MEETING WITH EU SOCIAL PARTNERS ON

THE PHARMACEUTICAL STRATEGY AND EUROPE'S BEATING CANCER PLAN

12 November, 12h00- 13h30

Virtual meeting

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1. Main messages

1.1. Session I: Europe's Beating Cancer Plan

Opening speaking points

- **I would like to start by thanking** you for meeting me today. Vice-President Schinas was very keen to meet with you also, and it is with much regret that he is unable to be with us today.

- As you know, President von der Leyen in her State of the Union speech, called on Europe to draw lessons from the current crisis and build a "European Union of Health".

- Yesterday (11 November) we presented our vision of a European Health Union and its concrete first building blocks with proposals to enhance the roles and competences of both the European Centre for Disease Control and the European Medicines Agency.

- The Europe's Beating Cancer Plan and the Pharmaceutical Strategy will be key components of this European Union of Health.

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- Let's turn our attention to the future Europe's Beating Cancer Plan.

- 2020 has been a highly **challenging year,** as many health and care services have been severely disrupted due to the **COVID-19 pandemic.** This has in particular affected cancer patients and those working to provide the best care for cancer patients.

- In these circumstances, Europe's Beating Cancer Plan remains a top **priority** for the Commission, and the plan will also address the impact of the current pandemic on cancer care.

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- **Cancer** is an issue which affects so many of us. It is a major cause of death and illness in the EU, and an enormous burden on our health and social systems, including the workforce and employers. In the EU, there are around 3.4 million cancer diagnoses every year, and the economic impact of cancer exceeds EUR 100 billion per year.

- We have held extensive **consultations** with stakeholders on the Cancer Plan, and has received nearly 2500 contributions, including one from the ETUC – thank you.

- Given the complex challenge posed by cancer, the Cancer Plan will be a **crosscutting priority** with many policy areas needing to contribute.

- We will therefore adopt a true '**Health in All Policies'** approach combining actions at national and EU level. The plan will be closely linked to other Commission priorities and policies, for instance in the area of employment and social policy, research and innovation, climate and environment, energy, education, agriculture, transport, and taxation.

- **Europe's Beating Cancer Plan** will promote a holistic and inclusive approach, putting patients at the centre through its four pillars: (1) prevention; (2) early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors.

- The objective of the **first pillar** of the Plan is to prevent the preventable through actions such as healthy lifestyle, environmental pollution and vaccination. This focus will also benefit other major non-communicable diseases.

- The **second pillar** on early detection of cancer will include actions to step up screening through better implementation of population-based screening programmes (breast, cervical and colorectal cancers).

- The **third pillar** on diagnosis and treatment will propose actions to ensure better integrated and comprehensive cancer care, and address unequal access to quality care and medicines.

- The **fourth Pillar** will look at survivorship and quality of life issues, such as rehabilitation, emotional distress, potential tumour recurrence, and metastatic disease.

- While EU **Member States are responsible** for their healthcare, the Cancer Plan will aim to support, encourage and strengthen the implementation of optimal cancer prevention and care for all citizens in Europe through a number of concrete actions and measures.

- Evidence shows that around 40% of cancer cases in the EU **can be prevented** through practices and actions targeted towards risk prevention.

- For example, reducing exposure to hazardous substances and radiation will contribute to cancer prevention globally and in specific settings, such as at the workplace where 52% of annual occupational deaths in the EU can be attributed to work-related cancers.

- As part of the Cancer Plan, the Commission very recently adopted an update of **the Carcinogens and Mutagens Directive**.

- The development of EU occupational safety and health legislation is **based on close dialogue** with social partners, who also play a crucial role in contributing to the **effective implementation** of the existing occupational safety and health rules and policies.

- Preparations for the EU Cancer Plan are progressing and I am pleased we are on track to present the plan by the end of this year.

- The input of the European Social Partners is critical in the fight against cancer, and this is why we'd like to hear from you today what you see as the main challenges that Europe's Beating Cancer Plan can and should address at EU level.

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- Understanding a complex issue such as cancer is a big challenge. I would like to raise the issue of **health literacy** and how to improve the understanding of health information and services, including improving people's access to health information and their capacity to use it effectively.

- The **European Code Against Cancer** is an initiative of the European Commission to inform people about actions they can take for themselves or their families to reduce their risk of cancer.

- **Employers and workers representatives** can play an important role in increasing health literacy, for instance through promoting the knowledge of the key actions of the code.

    - We are particularly interested in hearing your views on the role of employers and workers representatives in improving health literacy and actively promoting health and cancer prevention.

- Health and social care professionals have the responsibility to deliver good information and ensure that their patients understand the information provided. This requires good **training in communication skills**. At the same time, health and social care providers and their workforces are under more pressure than ever.

- In regard to this sector, what do you see as the key jobs, skills and investment needs, both currently and in regard to future trends?

- I would like to hand over to [redacted] from DG SANTE to moderate the discussion

[redacted]

<u>Closing speaking points</u>

- Considering that Europe has a quarter of all cancer cases and less than 10% of the world's population, it is evident that cancer is a **huge threat for Europe**.

- In addition to the Cancer Plan, the Commission will implement a new **EU4Health programme**, which will provide greater financial resources to address public health in general, and cancer in particular.

- Europe's Beating Cancer Plan is about building a more **coherent approach** to cancer, **strengthening partnerships** and **building links** between fields. Governments and

public health authorities alone cannot address the increasing challenges associated with cancer.

- An **active role** of employers, employees, and their representatives in health promotion and cancer prevention is needed to succeed.

- Successful cancer prevention requires **individual actions** to be supported by governmental policies and actions.

- Putting the **citizen at the very centre** of our work, we will pull together the efforts and expertise of different actors and stakeholders, and take a "**health in all policies**" approach.

- By increasing **health literacy**, improving continuous health **professional training** and addressing cancer risk factors, common to a number of other non-communicable diseases, this work will have a broad positive impact on citizens.

- This is an exciting time for cancer prevention and care. I thank you for sharing your views, and I look forward to seeing continuous **exchange of ideas** and **best practices** within the EU to defeat cancer – to increase our **knowledge** and **proactive action** in the area of cancer prevention and care. Let us now move to our next discussion.

1.2. Session II: The Pharmaceutical Strategy

Opening speaking points

- For the first time in many years, we intend, with the EU Pharmaceutical Strategy to be unveiled on 24 November, to take a holistic look at pharmaceutical policy and EU legislation to address today's and tomorrow's challenges but also grasp new opportunities. Over the past 20 years, we have continuously updated the framework through amendments here and there. However, this kind of patchwork approach is no longer sufficient.

- The ambition is simple: to create a future-proof system, and - needless to say in times of COVID-19 - a crisis-resistant system.

- With this objective in mind, the strategy will address long-standing challenges like access, availability and affordability of medicines for all European citizens – but it will also include ambitious actions to support: innovation of our industry, an open strategic autonomy and reinforcing the EU's global position as a place where medicines are developed, manufactured and made available to patients.

- The publication of the strategy is the first step in a project that will be implemented over the following years, with both legislative and non-legislative measures.

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- While a healthy lifestyle is essential for good health, medicines are still part of daily life. They are important not only for patients, but also for healthcare professionals, hospitals and pharmacies.

- The pharmaceutical sector is of strategic importance for the EU. It serves public health; it is the biggest sector for research investment; it contributes with to more than 1 million jobs in Europe; it has a trade surplus of more than EUR 100 billion.

- A strong pharmaceutical industry with research and innovation, investment and production in the EU, is essential, not only because it create jobs in the EU, but also because it is key to patients' access to medicines.

- Today, the pharmaceutical system is challenged by shortages, unequal access and affordability of medicines. These challenges have been even further exacerbated by the current unprecedented health crises.

- We need to recognize this and work together to improve the availability and affordability of medicines for patient and for the sustainability of health systems while supporting competiveness and innovation in the pharmaceutical industry.

- We also need to make the EU a hub for high-quality innovation for patients' needs, in a way that harnesses the benefits of digital and emerging science and technology and addresses environmental aspects in line with the objectives of a green economy.

- We are here today to discuss which elements of the Strategy are most important for employers and employees.

- I am very pleased that social partners have already contributed to the Strategy through our consultation and outreach activities. Thank you to CEEP and IndustriAll for your written contributions to the consultation. I am very pleased that social partners overall support the objectives of the Strategy.

- As I mentioned, the adoption of the Strategy is the first important step of a process. It is setting our common agenda for the implementation, process in which you will be closely involved.

- Only working together, will we be able to deliver on our commitment to create a future-proof, patient-centred pharmaceutical environment in which EU industry can innovate and flourish. You have an important role to play, and I look forward to discussing with you some of our key proposals in the area of health, which will also have an impact on the work force in the healthcare sector.

- With these issues already raised in mind, I am very much looking forward to the discussions on the three key questions:

    - What do you expect as future trends with regard to the sectors concerned by the pharmaceutical strategy, notably as regards jobs, skills and investment needs?

    - What do you see as challenges, which should be addressed at EU level in this regard?

- What are your positions and recommendations with regard to possible EU measures – legislative or non-legislative?

<u>Closing speaking points</u>

- Thank you very much for our exchange on the Pharmaceutical Strategy. I value and appreciate it.

- For the Strategy to be successful, it is crucial that the views from all interested parties are heard.

- Today's discussion on future trends and on proposals to address challenges at EU level have been very useful. They will inform our further work on the Pharmaceutical Strategy and its implementation.

- The Pharmaceutical Strategy will be presented on 24th November. It is an ambitious initiative shaping a comprehensive pharmaceutical policy for the next decades. We need to join our efforts to make it successful.

- I thank for your continuous support and contribution and I very much look forward to working with you to translate the objectives of the strategy into reality by giving patients access to affordable innovative and established medicines while supporting EU pharmaceutical industry to remain a world leader.

- In closing this meeting, I would like to thank you again for your openness today. I very much appreciate this opportunity to exchange views on these two priority initiatives. And I look forward to our ongoing cooperation on all health files.

[Meeting closed]

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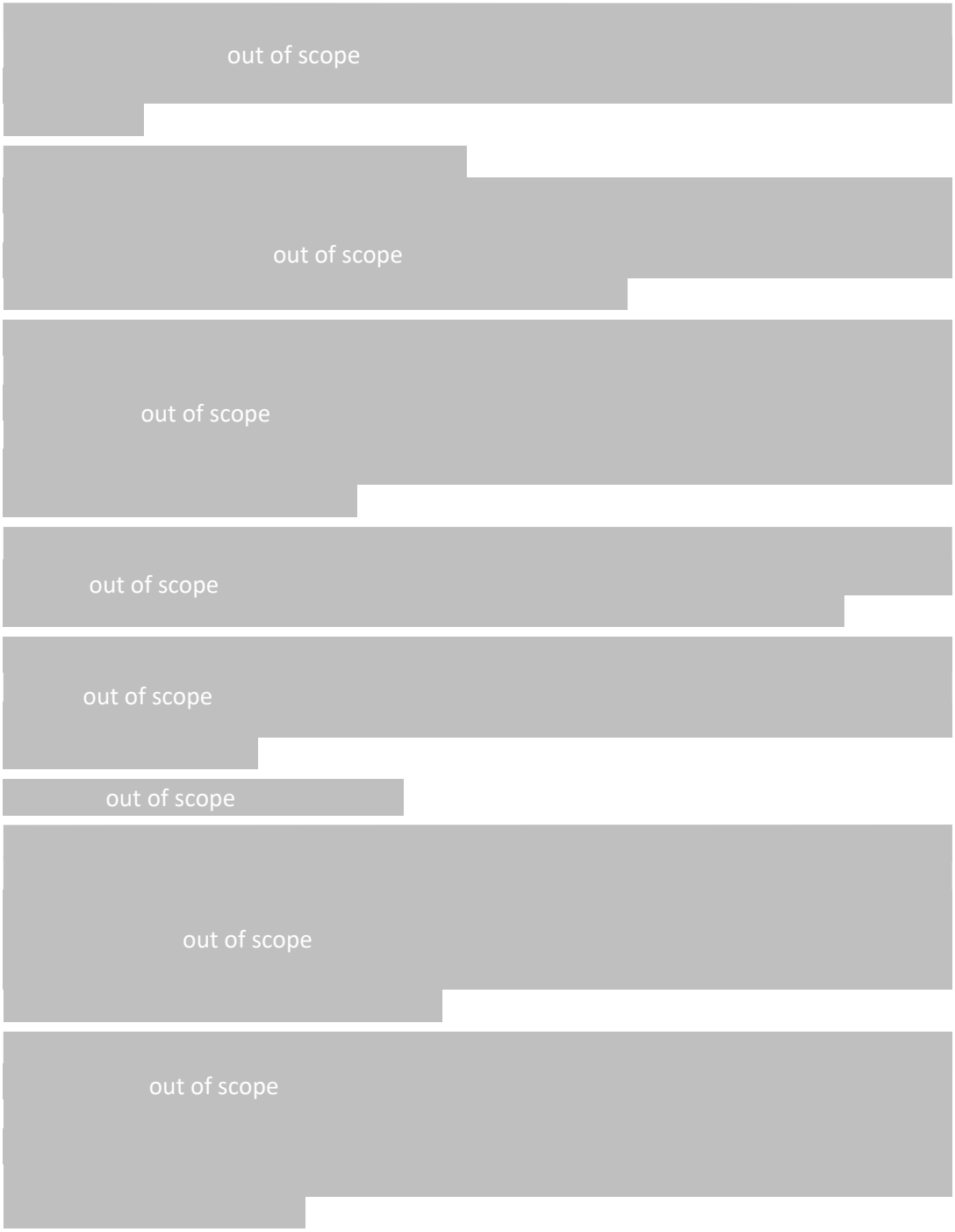
2.1. Europe's Beating Cancer Plan

State of play/background information

The Commission has received around 2,400 contributions to the roadmap and public consultations. The Commission has organised targeted stakeholder workshops around topics that required further discussion, such as on the impact of COVID-19 on cancer patients and care. An external contractor is currently producing an in-depth analysis of the results (consultations and workshops).



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2.2. Pharmaceutical strategy for Europe

State of play/background information

Skills and training are mentioned in the draft Pharmaceutical Strategy: a skilled and specialised workforce is a requisite for a competitive pharmaceuticals industry. The skills agenda for Europe is a tool in this regard and will also contribute to increase so-called STEM (science, technology, engineering and mathematics) skills.

The draft strategy also touches upon regulators' and public procurers' need for the right expertise and academia's need for training in regulatory science to better translate research into product development with accompanying actions.

Outside of the draft Pharmaceutical Strategy is how digital transformation of the healthcare systems requires new skills of healthcare professionals to handle e.g. e-product information for medicines, Electronic Health Records, a tailored approach in diagnostic and management of patients' health needs.

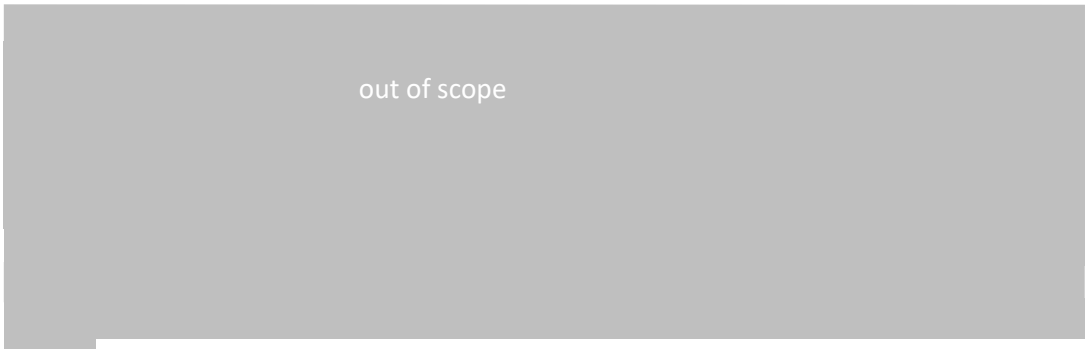
As stressed in the State of Health in the EU Companion Report 2019, this requires reforms in education and training with the broadest possible participation of relevant stakeholders (workforce planners, health professions' representatives, experts in education policy, national policy-makers, patients' organisations, higher education institutions delivering research, education and training).

There were already nearly EUR 1 billion invested from European and Structural Investment Funds (2014 to 2018) in more than 270 health workforce-related projects in 20 Member States. These projects aim at addressing shortages of qualified medical professionals, movement of healthcare workers across Member States, and at providing support for new and innovative curricula and educational approaches.

The new proposed Multiannual Financial Framework 2021-27 includes increased opportunities for digital training and upskilling of healthcare professionals.

The Pharmaceutical Strategy for Europe links to **Europe's Beating Cancer Plan** and will also endeavour that the cancer patients' perspective is taken into account early on in therapy development so that medicines are designed to improve tolerability and otherwise reduce treatment burden and increase associated clinical benefit.

Social Partners contribution to the Pharmaceutical Strategy

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3. Defensive points

Cancer Plan

3.1. Will the impact of COVID-19 on cancer be addressed in the Europe's Beating Cancer Plan?

Through Europe's Beating Cancer Plan, the Commission will support national cancer control plans with actions that reduce the impact of COVID-19 on the entire cancer pathway.

Through the new EU4Health programme, the Commission will be able to financially support the Member States and their health care systems. It aims to support not only actions on prevention, early detection, diagnosis and treatment, and quality of life for cancer patients and survivors, but also actions to reduce the impact of COVID-19.

3.2. What parts of the EU Cancer Plan will be addressed first in terms of priorities?

Once the EU Cancer Plan is adopted by the Commission, the key phase of implementation of its actions will start. The Cancer Plan will be accompanied by an Action Plan that sets out the target dates for the presentation of legislative and other measures under the Plan.

In addition, the prioritisation of certain actions/elements will be done in close discussion and cooperation with the Member States for instance through the Steering Group on Health Promotion and Disease Prevention.

The funds of the EU4Health Programme will be allocated according to the different objectives, priorities and needs, on the basis of annual work programmes.

3.3. Will commitments become binding once the EU Cancer Plan is made?

The EU Cancer Plan will set out a strategy to address cancer in the EU. It will first and foremost commit the Commission to take certain actions, either within its own mandate, or actions to support, coordinate and supplement Member States in improving cancer prevention and care.

The proposed actions will also seek to prioritise areas where the EU has direct competence or could deploy financial resources and common instruments in support of Member States.

The EU Cancer Plan will include a combination of legislative and non-legislative measures. In areas where the Commission does not have competence, possible action will be undertaken in close cooperation and agreement with the Member States.

3.4. How will the EU Cancer Plan coordinate with other international research/institutions such as the WHO or within Member States?

In order to make the EU Cancer Plan as inclusive as possible, an EU-wide consultation is currently ongoing to ensure that key concerns are heard and that input is collected from all stakeholders. This process includes also engagement with relevant international organisations such as WHO and IARC, as well as competent authorities in the Member States for instance through the iPAAC Joint Action (Innovative Partnership for Action Against Cancer).

Stakeholders have been given the opportunity to give feedback on the Roadmap and on the Public Consultation. Additional targeted stakeholder workshops are being organised around issues that deserve further discussion.

Cancer Plan and Occupational Safety and Health Issues (from DG EMPL)

3.5. How does the Commission propose to protect workers against exposure to hazardous medicinal products such as those used to treat cancer patients?

Existing EU rules already apply to this type of risk (in particular: the Framework Directive, Chemicals at Work Directive, Carcinogens and Mutagens Directive (when hazardous medicinal products are also carcinogens) and Pregnant and Breastfeeding Workers Directive (when hazardous medicinal products are also reprotoxics).

To further explore this issue, the Commission (DG EMPL) has launched an independent study to support the Commission's assessment on what would be the best option to further improve workers protection from the exposure to hazardous medicinal products, including cytotoxics.

Together with other stakeholders, the European Social Partners have been involved in this study, in particular through a targeted consultation, workshops and conference, to ensure that views are heard and taken into account in this assessment.

3.6. Why are hazardous drugs not included in the 4th amendment of the Carcinogens and Mutagens Directive? Why hasn't the Commission presented a way forward by end of June 2020 as committed?

In the frame of the third amendment of the Carcinogens and Mutagens Directive, the co-legislators requested the Commission to assess by 30 June 2020 the option of amending this Directive in order to include hazardous drugs or to propose a more appropriate instrument to ensure the occupational safety of workers exposed to such drugs.

But due to the COVID-19 pandemic, it was not possible to carry out the supporting study as planned.

This was due to the fact that the key stakeholders of this study – healthcare workers – were especially busy in this period providing essential care.

In collaboration with the stakeholders, the timeline was adapted in order to secure maximum involvement of the concerned parties to ensure a good quality of the study and – at the same time – avoid excessive delays.

Despite these difficulties, work is progressing as mentioned above.

3.8. Why did the Commission so far only set Occupational exposure limit values (OELs) for 26 substances, half of the 50 set as a target by 2020?

There is no Commission target of setting 50 Occupational exposure limit values by 2020.

This target was a request from the European Trade Union Confederation.

The way we proceed is that we identify and target priority substances. It is crucial to avoid competition and overlap with REACH in this respect.

Priority substances are selected based on clear criteria, such as the potential to cause adverse health effects, the severity of these effects and the number of workers exposed.

This is always done in agreement with representatives of workers, employers and EU Member States within the Advisory Committee on Safety and Health at Work.

Pharmaceutical Strategy

3.9. Will you review the Pharmaceutical legislation and if so, how will such review address the need for incentives for innovation?

We have preliminary ideas on limits and strengths of the current legislation. We are engaging with all relevant stakeholders to evaluate whether the system is future-ready and address its weaknesses in a holistic way. We welcome all arguments which we will carefully consider before making any policy decisions in the implementation phase of the strategy. Overall, this is not about turning the system upside down, but about a careful evolution.

3.10. How will COVID-19 influence the Pharmaceutical Strategy?

The Pharmaceutical Strategy aims to create a strong, efficient and flexible pharmaceutical system to take into account advances in science and technology.

While safety, quality and efficacy remain essential principles, our system must be ready to respond in a timely and coordinated way to crises like the COVID-19 pandemic.

The strategy aims to ensure better availability and access to medicines for patients across the EU, reduce shortages of medicines and international dependency on their supply.

These are all aspects that can help the system operate effectively and be ready to better respond to public health emergencies and their fallout (e.g. shortages of medicines).

We will integrate the early learnings from the current crises in the strategy to make it future proof and crises resistant.

3.11. Will the Commission set up a high-level pharmaceutical forum where industry, patients, political decision-makers and other stakeholders could discuss shortages and access?

Regular engagement with stakeholders is essential during the preparation and implementation of the Strategy.

The Pharmaceutical Committee extended to other constituents will be the main forum for active engagement.

Other activities will continue to be arranged to allow input from all stakeholders on the specific issues.

The Commission is not planning to establish such a forum right away, but the mechanism to engage with all stakeholders is being considered.

3.12. What will the Commission do to promote regulatory and administration simplification? And to improve conditions for generic and biosimilar medicines?

In the Pharmaceutical Strategy, the conditions for generic and biosimilar medicines will be considered both in terms of market access and the regulatory aspects.

Regulatory efficiency will be also considered as part of the Pharmaceutical Strategy and its implementation.

Both the reduction of administrative burden and use of digital tools, like the electronic package leaflet, will be explored for the implementation of the strategy.

3.13. Will Commission propose to reshore the production of medicinal products?

The Commission considers that what is necessary in the first place, is to gain better understanding of the supply chain design and identify its vulnerabilities. Only on this basis, and taking all other factors into account such as a necessity for better crisis preparedness, it will be possible to assess whether and to what extent there is a need for increasing certain critical manufacturing capacity in the European Union.

It is important to highlight that the EU will remain open and promote open trade. EU is, and always will be, relying on the international trade. Reshoring for the sake of it is not in the European interest.

3.14. How will the EU Pharmaceuticals Strategy address the environmental challenges?

To respond to the objectives of the Green Deal and green economy, for a more sustainable pharmaceuticals sector, the regulatory framework needs to address the challenges raised by the environmental pollution caused among others by the pharmaceutical residues, including those from antibiotics which are a major challenge.

It will address the whole life cycle of pharmaceuticals and will do so on the basis of the EU Strategic approach of pharmaceuticals in the environment, adopted by the Commission in 2019, that we are currently implementing with the Member States. We will take into account the EP resolution on this EU strategic approach in the implementation of the Pharmaceuticals Strategy.

3.15. How will the Pharmaceutical Strategy address hazardous medicines in the workplace?

The Pharmaceutical Strategy has a holistic approach to solutions to the challenges the pharmaceutical sector is facing. Safety in the workplace is important for the Commission. Outside of the Strategy, the Commission (DG EMPL) is carrying out a study supporting the assessment of different options concerning protection of workers from exposure to hazardous medicines (e.g. classified as toxic, carcinogenic, mutagenic or toxic for reproduction). The study is intended to provide robust information in order to identify the risks to workers' health that arise from exposure to such hazardous medicines in the workplace and explore the best ways to address these risks, including possible amendment to the Carcinogens and Mutagens Directive (CMD).

EU4H

3.16. How could the European Social Partners benefit of financial support for actions related to pharmaceuticals and fighting cancer?

The EU4Health proposal – under negotiation by the European Parliament and the Council – has specific objectives and implementing actions on both pharmaceuticals and on fighting cancer. Only actions implementing the general and specific objectives of the text finally agreed by the co-legislators, and included in the future EU4Health work plans shall be eligible for funding.

The eligible legal entities are those entities established in any EU Member State or an overseas country or territory linked to it, third countries associated to the Programme or listed in the work plans.

The programme does not limit participation to specific organisations or groups – so long as entities meet the conditions of the programme. The most important contribution social partners can make is in helping advise on actions to be taken to pursue the cancer and pharma objectives.

4. Annexes – CVs, agenda, etc.

- Invitation letter with summaries of the Pharmaceutical Strategy and Europe's Beating Cancer Plan