EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 816

PHARMACEUTICAL COMMITTEE
11 December 2020

Subject: **Pharmaceutical strategy for Europe**[1]

Agenda item 4

The Commission Communication on a pharmaceutical strategy for Europe was adopted on 25 November 2020. It includes a list of actions, which will guide its implementation. Among the flagship actions is the revision of the basic pharmaceutical legislation, with a proposal expected in 2022.

The text of the Commission Communication can be found here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761

A dedicated web page, which will be continuously updated, has been created: https://ec.europa.eu/health/human-use/strategy_en

Following is a table listing the 55 actions mentioned in the Communication with accompanying information. This will serve as a background document for the discussion.
The actions are wide-ranging and cover different policy areas. The Pharmaceutical Committee will be instrumental in the implementation of a great number of actions in the next years. In addition, the European Medicines Agency and the network of national competent authorities (Heads of Medicines Agencies) will be important, as well as other groups of national authorities. Synergies between the work of the Pharmaceutical Committee and those groups will be essential. Some of the actions are at an advanced stage, as they build on activities that have already been initiated, while others will start afresh. While certain actions represent the ones where DG SANTE services are particularly interested to hear your views, members of the Committee are welcome to comment on the entire table.

The aim of the discussion is to exchange views on the strategy actions in general and on how to plan the work of the Committee towards the implementation of the actions and delivery of results.

[1] This document has not been adopted by the European Commission and, therefore, it does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.

Implementation of the Pharmaceutical strategy for Europe

	Actions	Who?	How?	By when?
AMR				
1.	Pilot innovative approaches to EU R&D and public procurement for antimicrobials and their alternatives aiming to provide full incentives for novel antimicrobials	Commission	New business approaches including new incentives to develop antimicrobials as well as new pricing systems	2021
2.	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	Commission	Creation of the Health Emergency Response Authority – pilot project on antibiotics	2021
3.	Consider in the review of the pharmaceutical legislation to introduce measures to restrict and optimise the use of antimicrobial medicines. Explore new types of incentives for innovative antimicrobials.	Commission	Part of revision of basic acts.	2022
4.	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 and new diagnostics, promote the prudent use of antibiotics and communication to healthcare professionals & patients	Commission, Member States	Measures to reduce excessive and inappropriate use incl. product information, guidelines on diagnostic tests, information, training, and education of HCPs, adequate disposal of unused medicines/antibiotics, environmental friendly packaging and manufacturing practices.	2021
Prioritising unmet medical needs				
5.	Propose to revise the legislation on medicines for children and rare diseases to improve the therapeutic landscape and address unmet needs through more tailored incentives	Commission	Part of revision of O/P legislation. ***Point discussed in detail in the morning session.***	2022
6.	Facilitate collaboration on unmet needs and evidence	Commission	Define/set criteria for unmet need in the different	2021

	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		contexts. Discussions among stakeholders, regulators in joint meetings of the Commission's consultative committee's (Pharmaceutical Committee, STAMP, payers') and in the Health Policy Platform	
7.	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	Commission	Part of revision of basic acts.	2022
8.	Enable parallel scientific advice on clinical study design for medicines by HTA bodies and the EMA, as provided for by the proposed HTA Regulation	Commission	Parallel scientific advice between regulators, HTA bodies and other players.	2021
Ensuring patients' access to medicines				
9.	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.	Commission	Part of revision of basic acts.	2022
10.	Review the pharmaceutical legislation to address market competition considerations and thus improve access to generic and biosimilar medicines, including interchangeability and the 'Bolar' exemption.	Commission	Part of revision of basic acts.	2022
11.	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	Commission	Initiate a pilot together with the EMA and Member States, with the engagement of future marketing authorisation holders of medicines containing oncology and/or orphan indications as to their market launch intentions and reasons for non-launch if applicable.	2021

12.	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	Commission		2021
Ensuring affordability of medicines for patients and health systems' financial and fiscal sustainability				
13.	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	Commission	To be discussed in the Healthcare Payers Group	2021-2024
14.	Propose to review the pharmaceutical legislation addressing aspects that impede the competitive functioning of the market and to take account of market effects impacting on affordability	Commission	Part of revision of basic acts.	2022
15.	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	Commission	To be discussed in the Healthcare Payers Group	2021-2024
16.	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	Commission		
Providing a fertile environment for Europe's industry				
17.	Optimise the supplementary protection certificates system, to make it more transparent and efficient as foreseen in the Intellectual Property Action Plan	Commission		2022
18.	Legislative proposal on a European Health Data Space, enabling better healthcare, health research, innovation and evidence-based decisions	Commission		2021
19.	Establish by 2025 interoperable data access infrastructure for the European Health Data Space in	Commission		2021-2025

	order to facilitate secure cross-border analysis of health data; tested in 2021 with a pilot project involving EMA and national authorities			
20.	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	Commission		2021
21.	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	Commission		2022
Enabling innovation and digital transformation				
22.	Propose to revise the pharmaceutical legislation, to adapt to cutting-edge products, scientific developments (e.g. genomics or personalised medicines) and technological transformation (e.g. data analytics and digital tools) and provide tailored incentives for innovation	Commission	Part of revision of basic acts.	2022
23.	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	Commission		2021
24.	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	Commission		2021-2022
25.	Establish the secure federated access to 10 million genomes across borders for research, innovation and clinical applications, including personalised medicine	Commission		2025

26.	Full implementation of the regulatory framework for clinical trials, which supports innovative trial designs and a more patient-oriented medicine development	Commission	Discussed in the Commission expert group on clinical trials (CTEG) and clinical trials facilitation group (CTFG)	2021
27.	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	Member States/ EMA/ Commission	A pilot run by national agencies and EMA (at a second stage) will set up a framework for academia and not-for-profit organisations who wish to research the possibility of repurposing existing medicines for additional indications. ***A detailed update will be given in the morning session.***	2021
28.	Launch a vaccine platform to monitor the effectiveness and safety of vaccines supported by an EU-wide clinical trials network	EMA/ECDC		2021
29.	Strengthen support and training of academia and non-for-profit organisations in regulatory science for better translation of research into product development	Commission		2022
30.	Initiative for regulatory pilots in a 'sandbox' environment provided by the EMA and the Commission to test the adaptability of the pharmaceutical frameworks for new cutting-edge product developments	EMA/ Commission – Follow-up with the Agency		2022
A sound and flexible regulatory system				
31.	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	Commission	Part of revision of basic acts.	2022
32.	Proposal for revised EMA fee legislation	Commission		2021

33.	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	Commission	Part of revision of basic acts.	2021-2023
34.	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	Commission	Part of revision of basic acts.	2022
35.	Consider adapting regulatory requirements in the pharmaceutical legislation, applicable to medicines for human use that contain or consist of genetically modified organisms (GMOs)	Commission	Part of revision of basic acts.	2022
36.	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	Commission		2021
37.	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	Commission	Part of revision of basic acts.	2022
38.	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	Commission	Part of revision of basic acts.	2022
39.	Simplify and streamline the system of penalties to address non-compliance in a proportionate and efficient way	Commission	Revise the penalty regulation.	2024
Enhancing Europe's health crisis response mechanisms				
40.	Proposal for an EU Health Emergency Response Authority	Commission	Creation of the Health Emergency Response Authority	2021
Secure the supply of medicines across the EU and avoid shortages				

41.	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	Commission	Part of revision of basic acts. Ongoing study, results expected in September 2021.	2022
42.	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 options and propose actions to strengthen the continuity and security of supply in the EU	Commission	To be discussed in the ad hoc subgroup on security of supply	2021
43.	Consider actions to ensure that the industry increases the transparency on the supply chains through voluntary process	Commission	To be discussed as part of the Structured Dialogue	2021
44.	Encourage MS 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	Commission	To be discussed in the ad hoc subgroup on security of supply .	2021-2022
45.	Promote WTO-based actions to increase the resilience in global supply chains in essential goods	Commission		2021
High quality, safe and environmentally sustainable medicines				
46.	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	Commission	Part of revision of basic acts.	2022

	environmental sustainability, safeguard the quality of medicines and ensure preparedness for new manufacturing technologies			
47.	Propose to revise the pharmaceutical legislation to strengthen the environmental risk assessment requirements and conditions of use for medicines, and take stock of the results of research under the innovative medicines initiative.	Commission	Part of revision of basic acts.	2022
48.	Review the framework on good manufacturing practice and encourage inspections of good manufacturing and distribution practice to improve compliance	Commission		2022
49.	Work with the MS to enhance their capacity to participate in international inspection & audit programme	Commission		ongoing
50.	Engage with international partners through cooperation to ensure the quality and environmental sustainability of the API imported from non-EU countries	Commission		ongoing
51.	Assess with Member States 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	Commission /EMA	Follow-up with EMA in the context of nitrosamine lessons learned and explore possibilities in Article 57 database.	2022
52.	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	Commission	Actions under the strategic approach and links to the revision of the basic acts. To be discussed in the ad hoc subgroup on this subject	ongoing
53.	Engage with MS and stakeholders in developing best practices for decarbonising value chains	Commission		2021
Ensuring a strong EU voice globally				
54.	Work at global level, with the EMA and the network of	Commission	Continue to exercise leadership in key international	ongoing

	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		fora with a view to promote the EU model, share best-practices and advance regulatory convergence.	
55.	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	Commission	ICH guidelines and revisions of existing guidelines to enhance international harmonisation in line with the latest scientific developments. In bilateral relations with third countries, encourage membership in ICH and thus the uptake and implementation of international standards.	ongoing