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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Pharmaceutical Strategy for Europe

{SWD(2020) 286 final}

1. Medicines - a strong ecosystem at an important crossroads

Good health is central to wellbeing and depends on a multitude of factors including healthy lifestyles and fair and equitable access to healthcare, a central pillar of the European way of life. Healthcare in turn requires safe, effective and affordable medicines.

Great progress has been made on human health in the European Union in recent years, with average life expectancy at birth in the EU having increased by 3.3 years since 2002[1]. New medicines, vaccines and treatments have helped to tackle some of the leading causes of disease and life threatening illnesses.

Milestones of major progress in treatments in the EU in the past 20 years:

Biotech products offer treatment for many chronic conditions such as diabetes, or anaemia in patients with renal failure. A new generation of antiviral medicines for the treatment of chronic hepatitis C has become available since 2014.

Several widely used vaccines offer protection against hepatitis B, papilloma virus or cholera. In 2020 the Commission authorised the first Ebola vaccine.

Personalised therapies dramatically improved the prognosis of patients with some cancers, an example being trastuzumab that improved cure rate of HER2[2] positive breast cancer and advanced disease overall survival.

Advanced therapy medicinal products such as cell-based and gene therapy products are paving the way for new promising therapies. CAR-T cell[3] therapies for the treatment of certain blood cancers and a medicine to treat transfusion-dependent beta thalassaemia, a blood disorder, were authorised more recently.

At the same time, though we are experiencing a period of rapid change and innovation, many patients do not benefit from that innovation, because medicines are either unaffordable or unavailable. And there is greater awareness of the need to ensure that our use of pharmaceuticals is sustainable.

The COVID-19 pandemic has, and continues to have, a very serious impact on Europe. Though Europe's response has demonstrated strengths, existing vulnerabilities have been thrown into sharp focus, including those related to data availability, the supply of medicines or the availability of manufacturing capacities to adapt and support the production of medicines. The conclusion of advance purchase agreements for vaccines is nevertheless an example of effective co-operation between public and regulatory authorities, industry and civil society organisations. The anticipated widespread and equitable availability of safe and effective vaccines in record time raises hope for an exit from the crisis and provides inspiration for a renewed, innovative, patient-centred and world-leading pharmaceutical sector.

A new EU approach is needed to ensure we have a strong, fair competitive and green industry that delivers for patients, and which draws on the potential of the digital transformation of

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1 Eurostat: mortality and life expectancy statistics.
2 Human epidermal growth factor receptor 2.
3 Chimeric antigen receptor T cells.

health and care, driven by technological advances in fields such as artificial intelligence and computational modelling. We need well-functioning international supply chains and a well performing single market for pharmaceuticals, through an approach that covers the entire lifecycle of pharmaceutical products, from production to distribution, consumption and disposal.

In this context, the Commission proposes a **new pharmaceutical strategy for Europe**. It is a patient-centred strategy that aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness. It is a key pillar of the Commission's vision to build a stronger European Health Union[4], which President von der Leyen set out in her 2020 State of the Union speech.

The new pharmaceutical strategy acknowledges that the EU is starting from strong foundations. Europe has a comprehensive pharmaceuticals system, from the development and authorisation of medicines to their post-authorisation monitoring. The Commission, the European Medicines Agency (EMA), the medicines regulatory authorities in the Member States and the European Economic Area work together in the European medicines regulatory network to ensure that patients have access to **high-quality, effective and safe medicines**.

EU Member State health systems making use of these medicines are a crucial part of Europe's high levels of social protection and cohesion and build on the common values of universal access to good quality care, equity and solidarity.

There is a strong and competitive pharmaceutical industry in the EU. Together with other public and private actors, it serves public health and acts as a driver of job creation, trade and science. Medicine producers made the biggest contribution to research investment in 2019, with over €37 billion. The sector provides 800 000 direct jobs and a €109.4 billion trade surplus[5]. The EU is the second largest market in the world for pharmaceuticals, with many stakeholders involved, from start-ups to large companies, from producers of patented medicines to generics and biosimilars, from wholesalers and distributors to parallel traders, from medical device to software developers. Emerging biopharmaceutical companies account for over 70% of the research pipeline[6], contributing to a vibrant sector.

The Pharmaceutical Strategy for Europe builds on these foundations. It will foster patient access to innovative and affordable medicines. It will support the competitiveness and innovative capacity of the EU's pharmaceutical industry. It will develop the EU open strategic autonomy and ensure robust supply chains so that Europe can provide for its needs, including in times of crisis. And it will ensure a strong EU voice on the global stage. The strategy has four work strands which flow from these objectives. Each strand contains flagship initiatives and flanking measures to ensure the objectives deliver tangible results. Taken together, they will ensure Europe's pharmaceutical policy evolves in line with the green and digital transitions, demographic change and remains relevant given the realities of today and the ambitions of tomorrow, as part of a stronger Health Union.

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4 European Health Union package: COM(2020) 724, COM(2020) 725, COM(2020) 726, COM (2020) 727.
5 Eurostat, international trade in goods by type of good.
6 IQVIA Institute for Human Data Science (2019), 'The global use of medicine in 2019 and outlook to 2023'.

The strategy will also help to deliver other Union objectives. By boosting innovation to address unmet needs, including vaccination against treatable infections that cause cancer, as well as medicines for paediatric and rare cancers, it directly contributes to 'Europe's Beating Cancer Plan'. Together, the Pharmaceutical Strategy and the Cancer Plan will ensure that patients across Europe can access high-quality treatment and new therapies when they need them and ensure the availability and affordability of essential medicines for cancer patients across the EU. The strategy's actions to address access to medicines will also help to meeting EU-level commitments under the UN's sustainable development goals.

The strategy[7] is also complementary to the European Green Deal[8] and more particular the Zero Pollution ambition for a toxic-free environment, notably through the impact of pharmaceutical substances on the environment. The pharmaceutical strategy paves a way for the industry to contribute to EU's climate neutrality, with a focus on reducing greenhouse emissions along the value chain. It also contributes to the action plan to implement the European Pillar of Social Rights[9], the strategic frameworks on achieving a Union of Equality[10], the upcoming Green Paper on Ageing, the strategy on Shaping Europe's digital future[11], the European strategy for data[12], the work on the creation of a European health data space, the European One Health Action Plan against antimicrobial resistance[13] and the new industrial strategy for Europe[14].

Finally, the strategy is of key relevance for non-EU countries as well, in particular in the Western Balkans and the EU's neighbourhood, as candidate countries, potential candidates and DCFTA[15] countries have an obligation to align to the EU acquis of the pharmaceutical legislation.

2. Delivering for patients: fulfilling unmet medical needs and ensuring accessibility and affordability of medicines

2.1. Prioritising unmet medical needs

Investment in research and development (R&D) for innovative medicines and treatments is essential for making progress in preventing and treating diseases. Access to safe, high quality and effective medicines is a key element of social well-being, including for persons from disadvantaged, vulnerable groups, such as people with disabilities, people with a minority

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7 The implementation of the Strategy will be compatible with the resources available in the 2021-2027 Multiannual Financial Framework and will be aligned with the relevant programmes and policies.

8 COM(2019) 640.

9 https://ec.europa.eu/social/main.jsp?catId=1226&langId=en

10 See the Gender Equality Strategy (COM(2020) 152), the Anti-racism action plan COM(2020) 565), the EU Roma strategic framework for equality, inclusion and participation (COM(2020) 620) and the LGBTIQ+ equality strategy and the forthcoming Strategy for the Rights of Persons with Disabilities the Action Plan on Integration and Inclusion 2020-2027.

11 European Commission (2020), Shaping Europe's digital future (ISBN 978-92-76-16363-3).

12 COM(2020) 66.

13 https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

14 COM(2020) 102.

15 Deep and Comprehensive Free Trade Areas (DCFTA) are established between the European Union, and Georgia, Moldova and Ukraine, respectively.

ethnic or racial background and older people. There is a growing consensus that policies need to be rethought so as to stimulate innovation in particular in areas of unmet needs, and for pharmaceutical innovation to be more patient-centred, health system oriented and take account of multi-disciplinary requirements, such as in long-term care settings.

Currently, investment does not necessarily focus on the greatest **unmet needs**, due to the absence of commercial interest or limitations of the science. Treatments for important diseases, for example, neurodegenerative diseases and paediatric cancers are still lacking. In addition, there are over 7 000 known rare diseases, including rare cancers, of which 95% still have no treatment option[16]. Other shortcomings concern the lack of development of new antimicrobials, treatments or vaccines for emerging health threats (including those similar to the present pandemic, such as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or Middle East respiratory syndrome (MERS)) and the lack of treatments for specific population groups such as pregnant and breastfeeding women and older people.

Development of novel antimicrobials or alternatives is a prime example of unmet medical need, given the lack of therapeutic options to address **antimicrobial resistance** (AMR). AMR decreases our capability to treat infectious diseases, and threatens our ability to perform routine surgery. As underlined in the EU One Health Action Plan on AMR[17], it is a multifactorial problem of global concern, with serious health and economic ramifications. An important challenge is the excessive and inappropriate use of antimicrobials in animal and human healthcare, leading to the development of resistance, causing an estimated 33 000 human deaths in the EU/EEA every year[18]. While measures to reduce excessive and inappropriate use, described elsewhere, must be pursued, they can have the unintended effect of reducing investment in new antibiotics. Current incentive models do not provide a sustainable solution; new business approaches are required, including new incentives to develop antimicrobials as well as new pricing systems.

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[16] Joint evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products SWD(2020) 163.

[17] https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

[18] Cassini et al., (2019) 'Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis', in Lancet Infect Dis. Vol.19, issue 1, pp. 55-56.

Flagship initiatives related to antimicrobial resistance

- Pilot innovative approaches to EU R&D and public procurement for antimicrobials and their alternatives aiming to provide pull incentives for novel antimicrobials – target date 2021.
- Promote investment and coordinate research, development, manufacturing, deployment and use for novel antibiotics as part of the new EU Health Emergency Response Authority, prior to the start of the authority's operations preparatory action on AMR – 2021.
- Consider in the review of the pharmaceutical legislation[19] to introduce measures to restrict and optimise the use of antimicrobial medicines. Explore new types of incentives for innovative antimicrobials – 2022.

Other action

- Propose non-legislative measures and optimise the use of existing regulatory tools to combat antimicrobial resistance, including harmonisation of product information, draft evidence-based guidance on existing and new diagnostics; promote the prudent use of antibiotics and communication to healthcare professionals and patients – 2021.

Our reply to the challenges, raised by persisting unmet medical needs, should be multi-facetted. **Research priorities should be aligned to the needs of patients and health systems.** Enabling collaboration between scientific disciplines by involving regulators, academia, healthcare professionals, patients' organisations and healthcare deliverers and payers at early stages of R&D, as pioneered by innovative partnerships for health research and innovation, can support this ambition.

We need to **break silos** so that various public authorities responsible for authorisation, health technology assessment, healthcare provision, health insurance and financing, work together. Increased cooperation in scientific advice and convergence on key concepts, such as 'unmet medical need', will facilitate the design of clinical trials, generation of evidence and assessment, ensuring that innovation matches the needs of patients and of the national health systems. The outcomes of these discussions could also guide funding into specific areas, such as basic research in new therapeutic areas.

To complement existing cross-country collaborative approaches in public procurement, joint pricing and reimbursement negotiations, new ways of information sharing, such as horizon scanning, should be considered. The proposed Health Technology Assessment Regulation[20] will, when adopted, promote evidence-based investment decisions in innovative health technologies with added clinical value for patients.

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[19] References to the 'pharmaceutical legislation' are to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67) and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[20] Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (COM(2018) 51).

A process of reflection has begun on how to **tailor the system of incentives** provided by the EU pharmaceuticals framework better in order to **stimulate innovation in areas of unmet medical needs** (e.g. neurodegenerative and rare diseases and paediatric cancers). Wide stakeholder engagement and multidisciplinary input will be sought. The findings of the study on pharmaceutical incentives[21] and the evaluation of the legislation on medicines for children and rare diseases[22] will inform any future review, in line with the principles of better regulation.

Flagship initiatives on unmet needs

- Propose to revise the legislation on medicines for children and rare diseases to improve the therapeutic landscape and address unmet needs (e.g. in paediatric cancer) through more tailored incentives – 2022.
- Facilitate collaboration on unmet needs and evidence generation in joint meetings of existing committees/networks of regulators, health technology assessment (HTA) bodies and payers, involving key actors in the development, authorisation and access to medicines for a lifecycle approach and improved availability and affordability. Work with the European Parliament and the Council towards the adoption of the Regulation on health technology assessment – 2021.

Other actions

- Incorporate the European Medicines Agency (EMA) priority medicines scheme (PRIME) in the regulatory framework to provide enhanced support so as to accelerate product development and authorisation in areas of unmet needs – 2022.
- Enable parallel scientific advice on clinical study design for medicines by HTA bodies and the EMA, as provided for by the proposed HTA Regulation – 2021.

2.2. Ensuring patients' access to medicines

Innovative and promising therapies do not always reach the patient, so patients in the EU still have different levels of **access to medicines**. Companies are not obliged to market a medicine in all EU countries; they may decide not to market their medicines in, or withdraw them from, one or more countries. This can be due to various factors, such as national pricing and reimbursement policies, size of the population, the organisation of health systems and national administrative procedures resulting in smaller and less wealthy markets in particular facing these problems. Experience in the area of medicines for children and rare diseases illustrates the problem. The availability of such medicines has increased since the adoption of the specific regulations, but access varies considerably across Member States.

Lack of transparency of research costs or return on investment can influence decisions that impact affordability and ultimately access for patients. Drawing on this and wider experience, the Commission will review the system of **incentives**. This may include greater 'conditionality' of incentives to support broader access for patients and ways to increase

[21] Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe: final report (2018).
[22] SWD(2020) 163.

competition. The Commission will also launch a pilot project to understand better the root causes of deferred market launches, including as regards cancer, to inform the evaluation of the pharmaceutical legislation.

Generic and biosimilar medicines provide a large number of patients with accessible and affordable treatments. They also allow health systems potential savings in costs through their positive effect on pricing competition. The Commission will consider targeted policies that support greater generic and biosimilar competition, based on the sound functioning of the single market, appropriate market protection mechanisms, the removal of barriers that delay their timely entry to market and increased uptake by health systems. This may include further clarifying the provisions for the conduct of trials on patented products to support generic and biosimilar marketing authorisation applications (the so-called 'Bolar' provision).

The aforementioned policies will be accompanied by **enforcement of the EU competition rules**. The Commission's Report on competition enforcement in the pharmaceutical sector[23] has shown that originator companies sometimes implement strategies to hinder the entry or expansion of the more affordable medicines of their generic and biosimilar competitors and that such strategies may require competition law scrutiny. The Commission will also continue to carefully review mergers between pharmaceutical companies to avoid distortion of competition.

New health technologies should demonstrate their clinical added-value and cost-effectiveness compared to what is already available. **Health technology assessment** is a tool to support this analysis and inform national pricing and reimbursement decisions. Currently, such assessment is highly fragmented across the EU. The proposed Health Technology Assessment Regulation will enable cooperation on clinical evidence requirements and clinical trial design. It can therefore support Member States' timely and evidence-based decision-making on patient access to new medicines.

Actions in the area of **public procurement** can foster competition and improve access. Public buyers should design smart and innovative procurement procedures, e.g. by assessing the role of 'winner-takes it all' procedures and improving related aspects (such as price conditionality, timely delivery, 'green production' and security and continuity of supply) including via the Big Buyers initiative launched under the SME Strategy.

This would allow to address through the use of public purchasing instruments some important key policy objectives. National authorities will be able to share their experience and develop common approaches based on best practices.

In addition, health systems and private companies can cooperate by using the new 'innovation partnership' tender procedure that allow public buyers to establish a partnership for the development, manufacturing and subsequent purchase of medicines with limited demand.

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[23] COM(2019) 17.

Finally, the Commission will support regional initiatives of joint negotiation or joint tendering, as these can also contribute to improving access to medicines[24].

Flagship initiatives on access to medicines

- Propose to revise the system of incentives and obligations in the pharmaceutical legislation taking into account the relationship with intellectual property rights, to support innovation, access and the affordability of medicines across the EU – 2022.
- Review the pharmaceutical legislation to address market competition considerations and thus improve access to generic and biosimilar medicines, including interchangeability and the 'Bolar' exemption – 2022.

Other actions

- Initiate a pilot together with the EMA and Member States, with the engagement of future marketing authorisation holders, to understand the root causes of deferred market launches – 2021.
- Encourage buyers from the health sector to cooperate in view of implementing innovative procurement approaches for the purchases of medicine or medical devices, in the framework of the Big Buyers initiative – 2021.

2.3. Ensuring affordability of medicines for patients and health systems' financial and fiscal sustainability

The **affordability** of medicines has implications for both public and household finances. It poses a growing challenge for the majority of Member States. The business model has moved from selling blockbusters to marketing 'niche-busters'. Often, new products are priced even higher, with growing uncertainty as to their real-life effectiveness and related overall costs. This puts the budgetary sustainability of health systems at risk, and reduces the possibilities for patients to have access to these medicines.

There is a lack of **transparency** (in particular in R&D costs) and **consensus on costing principles**. Better understanding and greater clarity are fundamental as a basis for policy debates on the pricing of niche medicines and 'fair return' on research contributions. Changing business models (e.g. high value acquisitions of promising pipeline products) and novel payment approaches, such as risk-sharing arrangements and deferred payment schemes, may have long-term implications, and thus affect affordability of new medicines. The Commission will foster transparency of price information to help Member States take better pricing and reimbursement decisions, also considering possible knock-on effects for innovation.

Expenditure on medicines in hospital settings is incompletely reported at EU level and it is growing rapidly. Pharmaceutical budgets account for 20-30% of hospital expenditures and are growing faster than retail spending[25]. This is to be expected given budget increases for specialised medicines administered in hospitals. The Commission will assess the

[24] An example of such an initiative is the Beneluxa initiative, see https://beneluxa.org/collaboration.
[25] European Commission, State of health in the EU: companion report 2019 (ISBN 978-92-76-10194-9).

effectiveness of current financial protection mechanisms, working to optimise these to safeguard the affordability of medicines for individual patients and health systems. Improved knowledge on the efficiency and accessibility of medicinal care in Member States will inform country-specific knowledge on health systems (e.g. in the European Semester and the 'state of health in the EU' cycle) and possible reforms in the Member States. **Minimising waste and optimising the value of spending** on medicines are also critical to achieving efficient and sustainable health systems. A mix of policy levers can support this goal, including: ensuring value for money through health technology assessment; exploiting potential savings from generics and biosimilars; encouraging responsible prescribing; and improving patient adherence.

Decisions on the **pricing and reimbursement of medicines** are the purview of Member States. The Commission will step up co-operation with and among Member States on the affordability and cost-effectiveness of medicines and will launch a group to steer cooperation between national pricing and reimbursement authorities and healthcare payers. It will support mutual learning through information and best-practice exchange, including on public procurement and the coverage of pharmaceutical costs by social protection systems, price-increase criteria and rational prescribing.

Certain conditions such as newly launched niche products for a small number of patients or the absence of automatic substitution rules for biologicals, can create market barriers. This means that competing generics, biosimilars and 'older' products may find it hard to enter or stay in the market. This lack of **competition** thus inhibits price savings once innovative products lose their market exclusivities. Rules that do not directly regulate prices or reimbursement levels may nevertheless have a bearing on the affordability and cost-effectiveness of medicines through indirect effects on the contestability of markets or the economic viability of products in more mature markets. The Commission will take this into account in the review of the pharmaceutical legislation, to see how sound competition can best be fostered, leading to downward effect on prices of medicines. It will also continue to work, including through the exchange of best practices, on the uptake of biosimilars, in order to stimulate competition.

Flagship initiatives on affordability

- Propose to revise the pharmaceutical legislation addressing aspects that impede the competitive functioning of the markets and to take account of market effects impacting on affordability – 2022.
- Develop cooperation in a group of competent authorities, based on mutual learning and best-practice exchange on pricing, payment and procurement policies, to improve the affordability and cost-effectiveness of medicines and health system's sustainability, including on cancer treatment – 2021-2024.

Other actions

- Engage with Members States in implementing non-legislative measures to improve transparency, such as guidelines on principles and costing methods for establishing the R&D costs of medicines – 2021-2024.
- Continue the assessment through the European semester of the adequacy and sustainability of national health systems and issue country specific recommendations as relevant to ensure they are accessible and efficient.

3. Supporting a competitive and innovative European pharmaceutical industry

3.1. Providing a fertile environment for Europe's industry

A **competitive and resource-efficient EU pharmaceutical industry** is of strategic interest for public health, economic growth, jobs, trade and science. The EU aims to support industry to be competitive and resilient so that, in turn, it can better **respond to patients' needs**. The sector is changing rapidly. Established businesses are increasingly outsourcing functions and are focusing investment on a limited number of therapeutic areas, while disinvesting from others. New players, especially technology companies, have entered the market. The coming together of these separate industry segments will transform current business models and markets.

The new industrial strategy for Europe[26] provides key actions supporting industry in the EU. Drawing on that framework, the pharmaceutical strategy will create a **stable and flexible regulatory environment** that offers legal certainty for investment and accommodates technological trends. This includes providing balanced and fair incentives to reward and protect innovation and create the right conditions for companies of all sizes in the EU to be competitive.

Intellectual property rights offer protection for innovative products and processes, but in particular for patents and supplementary protection certificates, there are differences in their application in Member States.

This leads to duplications and inefficiencies thus hampering the competitiveness of industry. The Commission's intellectual property action plan[27], includes measures to simplify and streamline the EU pharmaceutical intellectual property system, notably as regards supplementary protection certificates.

Secure and efficient access to health data is key to fully exploiting the huge potential of new technologies and digitalisation. Industry and regulators require access to data through a robust EU-wide **data infrastructure** to support innovation. An interlinked system that gives access to comparable and interoperable health data from across the EU would be a real multiplier in terms of research, regulation and evidence generation. The Commission will propose a **European health data space** and establish **interoperable data access infrastructure,** which will improve exchange, federated access and cross-border analysis of health data in the EU. This will support better healthcare delivery and health research, policymaking and regulation, while protecting individuals' fundamental rights, notably their rights to privacy and data protection[28].

It is essential to continue creating quality employment opportunities in the EU throughout the pharmaceutical value-chain. To that end, a competitive pharmaceuticals industry requires

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[26] Cf. fn. 10.

[27] COM(2020) 760.

[28] In full compliance with the General Data Protection Regulation - Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1.

access **to a skilled and specialised workforce**. NextGenerationEU provides unprecedented funding opportunities to support the availability of a skilled workforce as well as its adaptability and the Skills Agenda for Europe[29] sets the way to make it happen. Specifically, it should help ensure that all key players in the pharmaceutical sector pool their resources and invest in upskilling and reskilling of all employees throughout the value chain, including through commitments that need to materialise under the Pact for Skills[30], launched on 10 November 2020. Contributing to the increase in STEM[31] specialists the skills agenda will aim to boost the number of (male and female) STEM graduates and teachers by making these studies and careers more attractive. Researchers are at the forefront of science and innovation and require a specific set of skills too. More will be done to upskill scientists, in line with the skills agenda, and to foster their mobility across Europe.

Diverse sources of **funding** are an essential tool to support innovation. A key element of support to the Strategy will be the new and ambitious standalone EU4Health programme. In addition, Horizon Europe, Cohesion Policy, the European Defence Fund, public-private and public-public investment partnerships such as the Innovative Health Initiative[32], and national schemes are important enablers for R&D, including for small and medium-sized enterprises (SMEs) and academia. Some of these partnerships may help early uptake of innovation in health systems. Commission initiatives such as the SME strategy for a sustainable and digital Europe[33], Startup Europe[34], the European Innovation Council and the European Institute of Innovation and technology will help provide the right environment for SMEs and start-ups active in the health sector to grow and attract venture capital. Likewise, there are opportunities to invest in international partnerships in the area of health through international cooperation instruments such as the EU external investment plan. At the same time increased transparency in the cost of research and development of pharmaceuticals is needed.

Flagship initiatives on competitiveness

- Optimise the supplementary protection certificates system, to make it more transparent and efficient as foreseen in the Intellectual Property Action Plan – 2022.
- Legislative proposal on a European Health Data Space, enabling better healthcare, health research, innovation and evidence-based decisions – 2021.
- Establish by 2025 interoperable data access infrastructure for the European Health Data Space in order to facilitate secure cross-border analysis of health data; tested in 2021 with a pilot project involving EMA and national authorities – 2021 – 2025.
- Support public-private and public-public partnerships, financially and technically for example through the Innovative Health Initiative, with particular attention to SMEs, academia, not-for profit organisations, and through the health care systems transformation partnerships – 2021.

[29] COM(2020) 274.
[30] The Pact for Skills: mobilising all partners to invest in skills.
[31] Science, technology, engineering and mathematics.
[32] European Partnership for Innovative Health (Initiative).
[33] COM(2020) 103.
[34] https://ec.europa.eu/digital-single-market/en/startup-europe.

Other action

- Prioritise skills investment to support the availability of a skilled workforce and its adaptability through the NextGenerationEU, and within the new Recovery and Resilience Facility and through commitments under the pact for skills – 2022.

3.2. Enabling innovation and digital transformation

Patients in the EU expect that they can benefit from state-of-the art healthcare. Scientific and technological advances are crucial to improve patients' health, and support a more efficient, and cost effective, way of discovering and using medicines. These advances can translate not only into entirely new medicines, but also into alternative uses for existing ones.

Advanced therapy medicinal products and some medicines for rare diseases are challenging concepts, both in terms of science and manufacturing. An increasing number of **gene and cell therapies** under development may offer curative treatments and would require a new business model to address the shift in cost from chronic to one-time treatment. 'Bedside' manufacture[35] of more individualised medicines could be a future trend.

Vaccines, early detection and the improvement of well-being can affect the management of diseases and the use of treatments. The COVID-19 pandemic has shown that innovative approaches to the development, approval and post-authorisation monitoring of vaccines and repurposing of medicines are needed. Platforms to monitor the safety and effectiveness of vaccines post-authorisation will be developed in addition to regular pharmacovigilance. COVID19 has also underlined the importance of collaboration between different stakeholders and secure, open access to different kind of health data, such as databases of molecules held by companies, using data sharing agreements. This requires open platforms and greater collaboration to identify datasets that can be made available for reuse[36].

Digital transformation is affecting the discovery, development, manufacture, evidence generation, assessment, supply and use of medicines. Medicines, medical technologies and digital health are becoming increasingly integral to overarching therapeutic options. These include systems based on artificial intelligence for prevention, diagnosis, better treatment, therapeutic monitoring and data for personalised medicines and other healthcare applications.

Personalised medicine is an integrated package of healthcare solutions comprising elements of medicines and medical devices that are structured to meet an individual patient's needs. In the future, patients may still be prescribed a tablet but that tablet may be combined with a new technology to determine the right usage, the right schedule and the right dosage according to their personal situation. This can also support treatments in multi-disciplinary settings like long-term care. Digital therapeutics can use app-based platforms to help patients manage chronic diseases such as diabetes, depression and heart conditions, and reduce medication.

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[35] This refers to a shift from the production of personalised medicines from being exclusively in the factory towards a fine-tuning at the patient's bedside.

[36] In line with the EU data strategy, notably for data reuse and business to government data sharing.

Initiatives such as the **'1+ million genome'**[37] are exploring ways to access genetic data with the potential to improve disease prevention, also via an enhanced understanding of the impacts of environmental determinants such as climate change and pollution, allow for more personalised treatments and provide sufficient scale for new clinically impactful research including on different cancer types.

High performance computing and artificial intelligence can help accelerate the identification of potential active substances for repurposing and reduce the high failure rates. Supercomputing is used in the COVID-19 pandemic for example through the Commission project Excalate4COV. Due care should be taken to avoid any gender, race or other bias in the data produced by artificial intelligence. Technological advances can also support the '3 Rs' principles (replace, reduce, refine) for the ethical use of animals in medicine testing.

The main source of evidence for the authorisation of innovative medicines should remain robust clinical trials with suitable comparators reflecting the standard of care in the EU. The full implementation of the **Clinical Trials Regulation**[38] will put in place a harmonised, highly coordinated, robust and agile system for the assessment and oversight of clinical trials in the EU. It will improve transparency of information, independently of the outcome of the trials, to allow public scrutiny and will address new developments such as adaptive and complex trials, and the use of in-silico techniques and virtual approaches. Experience with EU funded R&I projects with adaptive trials shows that research can initiate changes that can reduce costs and decrease development times.

The Commission will work to ensure that the new framework supports **innovative trial designs**. Moreover, in coordination with the European regulators, patient groups and stakeholders, it will support more patient-oriented design, planning and conduct of clinical trials through harmonised international guidance documents and taking into account the experience acquired from clinical trials for COVID-19 vaccines and treatments. This includes representative participation of population groups, for example gender and age groups, that are likely to use the medicinal product investigated in the clinical trials to ensure appropriate safety and efficacy. **Pragmatic trials**, where the treatment is prescribed and used as in normal daily practice, can improve patient compliance and treatment tolerance by identifying optimal posology and use with other treatments. Commercial interest is often weaker for these trials, so they are mainly organised by academia, where the price of trial medication and insufficient regulatory knowledge can be bottle-necks.

The Commission supports initiatives to improve academic researchers and not-for-profit stakeholders' regulatory knowledge via scientific and regulatory advice so that the evidence they generate can be seamlessly used to **repurpose off-patent medicines** for new therapeutic uses. Industry engagement and partnership in this process will be promoted.

The new models of product development and care delivery mean that regulators are seeing the limits of the legislation and the potential needs for regulatory adaptability. The rapid

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[37] *Towards access to at least 1 million sequenced genomes in the EU by 2022*; https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative.

[38] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (OJ L 158, 27.5.2014, p. 1).

developments in products combining medicines and **medical devices** are reflected in new legislation[39], but some challenges remain. These include clarifying roles and responsibilities, streamlining requirements and procedures, and building up the necessary regulatory expertise and collaboration between sectors. Access to testing facilities to test devices involving artificial intelligence is important to ensure the quality of these devices.

The Commission will propose to **revise the pharmaceutical legislation** to consider how to make best use of this transformation. This includes **new methods of evidence generation and assessment**, such as analysis of big and real world data to support the development, authorisation and use of medicines. Regulators may require access to the raw data at the time of authorisation to fully appreciate these innovative elements of the treatment. Also incentivising the development and validation of relevant biomarkers would support the effectiveness in the intake of some new and expensive medicines, but also generics, contributing to the sustainability of healthcare systems.

Flagship initiatives on innovation

- Propose to revise the pharmaceutical legislation, to adapt to cutting-edge products, scientific developments (e.g. genomics or personalised medicine) and technological transformation (e.g. data analytics and digital tools) and provide tailored incentives for innovation – 2022.
- Enhance dialogue among regulatory and other relevant authorities in the area of medicines and medical devices to increase cooperation on evidence generation within their respective fields – 2021.
- Support collaborative projects bringing together stakeholders to take forward the use of high performance computing and artificial intelligence in combination with EU health data for pharmaceutical innovation – 2021-2022.
- Establish the secure federated access to 10 million genomes across borders for research, innovation and clinical applications, including personalised medicine – 2025.

Other actions

- Full implementation of the regulatory framework for clinical trials, which supports innovative trial designs and a more patient-oriented medicine development – 2021.
- Launch a pilot project with engagement of industry and academia to test a framework for repurposing of off-patent medicines and inform possible regulatory action – 2021.
- Launch a vaccine platform to monitor the effectiveness and safety of vaccines, supported by an EU-wide clinical trials network – 2021.

[39] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1 and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU,OJ L 117, 5.5.2017, p. 176.

- Strengthen support and training of academia and not-for-profit organisations in regulatory science for better translation of research into product development – 2022.
- Initiative for regulatory pilots in a 'sandbox' environment provided by the EMA and the Commission to test the adaptability of the pharmaceuticals framework for new cutting-edge product developments – 2022.

3.3. A sound and flexible regulatory system

Regulatory efficiency is a prerequisite for a modern pharmaceutical system. The EU has continuously updated its framework to ensure that a comprehensive system covers the entire lifecycle of medicines. It builds on a dual system where the Commission authorises innovative medicines for the entire EU on the basis of a positive opinion from the EMA and national regulators authorise a great number of generic and other essential medicines.

The Commission will explore the need to recognise more formally the **role of the network** of national medicines agencies (Heads of Medicines Agencies) and its operational structure in the regulatory system.

The Commission will evaluate procedures to explore new approaches to assessing scientific evidence for the safety and efficacy of medicines as part of the review of the legislation and seek to bring EU **regulatory approval times** onto par with those in other parts of the world. It will consider how infrastructure and adapted regulatory processes could leverage digital technology and artificial intelligence to support regulatory decision-making and increase efficiency. The experience of the EMA during the COVID-19 pandemic (e.g. in the rolling review of incoming scientific evidence to speed up assessment) will inform future action. The Commission aims to revisit existing regulatory tools, such as priority review and scientific advice to support companies, especially SMEs, in the development of innovative products for unmet medical needs.

A study[40] on the authorisation and monitoring of medicines for human use will inform the evaluation of the regulatory framework to **simplify and streamline procedures** and reduce costs. The management of variations of marketing authorisations and the assessment of quality files relating to active substances are two examples of areas in which simplification is required. A process of reflection will be initiated on the functioning of, and synergies between the scientific committees and on the role of patients and healthcare professionals.

Moreover, better use of **product information in electronic format** (ePI) could facilitate the delivery of information on the medicine to healthcare professionals and patients in the EU's multilingual environment and support wider availability of medicines across Member States. Any measures should take into account the needs of all patients and healthcare professionals. Measures should also be considered with the aim to ensure that medicines are safely handled by workers, including when administrating treatments.

The Commission will assess **classification and interplay challenges** relating to other regulatory procedures (such as medical devices and substances of human origin) and consider

[40] *Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use* – to be published in 2021.

action to increase cooperation between regulatory sectors and, where necessary, clarity for stakeholders on innovative products, while maintaining high standards of quality, safety and efficacy.

The regulatory requirements for the authorisation of medicines for human use that contain or consist of **genetically modified organisms** (GMOs) should be fit for purpose when it comes to addressing the specificities of medicines and the conduct of clinical trials with those products in the EU (which is currently hindered by the fragmentation of national requirements). Solutions will be explored during the evaluation of the pharmaceutical legislation. In general, consideration should be given to mechanisms for the continuous and timely adaptation of its technical requirements in light of emerging science and technologies with a view to enhance effectiveness to protect human health whilst minimising harmful impacts on the environment.

Regulators also need to adapt to new scientific and technological developments by upscaling necessary expertise and achieving operational excellence to deal with novel and more complex therapies. One important factor in this respect is the availability of sufficient funding at all levels. The EMA fees system is key in funding regulatory activities at EU level and ensuring coverage of the relevant costs. The Commission will consider this in the upcoming revision of the EMA fee legislation.

Flagship initiatives on regulatory efficiency

- Propose to revise the pharmaceutical legislation to provide for simplification, the streamlining of approval procedures and flexibility for the timely adaptation of technical requirements to scientific and technological developments, in order to address the challenges relating to the interplay of medicines and devices, and to strengthen pro-competitive elements – 2022.
- Propose to revise the variation framework for medicines, through changes in legislation and guidelines, to make the lifecycle management of medicines more efficient and adapted to digitalisation – 2021-2023.

Other actions

- Proposal for revised EMA fee legislation – 2021.
- Provide for a single assessment process across Member States for active substances used for different generic medicines (active substance master files) to facilitate their authorisation and life-cycle management – 2022.
- Consider adapting regulatory requirements in the pharmaceutical legislation, applicable to medicines for human use that contain or consist of genetically modified organisms (GMOs) – 2022.
- Upgrade the Commission's Union Register of centrally authorised products to include a statistical dashboard and make data fully available for secondary use as part of the EU open data initiative – 2021.
- Develop and implement electronic product information (ePI) for all EU medicines with involvement of Member States and industry, evaluate and revise relevant provisions in the legislation – 2022.

- Propose to revise legislation to give regulatory authorities more power to adapt on their own initiative the terms of marketing authorisations on the basis of scientific evidence – 2022.
- Simplify and streamline the system of penalties to address non-compliance in a proportionate and efficient way – 2024.

4. Enhancing resilience: Diversified and secure supply chains; environmentally sustainable pharmaceuticals; crisis preparedness and response mechanisms

4.1. Secure the supply of medicines across the EU and avoid shortages

The European Council[41] has recognised that "achieving strategic autonomy while preserving an open economy as a key objective of the Union". **Shortages** of medicines have been a serious concern in the EU for several years and have increased during the COVID-19 pandemic. Shortages compromise patient health and severely burden healthcare systems and healthcare professionals. They can lead to under-treatment and increased hospital stays. Shortages are increasingly frequent for products that have been on the market for many years and are widely used[42]. The reasons are complex; they include marketing strategies, parallel trade, scarce active pharmaceutical ingredients and raw materials, weak public service obligations, supply quotas or issues linked to pricing and reimbursement.

Building up **EU's open strategic autonomy** in the area of medicines requires actions to identify strategic dependencies in health, and to propose measures to reduce them, possibly including by diversifying production and supply chains, ensuring strategic stockpiling, as well as fostering production and investment in Europe. Minimising the impact of medicines shortages on patient care will require both preventative and mitigating measures to significantly reinforce the obligation of continuous supply. This year, the Commission launched a study to map the root causes of shortages and assess the legal framework. The study will inform the evaluation and revision of the current legislation. Legislative measures could include stronger obligations on industry to ensure the supply of medicines, earlier notification of shortages and withdrawals, enhanced transparency of stocks across the supply chain, and a stronger coordinating role for the EMA in monitoring and managing shortages. Such measures will be complemented by enhanced cooperation between Member States, for example improved procurement approaches and strategies, joint procurement for critical medicines and EU-level cooperation on tools and instruments for national policy making on prices and reimbursement. For products with small volumes or limited use, new business contracting and/or payment models will be crucial.

Pharmaceutical manufacturing and supply chains are complex, increasingly globalised and sometimes not sufficiently diversified. Multiple actors, in different parts of the world with varying environmental performance of the production processes, may be involved in the various production steps for a single ingredient. Certain technologies necessary for the production of raw materials are no longer available in the EU. Even before the COVID-19 pandemic there were concerns about the resilience of pharmaceutical manufacturing chains,

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41 European Council Conclusions of 2 October 2020 (EUCO 13/20).

42 Pharmaceutical Group of European Union (PGEU), *Medicine shortages survey: 2019 results.*

both the European Parliament and Member States have called on the Commission to address this issue[43]. Notably as regards the supply of raw pharmaceutical materials, intermediates and active pharmaceutical substances, which may contribute to risks of shortages of critical medicines. The pandemic showed that public authorities do not often have access to complete information about the structure of the manufacturing and supply chains. An appropriate crisis response requires resilient and sufficiently diversified supply chains that operate in a predictable and resource-efficient trading environment.

The Commission will therefore initiate and steer a **structured dialogue** with the actors in the pharmaceuticals manufacturing value chain, public authorities, patient and health non-governmental organisations and the research community. In its first phase, the structured dialogue will aim to gain a better understanding of the functioning of **global supply chains** and identify the precise causes and drivers of **different potential vulnerabilities**, including potential dependencies threatening the supply of critical medicines, active pharmaceutical ingredients and raw materials based on data collection and analysis.

In a second phase, the structured dialogue will serve to put forward a set of **possible measures** to address the identified vulnerabilities and **formulate policy options** to be considered by the Commission and other authorities in the EU to ensure the security of supply and the availability of critical medicines, active pharmaceutical ingredients and raw materials. While it is important to assess whether manufacturing capacity for certain critical medicines may be required in the EU from the perspective of public health and crisis preparedness, any potential measures would have to be in full compliance with EU competition and World Trade Organization (WTO) rules.

In order to improve the predictability of the trading environment in health products, including medicines, the EU will **work together with WTO members** on an initiative that would aim to facilitate trade in healthcare products and contribute to an effective response to a health emergency. Such an initiative would help to strengthen the resilience and robustness of supply chains in the EU and in all other WTO partners. It would rely on increased cooperation of trade partners to avoid unnecessary disruptions in the production and distribution of essential goods, which is crucially important in times of need.

Flagship initiatives on open strategic autonomy

- Propose to revise the pharmaceutical legislation to enhance security of supply and address shortages through specific measures including stronger obligations for supply and transparency, earlier notification of shortages and withdrawals, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages – 2022.
- Follow up on the European Council request for open strategic autonomy and launch a structured dialogue with and between the actors in the pharmaceuticals manufacturing value chain and public authorities to identify vulnerabilities in the global supply chain of critical medicines, raw pharmaceutical materials, intermediates and active pharmaceutical substances in order to formulate policy

[43] European Parliament resolution of 17 September 2020 on the shortage of medicines — how to address an emerging problem (2020/2071(INI)) and European Council Conclusions of 2 October 2020 (EUCO 13/20).

options and propose actions to strengthen the continuity and security of supply in the EU – 2021.

- Consider actions to ensure that the industry increases the transparency on the supply chains through voluntary process – 2021.

Other actions

- Encourage Member States and provide support to engage in close cooperation through funding provided by EU4Health to develop guidelines, measures and tools that could be used both at EU level and in national policy making to address structural shortages – 2021-2022.
- Promote WTO-based actions to increase the resilience in global supply chains in essential goods – 2021.

4.2. High quality, safe and environmentally sustainable medicines

The recent experience with the unexpected presence of nitrosamines impurities in some medicines[44] has highlighted the importance of a sound system for detecting quality problems and of compliance management. Strengthening oversight of the global manufacturing chain and ensuring more transparency across the supply chain are vital. The accountability of all actors for the quality of the medicines is essential, but especially that of the marketing authorisation holders. Compliance with good manufacturing and distribution practices should be enhanced.

Internationally, the EU plays an active role in the promotion of **good manufacturing practices**, which ensure the highest quality of pharmaceutical products. This can be achieved through fora such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and bilateral and multilateral cooperation in the area of inspections. Bilateral cooperation mechanisms are beneficial, in particular mutual reliance on inspections avoiding duplicative efforts and allowing a more efficient use of inspectors. Within the EU, the Commission will support Member State cooperation on inspections and help improve capacity.

The Commission will also analyse the regulatory impact of emerging **new manufacturing methods** such as decentralised or continuous manufacturing. These methods create new manufacturing models, with a shift from industrial to 'bedside' manufacturing. While speeding up production times, they create new challenges in terms of appropriate quality, inspection and oversight.

The production, use and disposal of medicines have environmental implications, as residues and waste products may enter the **environment**. Not only does this have a negative impact on the environment itself, some waste and residues may have endocrine-disrupting potential and others may increase the risk of antimicrobial resistance. The presence of antimicrobial pharmaceuticals in water and soil may play a role in accelerating the development of resistant bacteria. The **European Green Deal** zero-pollution ambition aims to protect both public

[44] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities

health and ecosystems. Action is required throughout the lifecycle of medicines to reduce resource use, emissions and levels of pharmaceutical residues in the environment. The overall exposure to such residues should be minimised and reduced as much as possible. There is still a lot of **waste** from unused medicines. The Commission recently adopted guidelines on the separate collection of household hazardous waste, which include pharmaceuticals[45]. Further measures limiting such waste should be considered including the reduction of pack sizes and their alignment to real use. The circular economy action plan[46] and the chemicals strategy for sustainability[47] establish a framework for generating an overall shift to a production and consumption of resources and pharmaceutical raw materials which are safe, and create the lowest possible impact on the environment and on the climate. Moreover, the EU strategic approach to pharmaceuticals in the environment[48] and the EU one health action plan on antimicrobial resistance[49] set out targeted actions that are currently being implemented (among others, actions that improve environmental risk assessment and waste management).

The Pharmaceutical Strategy for Europe builds on those measures and complements them, especially in the review of the pharmaceutical legislation, including by reviewing the provisions on environmental risk assessment. Innovation for environmentally sustainable and climate-neutral pharmaceuticals and manufacturing should become a driver for the EU pharmaceuticals industry which should apply the best available techniques at manufacturing level to reduce emissions and contribute to EU's climate ambition along their supply chains.

The Commission will further encourage, through international cooperation, actions to address the **environmental risks** in other countries where pharmaceutical emissions from manufacturing and other sources may contribute to the spread of AMR. The extent to which AMR can be addressed through the good manufacturing practices should be assessed. The Commission will cooperate with the World Health Organization (WHO), other key international organisations and bilaterally to raise awareness of environmental risks, including by sharing best practices and developing international guidelines. The Commission will foster the environmentally sustainable production and disposal of medicines globally including through political dialogue and voluntary commitments from the sector.

Flagship initiatives on quality and environmental sustainability

- Propose to revise the manufacturing and supply provisions in the pharmaceutical legislation to improve the transparency and reinforce oversight of the supply chain and clarify responsibilities to ensure overall environmental sustainability, safeguard the quality of medicines and ensure preparedness for new manufacturing technologies – 2022.

- Propose to revise the pharmaceutical legislation to strengthen the environmental risk

[45] Commission Notice - Separate Collection of Household Hazardous Waste (2020/C 375/01), 06.11.2020.
[46] COM(2020) 98.
[47] COM(2020) 667.
[48] COM(2019) 128. Additional information on the progress of the implementation of the strategic approach to pharmaceuticals in the environment can be found at https://ec.europa.eu/environment/water/water-dangersub/pharmaceuticals.htm.
[49] COM(2017) 339.

assessment requirements and conditions of use for medicines, and take stock of the results of research under the innovative medicines initiative – 2022.

Other actions

- Review the framework on good manufacturing practice and encourage inspections of good manufacturing and distribution practice to improve compliance – 2022.
- Work with the Member States to enhance their capacity to participate in international inspection and audit programme – ongoing.
- Engage with international partners through cooperation to ensure the quality and environmental sustainability of the active pharmaceutical ingredients imported from non-EU countries – ongoing.
- Assess with Member States and EMA the feasibility of improving information in existing databases or linked repositories with regard to manufacturing sites, their use for products authorised in the EU and inspection status – 2022.
- Continue the implementation of the actions under the strategic approach to pharmaceuticals in the environment, including the environmentally safe disposal of medicines and reducing pack size and packaging – ongoing.
- Engage with Member States and stakeholders in developing best practices for decarbonising value chains – 2021.

4.3. Enhancing Europe's health crisis response mechanisms

Effective co-operation between the public and private sector has been central to the Union's response to the COVID-19 pandemic. The ability to conclude multiple advance purchase agreements for vaccine are evidence of a diverse ecosystem of small and medium sized pharmaceutical enterprises and established industry multinationals, enabled by a robust regulatory and financing environment. The nature and speed of the response to COVID-19 nevertheless illustrates the need for a more structural approach to preparedness, as well as weaknesses in the sector's ability rapidly to respond to and prepare for emergency health events, with potential consequences for European strategic autonomy.

The **European Health Union** package is a first step to develop structural and future-proof solutions improvements to increase the EU's preparedness and resilience to cross-border health threats. It extends the role of the EMA to serve as central hub for scientific excellence. It gives EMA the ability to fast track scientific advice and evaluation procedures, to assess supply capacity and to monitor, quantify and mitigate shortages of crucial medicines during a crisis. It strengthens the mandate of the European Centre for Disease Prevention and Control to provide hands-on support to Member States and the European Commission through epidemiological surveillance, scientific recommendations for appropriate health measures to deal with health crisis. Finally, it includes a Regulation on serious cross-border threats to improve preparedness and response, including the announcement of a European Health Emergency Response Authority (HERA).

HERA fills a major structural gap in the EU's crisis preparedness and response infrastructure, and will strengthen the coordination of operations across the whole value chain and develop strategic investments for research, development, manufacturing, deployment, distribution and

use of medical countermeasures. This will require the assembly of ecosystems of public and private capabilities that jointly enable a rapid response when the need arises.

HERA will anticipate specific threats and enable technologies through horizon scanning and foresight. It will identify and address investment gaps in key countermeasures including the development of innovative antimicrobials. It will monitor and pool production capacity, raw material requirements and availability, thus addressing supply chain vulnerabilities. It will support the development of crosscutting technological solutions (e.g. vaccine platform technologies) that sustain preparedness and response planning for future public health threats and development of specific countermeasures, including through research, clinical trials and data infrastructure.

During an EU health emergency, additional resources, such as large scale and timely procurement mechanisms or stockpiles, will be required to adequately react in the interest of all Member States. Building on the experience with COVID-19 vaccines development and their common procurement, the Commission will evaluate and launch a preparatory action focusing on emerging threats to human health, such as infectious diseases and anti-microbial resistance. In parallel, it will launch an impact assessment and consultation on the establishment of an EU authority, with a view to proposing in 2021 a properly mandated and resourced dedicated structure to start operations swiftly. Synergies and complementarity with existing EU bodies and relevant spending programmes will be ensured.

A variety of additional measures to support resilience are planned. The EU4Health programme and public private partnerships will complement national policies aiming to protect people from serious cross-border health threats and contribute to crisis preparedness and response. Part of the review of the legislation will also examine how to create a more crisis-resilient system. In parallel, R&I, global value and supply chains, international cooperation and convergence and enhanced and diversified production facilities will complete the picture. In the context of its IP action plan, the Commission will analyse tools to better make intellectual property related to critical technologies available in times of crisis.

Flagship initiative on Europe's health crisis response mechanisms

- Proposal for an EU Health Emergency Response Authority – 2021.

5. Ensuring a strong EU voice globally

The EU regulatory system on pharmaceuticals is recognised as a well-developed reliable and mature system. In addition, the pharmaceuticals sector is economically strategic for the EU in terms of global trade.

In its work at global level, the Commission will work closely with the EMA and the national competent authorities in the regulatory network.

The Commission will continue its open dialogue with other regions and countries, including with low and middle income countries. It will explore how to make the procedure for issuing opinions on medicines intended exclusively for markets outside the EU more appealing as a means of cooperating with other countries and facilitating access to medicines outside the EU. Furthermore, the EU will continue its work in multilateral fora towards enhanced regulatory cooperation and where possible convergence, namely in the International

Pharmaceutical Regulators Programme[50] and the International Coalition of Medicines Regulatory Authorities[51].

The EU has an interest in working with its international partners towards more ambitious level of quality, efficacy and safety standards in international cooperation fora and organisations. **Common international standards** are a key tool. They facilitate the global development of pharmaceuticals. The EU will continue to play a leading role in international organisations that promote such standardisation, such as the ICH, whose guidelines are increasingly referred to as global standards. The Commission will actively work with other ICH partners to set the agenda for preparing and updating guidelines for further harmonisation.

Global markets are an essential source of growth, including for SMEs. This includes ensuring a **level playing field** and a regulatory environment that are conducive to innovation and competitiveness. In bilateral relations with other countries, the Commission will defend EU interests, including reciprocal access to procurement markets in third countries, but also identify common areas of strategic interest. In particular, Africa is an important partner with whom to explore cooperation on innovation, production and technology transfer. It will focus on international cooperation, strengthening global governance and alliances with partner countries, including through a WTO-based initiative or action to facilitate trade in healthcare products.

The EU will **support the work of the World Health Organization** (WHO) in strengthening regulatory capacity through encouraging reliance mechanisms and establishing a framework for designating regulators as WHO Listed Authorities.

Flagship initiative on international cooperation

- Work at global level, with the EMA and the network of national regulators, in international fora and through bilateral cooperation to promote regulatory convergence to ensure access to safe, effective high-quality and affordable medicinal products globally – ongoing.

Other actions

- Advance international harmonisation by proactively proposing topics in line with the latest scientific developments; promoting the uptake and implementation of international standards, and ensuring a level playing field for operators on the international market by enhancing the EU's bilateral and multilateral relations ongoing.

6. Working together for success: a cooperative and layered approach to implementing the strategy

The pharmaceutical strategy will ensure that we continue to deliver high quality, safe medicines and that the benefits of innovation reach patients in the EU. It will guarantee that

[50] http://www.iprp.global/home
[51] http://www.icmra.info/drupal/en/home

the EU remains an attractive place to invest, research and develop medicines. It will improve the resilience and crisis preparedness of the EU system. And it will strengthen the EU's voice on the global stage.

To ensure that this strategy succeeds we need **a comprehensive, integrated approach** that addresses the challenges and breaks down silos, working together across disciplines and regulatory competences throughout the lifecycle of medicines and medical technologies to find the right policy approaches.

A successful transition will depend on **collaborative dialogue**, as exemplified by the various consultation activities in the preparation of this strategy. The Commission is ready to continue this dialogue. Accordingly, it intends to reach out to all relevant national authorities and stakeholders so that they may not only provide their input, but also become partners in this process. An inclusive **civil society dialogue building on existing structures** will be used to facilitate the interaction with stakeholders: public authorities, industry, healthcare professionals, patient, consumer and civil society organisations and the research community.

The Commission will regularly report on the progress made and will keep the **European Parliament and the Council fully informed and engaged** in all relevant actions, taking account of their role in policy shaping and law making.

The Commission will pursue the objectives of the strategy and implement specific actions **in partnership with the Member States**, through enhanced dialogue, close interaction and a proactive exchange of information between the Member States and the Commission. The main forum for discussion with the Member States will be the Pharmaceutical Committee[52] while other existing collaboration mechanisms in the EU will be strengthened and streamlined for this purpose.

This strategy sets out a multi-year vision. It is the beginning of a process that will ensure that the EU's pharmaceutical policy delivers and serves public health in an economically, environmentally and socially sustainable manner in an ever-changing environment that brings transformation in both science and markets. Its implementation requires long-term engagement and mobilisation of resources. Its success will depend on the commitment and contribution of all actors in the pharmaceutical value chain to build common ownership.

[52] Council Decision 75/320/EEC of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).