), without underlying acute shortages, imposed by one Member State may result in an exacerbation of shortages in another Member State especially in cases where the latter heavily relies on imports from parallel trade to satisfy national demand. Stockpiling by one Member State may also deprive other Member States of sufficient stock to satisfy national demand.

GIRP highly appreciates the suggested efforts to better understand the different roles of the stakeholders including full-service healthcare distributors also referred as full-line wholesalers. The document mentions the impact of regulatory costs on low-priced generics and older medicines but we also encourage an impact analysis of the regulatory burden for full-service healthcare distributors who have to fulfil their stock-keeping and distribution function to comply with their public service obligation in exactly the same way, quality and service level regardless if it is a loss making product or a product with a positive net contribution. Whereas Marketing Authorisation Holders can withdraw economically not viable products from the market, full-service healthcare distributors cannot choose to stop storing and distributing economically unsustainable products. In recent years, the sector of full-service healthcare distributors has become increasingly strained and regulatory challenged and even is at a breaking point of sustainability in a couple of Member States. The consultation document references to matching supply data and forecast demand data by collecting information from various data sources. Data and data analysis will play an important role in eventual measures adopted. Today, there is no single data source which can provide a silver bullet into providing sufficient nor reliable information on which decisions related to medicine shortages can be taken. This does not mean that there are no potential sources for data to monitor medicine shortages. The consultation document alludes to a number of various data sources such as consumption data, e-prescription data, distribution data that could help prevent structural shortages and crisis time shortages. While not specifically mentioned in this document, some supply chain actors have been promoting the European Medicines Verification System (EMVS) as a solution for the monitoring of medicine shortages. See our position in our answer to question 9.1.

Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- Yes
- No

If yes, please specify

Please remember to specify if a particular comment relates specifically to the human or veterinary part.

A challenge inadvertently leading to shortages is the application of supply quotas by MAHs to full-service healthcare distributors /full-line wholesalers. We feel some supply chain system failures can be addressed through the full implementation, effective monitoring and enforcement of Article 81, paragraph 2 of the Directive 2001/83/EC. Article 81 paragraph 2 should be interpreted and appropriately set out in national legislations in a way that places separate obligations on both MAHs and full-service healthcare distributors, and most importantly provide the enforceable “right to be adequately and continuously supplied” for full-service healthcare distributors. GIRP calls for the European Commission to work with Member States to ensure the accurate interpretation of this provision in national legislation (as it is the case in Belgium, France and Germany) which should provide for an auditable right for full-service healthcare distributors to be appropriately and continuously supplied by MAHs with the full range of products in order to fulfil the needs of patients in the Member States in an appropriate manner. Full effective implementation can ensure that appropriate levels of buffer stocks are maintained at European and national level to help mitigate medicines shortages and effectively prepare for health emergencies such as possible future waves of the COVID-19 pandemic. In this context, we also would strongly encourage an investigation of current quota practices by the pharmaceutical industry and their impact on the supply chain.

Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- Yes
- No

If yes, please elaborate which ones and provide details on how these could be considered.

GIRP has analysed shortages monitoring systems in the EU Member States which include signals from the market and has identified best practice infrastructures in Member States across Europe: France, Spain, The Netherlands and Bulgaria.

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From the study of these systems, GIRP sees a set of points to be considered in the building of a European-wide early warning system:

- All and every stakeholder from the pharmaceutical supply chain must be involved.
- Critical to define which kind of data must be recorded (to be organised at national level).
- Data must be scrupulously safeguarded.
- The system should focus on early-warning, with 2 entries of notifications:
 - Signals from market, based on demand, and
 - Communication from manufacturers on anticipated and confirmed shortages as well as on actions they intend to undertake to mitigate the shortage of products
- Second layer of interpretation operated by NCAs: severity and expected duration.
- NCAs are crucial partners in establishing this system and must take the lead.
- The system should be built on existing infrastructure, such as the e-prescription system.
- NCAs must focus on the solving of the issue: short term and long term.
- Implement harmonisation between countries to facilitate solidarity.
- System to be automated both for collection of data and for reporting.
- System should be accessible for authorities and stakeholder of the pharmaceutical supply chain.

While the European Medicines Verification System (EMVS) cannot be a solution for the monitoring of medicine shortages – see in question 9.1 - Master data sets generated by the MAHs to upload their data to the EMVS (and later on to be used in the SPOR database) can be a very useful basis for stock level information. GIRP recommends a real time reporting by MAHs of available stock levels of medicines on national level as the only reliable source for monitoring the supply situation.

E-prescribing systems, which have been swiftly advancing especially during the COVID-19 crisis, can serve as basis for the most accurate estimation of demand.

GIRP has also analysed the lists of medicines shortages published by the Member States in July 2019 and again in April 2020 during the COVID-19 crisis. From the currently still 28 EU Member States only 17 countries have published a list of medicines in shortage, with inconsistent updating of said-lists, and only 11 countries have included their root causes – however - with very different degrees of granularity. Please find some of our findings on the root causes for shortages, summarising 11 countries on the GIRP website: GIRP publications.

GIRP recommends the introduction of shortages databases with harmonised root causes, including the API in short supply, in all EU Member States with a tool to compare these databases on European level to enable a swift analysis of the reasons and the extend of the problem and to counteract any product misallocations.

Lastly, we would like to raise our members' expertise in ensuring a fair and equitable allocation of products in case of insufficient supplies. This allocation is performed by reference to available data (including stock level data) and based on experience.

Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- Yes
- No

If yes, please provide details of the ongoing or planned initiatives.

The European Medicines Verification System (EMVS) and National Medicines Verification Systems (NMVS) have been flagged by industry stakeholders to be used for the purpose of monitoring shortages or as a source of data for addressing shortages.

While the EMVS indeed contains a wealth of data and information related to medicines verification (the objective of its legal base), this system has not been designed or built for the collection of data and information on shortages. Without specific modification to the features of the system, it does not allow for the identification of root causes of supply difficulties having a negative impact on patient care.

As one of the founding stakeholders of the approach used for medicines verification, GIRP does not support the use of data contained in the EMVS as they are misleading and will lead to wrong conclusions.

On the supply side, it may be feasible to 'clean' the data in relation to multi-market packs on European level to provide a rough overview of products produced for the European market if the pharmaceutical industry can confirm that the uploaded data correspond to the number of products shipped to Member States.

On Member State level, it is not possible to 'clean' the data from the uploaded multi-market packs as it is unknown in which country the multi-market pack is physically located and therefore these data would lead to a significant overestimation of available supplies.

The best data source for available supplies would be stock level information from MAHs of products actually shipped to the markets and available in the Member States for national demand.

On the demand side, GIRP strongly cautions against the use of the decommissioning data, contained in the national medicines verification systems as they lead to a completely distorted estimation of demand, as even if all products are decommissioned (which is not the case during the various national wavers), in case of a shortage they simply cannot be decommissioned as they are physically not available, and therefore the real national demand would be completely underestimated.

We would therefore urge regulators (and all relevant stakeholders) to explore other existing / potential tools for data supporting solutions for addressing medicines shortages such as for example the use of e-prescribing systems to estimate demand in primary care.

Strategic Theme area 2: Data analytics, digital tools and digital transformation

Question 6: Do the objectives adequately address the challenges ahead?

- Yes
- No

Comments on objectives of the strategic theme area:

GIRP supports the strategy to develop data analytics and data sharing to advance research in healthcare as a key asset to the patient-centric approach. GIRP also sees the necessity of a dynamic regulation especially in terms of patient consent. Although, digitalisation is an important process and while stakeholders mostly see the benefits of it, the cost involved in adapting systems and training of staff among other elements constitutes an obstacle to the advancement of new technologies in healthcare. An incentivisation programme towards stakeholders would be beneficial.

Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- Yes
- No

If yes, please specify

Please remember to specify if a particular comment relates specifically to the human or veterinary part.

Within the discussion of the digitalisation of the European healthcare sector, we believe there is room for improvement in electronic communication and data interchange processes with supply chain partners, especially between the pharmaceutical industry and full-service healthcare distributors. Currently, national standards of data interchange exist only in a few countries (e.g. Italy, Germany, France, Austria). Both pharmaceutical manufacturers and healthcare distributors could benefit from standardised EDI solutions which could significantly increase efficiencies, security and reduce costs for the supply chain.

Lastly, while the rise of data analytics is a strong component of digitalisation, we feel the objectives are overlooking other aspects of new technologies, such as 3D printing, connected devices and their application in healthcare, the implementation of e-prescription systems and their European compatibility, augmented reality, artificial intelligence, etc.

Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- Yes
- No

If yes, please elaborate which ones and provide details on how these could be considered.

GIRP has started a project to implement EDI communication standards between healthcare distributors and manufacturers in countries where there are no standards implemented yet, or where there is an appetite to increase standardisation. Austria has been selected to serve as the “best practice example”, with which pilot projects of EDI communication will be selectively started with interested representatives from manufacturing and distribution. The project is implemented in cooperation with GS1 Healthcare.

Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- Yes
- No

Strategic Theme area 5: Supply chain challenges

Question 6: Do the objectives adequately address the challenges ahead?

- Yes
- No

Comments on objectives of the strategic theme area:

GIRP welcomes the overall strategic goals outlined in this theme area – supply chain challenges. GIRP welcomes in particular reference to strengthening inspector training with respect to the implementation of the Delegated Regulation to the falsified medicines directive. In particular, we would like to highlight the need to ensure that all wholesale license holders be properly inspected. GIRP encourages inspectors and authorities to exchange best practice know-how and start an active dialogue, acknowledging our sector as relevant stakeholder when drafting papers and exchanging views in the EMA inspectors working group. GIRP furthermore welcomes reference to the EUDRA GMDP database and its links with other databases. A link should be made with the European medicines verification system and those operators that should connect, but do not, should have their authorisations suspended or revoked. GIRP fully supports the aim to have competences amongst local authorities, as regards GDP supervision, consolidated at national level to ensure a more consistent and comprehensive implementation of GDP guidelines in all countries. This would greatly improve the quality of the information contained in the EUDRA GMDP database on wholesale distribution authorisation holders and the status of inspections. We would call for the full population of the database including real-time information on the outcome of inspections and the status of authorisation holders. GIRP also encourages the timely inclusion of wholesale distribution authorisations in the SPOR database. GIRP would caution against an overhaul of the GDP guidelines as certain aspects are still not yet fully implemented. However, the scope of the GDP guidelines should be widened to include last mile distribution activities to patients to ensure that all activities are covered by the applicable standards for wholesale distributors. Additionally, GDP guidelines could also be modernised to reflect the shift towards electronic tools for record keeping and data sharing. An active and collaborative approach reviewing the GDP-Guidelines is offered by GIRP as the leading association of those directly affected and challenged with the implementation and adaption of GDP requirements.

Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- Yes
- No

If yes, please specify

Please remember to specify if a particular comment relates specifically to the human or veterinary part.

In order to improve safety and reliability while removing inequity from the supply chain, a distinction should be made between full-service healthcare distributors (pharmaceutical full-line wholesalers) - who ensure the continuous availability of all medicines and healthcare products they can procure within the limitations of the legal framework and market conditions - and other actors, distributing by choice only a selective range of mostly high margin products. GIRP therefore calls for a general revision of the wholesale distribution licensing system, differentiating full-service healthcare distributors by law in respect of their function as critical infrastructural (which is a significant difference to other wholesale distribution authorisation holders).

The National Medicines Verification Systems (NMVS) could act as indicator of active wholesale distribution authorisations and distributors not connected should see their license revoked. Ultimately, a single European licensing system – as it is the case for the distribution of veterinary products - would simplify the supply chain and regulatory processes.

Please also see our comments made in respect to strategic focus area 1.

Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- Yes
- No

If yes, please elaborate which ones and provide details on how these could be considered.

One of GIRP's main objectives is to support harmonised implementation of Good Distribution Practices with its members across Europe. For this purpose, GIRP and its member companies and associations form and provide a network of GDP expertise and collaborative exchange of best practices between authorities and full-service healthcare distributors wherever legally possible. Transparency and harmonisation of requirements are key elements for GDP compliance all over Europe. Therefore, GIRP organises its annual Supply Chain Conference, which brings together GDP/GMP inspectors from different national regulatory authorities in the EU (regular participants from AEMPS, AGES, AFMPS, HPRA, MHRA, etc.) with an audience of healthcare executives, distributors, manufacturers, supply chain experts and drivers of new technologies. The event aims to create better understanding of the expectations of GMP/GDP inspectors on how supply chain actors should implement the requirements of the Good Distribution Practice Guidelines as well as the more recent regulatory additions ("Falsified Medicines Directive", Medical Devices and In-Vitro Diagnostics Regulations). It provides a platform on which GMP/GDP inspectors and stakeholders can exchange views and share implementation experience in a constructive and positive environment and where inspectors can outline the reasons for their interpretation of the various provisions of the guidelines.

Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- Yes
- No

Any other comments

Please feel free to provide any other additional comments not provided in the previous questions

Thank you very much for completing the survey. We value your opinion and encourage you to inform others who you know would be interested.

Useful links

[EU Medicines Agencies Network Strategy \(https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-medicines-agencies-network-strategy\)](https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-medicines-agencies-network-strategy)

[European Medicines Agencies Network Strategy to 2025 \(https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf\)](https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf)

[Pharmaceutical Strategy for Europe \(https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1242-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation\)](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1242-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation)

Background Documents

[european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf](#)

Contact

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