

Informeel Raad – interventies – 12 mei 2020

1. (10)(2a)
 - Thank you (10)(2e) I would like to thank the Presidency for convening this meeting in order to discuss the impact of the COVID-19 on EU market for medicines and the forthcoming Pharmaceutical Strategy for Europe.
 - Strengthened cooperation and coordination with the aim to improve access to medicines was one of the topics also during the (10)(2a) Presidency and we look forward to the discussion today.
 - There is an important link between the Pharmaceutical Strategy for Europe and the Industrial Strategy, since medicines are commodities, and an essential part of the Industrial Strategy and the Economic Recovery Plan.
 - The objective of the Pharmaceutical Strategy is, of course, even broader – it focuses also on the safety of medicines and patients. In our view, there is an urgent need to focus on incorporating health objectives into all policies that have relevance for access to medicines, including research, innovation, trade and competition policies. In addition, we should continue our efforts to find new ways to strengthen the strategic cooperation between the Member States. Despite all the measures taken, an overall outcome leading to improved access to medicines has not been achieved this far and the COVID-19 crisis has further deteriorated the situation.
 - As we stated in the Council Conclusions on the Economy of Wellbeing last October shortages and high prices of medicines, combined with inefficiencies in the use of generic and biosimilar medicines, can threaten the sustainability and financing of national health systems. This gives us a good basis to continue policy discussions on affordability and security of supply. Ensuring access requires efficient measures at all phases of the lifecycle of a medicinal product. This means that we need mechanisms to support research and development.
 - We also need controlled introduction and equal access to new medicines, price competition, and continuous supply of medicines and maintaining of old medicines on the market. All these steps should be sustainable, and take into account the needs of the national healthcare systems.
 - The COVID-19 pandemic has especially highlighted the need for measures that improve continuous supply of medicinal products. Europe's dependence on the supply of Active Pharmaceutical Ingredients and finished products from Asia is one of the challenges that should be addressed.
 - There is a need for both national fora between industry and authorities as well as a mechanism coordinated by EMA in order to provide an overall picture of the disruptions in access to medicines. The single point of contact network to improve information sharing between the Member States, EMA and the European Commission is a useful tool to coordinate actions to help prevent and manage shortages. Such cooperation should be further developed. We may need both approaches also to assess the needs of patients in the future. Thank you!
2. (10)(2a)
 - Thank you for calling the EU Pharmaceutical Policy on the agenda of today's meeting.
 - DEU welcomes that the HRV presidency aims to discuss concrete measures to tackle shortages and address their root causes while not omitting an overall strategic approach.
 - As stated: The COVID-19 pandemic demonstrates that medicinal supply for European citizens vastly depends on third countries as Active Pharmaceutical Ingredients (API) production is concentrated in those countries. Thus to reduce vulnerability, it is crucial to strengthen the EU autonomy in medicinal supply.
 - DEU sees three areas as key to address root causes for shortages: Improving inspections to ensure API quality, diversifying supply chains and setting financial incentives to relocate API production to the EU.
 - In this regard, a link between the EU Pharmaceutical Strategy and the EU Industrial Strategy as well as the Economic Recovery Plan seems to be beneficial. But it is of utmost importance to embed economic considerations in an overall health policy framework. We need specific instruments that go beyond general economic approaches to ensure the safe and sustainable supply of medicines in the EU. Furthermore, the regular dialogue between national competent authorities, EMA and EU-KOM should be continued and institutionalised to tackle shortages, especially during the COVID-19-crisis.
 - We intend to take up and to continue discussions on these important issues with a focus on concrete solutions during our presidency. The first opportunity will be the Informal Meeting of Health Ministers on 16th of July in a digital format.
 - EU Pledging Conference for vaccines and therapeutics on May 4 was a success

3. (10)(2a)
- Dear President, Dear Commissioner, dear colleagues,
 - I'd like to thank the (10)(2a) presidency for this initiative, as well as the opportunity to debate this important topic. Portugal also wishes to express its gratitude to all front-line workers, in particular nurses, in the International Nursing Day.
 - Recognising that pharmaceuticals are important for Europe's security and autonomy in today's world, would you agree that there is an important link between the Pharmaceutical Strategy for Europe to both the Industrial Strategy and the announced Economic Recovery Plan?
 - Even before the COVID-19 crisis, Portugal had already welcomed the forthcoming Pharmaceutical Strategy.
 - We fully agree that pharmaceuticals are essential for Europe's security and autonomy. This applies to medical devices, such as medical masks and ventilators. Therefore, we recognise the strategic role of these health technologies for our common security and autonomy.
 - Consequently, there is a link between the Pharmaceutical Strategy for Europe and both the Industrial Strategy and the announced Economic Recovery Plan. These instruments should also include a coordinated approach to the development of measures and policies to incentivize and encourage the production of essential health technologies in Europe.
 - In fact, this crisis has shown it is essential to have the capacity to respond autonomously to our population needs in a context of a health crisis.
 - In the pharmaceutical area, we support a holistic approach and its action through legislative and non-legislative measures.
 - The focus will be on availability, access and affordability, while ensuring transparency and collaboration.
 - The regulatory flexibility and simplification should be carefully considered, as well a possible link to other areas, such as medical devices. Recent experience has shown not only the interdependencies but also the need for harmonised approaches in specific circumstances, such as identifying supply and demand as well as shortages to avoid duplications and unnecessary allocation of resources.
 - It is our view that the current context has increased the urgency of rapidly developing a renewed pharmaceutical strategy, with the aim of adapting to the EU regulatory framework, using the new digital tools while focused on the needs of the health systems and the patients.
2. Taking into consideration the impact of the COVID-19 crisis on the internal market, which actions would you see fit for inclusion in the Pharmaceutical Strategy for Europe to address shortages on the EU market for medicines?
- Some initiatives regarding coordination of measures at national and European level can generate best practices to be applied beyond the COVID crisis, in particular the monitoring and management of data and the interaction and communication with stakeholders.
 - Other wide-ranging measures may assist in tackling shortages/availability as a whole:
 - complete mapping of the causes of shortages at European level;
 - a digital platform that centralizes information on shortages, able to generate an overview of its causes and trends;
 - market supervision risk-based approach strategies for entities and activities, ensuring the ability to detect and act in a timely manner;
 - the establishment of a European strategic reserve of medicines for human use and medical devices;
 - reassess the European public procurement system, making it more agile and less bureaucratic, especially when responding to crisis;
 - Overall, we consider the need to reinforce the regulatory framework by making clear the obligations of all parts of the supply chain, particularly the pharmaceutical industry, as well as to increase our coordination.
 - Reflecting on the possibilities for strengthening the communication between national authorities and stakeholders, would you see added value in establishing an appropriate platform for regular dialogue with stakeholders for specific topics or would you rather build on the mechanisms coordinated by EMA that have been put in place in the context of the COVID-19 crisis?
 - The strengthening of the communication between national authorities and stakeholders is essential, namely when situations such as the one we face are at stake.
 - Therefore, we support action towards reinforcing such communication by bringing added value at European level.
 - The COVID-19 crisis has shown the lack of sufficient EU mechanisms to respond to member State's needs, but also the importance of developing such mechanisms that could ensure more integrated EU responses and solidarity.

- The European Medicines Agency relies on a network of national agencies based on their capabilities and expertise. This model has proven resourceful and efficient in delivering good results. To provide concrete examples, we point out coordination and management of shortages, or rather, the managing its prevention, ensuring that medicines, particularly essential ones, are available and cover the needs of our health systems.
- Building on the mechanisms coordinated by EMA that have been put in place in the context of the COVID-19 crisis is another way of promoting communication.
- Thank you.

4. (10)(2a)

- Regarding to your first question, let me point out that we strongly support the important link between the EU Pharmaceutical and the Industrial Strategy.
- In the case of the COVID-19 crisis, there is a need to ensure self-sufficiency within the EU market regarding medicines, active pharmaceutical ingredients (API) as well as personal protective equipment.
- In this way we would be able to provide EU based medicinal products manufacturers with the best possible support in setting up production of the most essential active ingredients. In that way EU would not be dependent on the Eastern markets (like on (10)(2a)).
- There is a clear learning from Covid-19 pandemic and need, that there should be a much stronger, if not exclusive, competence at EU level in treating pandemic, or when dealing with drug shortages.
- In answer to the second question and regarding measures to be included in the EU Pharmaceutical Strategy, (10)(2a) believes that the soft approach used so far has not delivered sufficient results to resolve the issue of medicine shortages.
- Equal availability is a key aspect of a well-functioning single market, and this goes for generic and new innovative medicines. It is necessary to change the legislative framework to achieve equal availability, for example through joint procurement practices for interested Member States or by better implementation of EU competences.
- An effective EU-level mechanism should be put in place that would allow Member States to agree on medicinal products where a joint procurement would be of interest and provide the necessary support for the implementation.
- This action would address equal availability. It should be in place for centrally authorised medicinal products and old, generic medicinal products like cytostatic medicines. This is, in our view, a relevant issue also in the context of the Europe's Beating Cancer Plan.
- As we said before the parallel trade is not the appropriate single market solution to ensure availability in small markets.
- In addition, within the framework of the Industry policy the economic incentives for small and medium-sized enterprises specifically to address EU pharmaceuticals production should be established. This would positively contribute to the uninterrupted supply of medicinal products to all EU citizens, especially for essential medicinal products, including APIs.
- Further, we should also give additional boost to the cooperation of Member States in the field of pricing and reimbursement, such as through a dedicated joint action.
- Finally, we find it relevant to highlight the idea regarding vaccine and antimicrobials research. (10)(2a) proposes the establishment of a joint EU laboratory, for example within the Joint Research Centre, that would be also capable of immediate response to crisis situations.
- Last but not least, the feasibility of the public manufacturing of essential medicines at EU level could be explored.
- With regard to your third question, we fully support establishing an appropriate platform at the EU level.
- As we have already mentioned in the past, (10)(2a) would be in favour of the revival of the Pharmaceutical Forum which has been set up for the period from 2005 to 2008. This forum was established under the Vice-President of the Commission and the Commissioner for Health. The highest-level political representatives of Member States as well as industry representatives have had a proper dialog about accessibility, pricing and reimbursement as well ethical issues.
- In our opinion a revival of the Pharmaceutical Forum could really contribute to ensuring patient access to medicinal product and lead to sustainability healthcare systems.
- A lot of medicines data is gathered under Falsified medicines directive and the question is how to make most out of this data with Big data analytics. When we resolve this question, we would need to implement models to be able to forecast maximum and minimum medical needs in each country in various metrics (DDD, mg per capita, ...).

- Just to conclude, (10)(2a) is of the opinion that concrete action should be taken regarding pharmaceutical issues. I mean a concrete follow-up should be taken in order to be able to achieve fast and effective response to the possible medical crises in the future.

5. (10)(2a)

- Though the COVID-19 outbreak has more than ever highlighted the need for a secure and autonomous European supply of health products and active ingredients of medicines.
- France hence reaffirms the need for a European industrial strategy, including a pharmaceutical strategy, backed by an EU recovery plan, and calls as such for the health value chain to be formalized as an industrial ecosystem in September.
- In the current geopolitical context, the industrialization of pharmaceutical production (including the production of raw materials) on European soil could be a guarantee of security of supply, all the more motivated as new investments in production capacity would be supported by the growth in demand, both in Europe and in the world, and would reinforce the EU's strategic autonomy in the field of health.
- France therefore proposes that the Commission and the Member States investigate any incentive levers to develop investment in production capacities for active ingredients, raw materials and medicines on the territory of the European Union. They include financial support for innovation and for the industrialization of more efficient production technologies, as well as regulatory measure to harmonize and streamline procedures for the qualification of industrial lines within the European Union.
- France suggests, for example:
 - an evolution of the doctrine on Important Projects of Common European Interest (IPCEI), which could help diversify sources of supply particularly within EU;
 - Notifying shortages earlier, with the establishment of an alert system. A requirement to put in place plans for the prevention and management of shortages should be considered;
 - In addition, the EU should consider innovative storage strategies;
 - Implementing administrative simplification and regulatory flexibility measures with a view to a European marketing authorisation for essential old medicines with a high risk of rupture;
 - Finally, we should consider harmonising the packaging of medicines at European level, including the introduction of an e-notice, with priority being given to older medicines. This could facilitate the distribution of medicines in the event of shortages.
- To conclude, France supports the initiative of a platform for regular exchanges with stakeholders on specific topics. Indeed, enhanced communication on supply disruptions, alternatives and measures to ensure continuity of supply is essential between national authorities and stakeholders. Transparency and quality of information are necessary to concretely reduce the impact of shortages.

6. (10)(2a)

- Dear (10)(2a) dear commissioners, dear colleagues, first of all I would like to thank the (10)(2a) Presidency for the possibility to discuss this topic against the current epidemiologic situation.
- In this context, I would like now to answer the questions submitted by the (10)(2a) Presidency.
- Regarding the first question, in context of the current COVID-19 crisis, we agree that availability and security of supply of pharmaceuticals is crucial to ensure sustainable and high quality healthcare for European citizens. Therefore pharmaceuticals should be considered a strategic resource, essential for security and autonomy of Europe. Lessons learned have already shown that we must reflect on the ability of the European Union to mitigate the impact of global shortages caused by the pandemic. We should take action to avoid disruption of medicines supplies. Therefore, one of the steps should be to bring manufacture of critical pharmaceuticals and API (Active Pharmaceutical Ingredients) back to the EU. Such considerations are not new as we may recall our discussion from February on this platform and even before that. We have already mentioned that the coronavirus outbreak had revealed a weak point in our supply chain that needs a strategic discussion and change in our approach in securing availability of medicines and APIs (Active Pharmaceutical Ingredients) on the European territory. The CZ sees the New Industrial Strategy and Economic Recovery Plan as an excellent opportunity to further elaborate on this idea.
- Concerning the second question, it is necessary to emphasize that medicine shortages in the EU are frequently suspected to be caused by concentration of manufactures outside the EU. As

I have mentioned before, regulatory measures and possible incentives have to be considered. The other category of changes which could be made at the EU level are those related to reporting of manufacturing capacity and batch release for each Member State. Sharing such data would better prepare countries for possible shortage issues in the future. It would allow us to react before the shortage hits.

- Concerning the last question, it is necessary to seek solutions for better medicines availability, discuss them properly and cooperate on them. The COVID-19 outbreak shows that our efforts are still not organized optimally as similar issues are discussed at various platforms. I would like to warn against creating more and more platforms and further division of working groups concerning medicines at the EU level. This pushes Member States to a position where they subsequently take actions and adopt uncoordinated national measures to protect their respective public health systems. Both European Medicines Agency and individual Member States must adhere to their respective responsibilities in order to enhance the cooperation and exchange of information.
- Thank you for your attention.

7. (10)(2a)

- Thank you (10)(2a)
- I'm very grateful for the opportunity to discuss these issues today.
- Access to medicines and shortages affects us all. These very important issues have been even more emphasized by the current pandemic.
- As highlighted by the presidency, these are complex questions with multifaceted roots. Pharmaceuticals are all handled on a global market and equally we need collaborative solutions.
- In this context (10)(2a) welcomes the work on the Pharmaceutical Strategy for Europe.
- The Strategy can play an important role in establishing a common ground to tackle medicines shortages.
- It is important that the coming pharmaceutical strategy goes hand in hand with the industrial strategy, which highlights availability, affordability, sustainability and security of supply.
- There are a range of actions that should be considered to address shortages on the EU market for medicines.
- I would especially like to highlight three aspects.
- Firstly, we need to cooperate at EU level to fight the causes of shortages.
- We should give increased attention on how the EU can contribute to reducing the vulnerability in highly specialized production and distribution chains.
- This is clearly noticeable in the current situation, especially regarding substances that are being produced in just a few factories globally.
- I believe we should put clear common obligations on pharmaceutical companies that deliver to the European market in order to reduce the vulnerability.
- I also believe that we can start closer cooperation already within the current legislative framework.
- Secondly, I would once again like to highlight the importance of a functioning internal market.
- Internal export restrictions must be avoided.
- This is essential to ensure a maintained logistical flow and goes for active substances as well as for pharmaceuticals.
- Thirdly, we support and welcome the work that is now being done by the EMA, the European Commission and the national medicines agencies to monitor shortages during the pandemic.
- This work should be continued also in the long run since we need a clear picture of actual EU logistic flows, shortages and needs.
- Of course, it is however important to properly analyze the consequences of any changes.
- We must take into consideration the effects on patients and health care systems as well as the willingness to put and maintain products on the market.
- Finally, I would also like to stress some other important aspects to take forward in the Pharmaceutical strategy.
- We strongly believe that the strategy must properly addresses environmental concerns throughout the life cycle of pharmaceuticals, including production, use and waste management.
- This clearly connects also to the need to fight the development of antimicrobial resistance.
- As I have stressed before we must work together to respond to this pandemic. Solidarity in this regard is key.
- Thank you!

8. (10)(2a)

This strategy also mentions that a new EU pharmaceutical strategy will be put forward, focusing on the availability, affordability, sustainability and security of supply of pharmaceuticals. Hence, it is clear that both the Pharmaceutical Strategy for Europe and the Industrial Strategy must be aligned to achieve the common goals to secure availability of medicinal products for all patients in the EU.

It is of the utmost importance to make Europe attractive to bring back to the EU the manufacturing of medicinal products especially critical and active substances and decrease the current high-dependency from third countries, such as (10)(2a). This interdependency and its huge impact in Europe has become even more evident during the COVID19 outbreak.

Global supply chains have rendered a considerable increase in efficiency. We must retain at least part of this efficiency while we move towards a scenario focused on research, development and technology (RD&T) rather than trying to compete with high competitive markets. Europe should evaluate how to reach the necessary balance in this highly dependent scenario.

We highly appreciate and support the adoption a wider strategy including of course the industrial strategy.

2. *Taking into consideration the impact of the COVID-19 crisis on the internal market, which actions would you see fit for inclusion in the Pharmaceutical Strategy for Europe to address shortages on the EU market for medicines?*

It is true that bringing back manufacturers from third countries to the EU will decrease the dependency from these countries but this will not prevent shortages from happening since there are also other contributing factors.

At the end of the day, shortages are the final result of a unbalanced set of incentives. At the EU level, we must deploy incentives that make attractive to maintain supply to our markets irrespective on where the medicine is manufactured. Pharmaceutical Industry in Europe should be promoted and wisely incentivized.

It is important to retain competition in the market at a sufficient level of profitability, for example a review of old products with a high value and making them profitable would be needed or secure that products still in the competition sector do not end up in the group of non-profitable medicines when they are needed.

We should also explore how to increase the efficient entry of innovation on the market from a pan European perspective while ensuring the sustainability of Health Care systems and maintaining the welfare state as it is an identity feature of the European Union.

Finally, we should ensure that the same principles are applied to manufacturing sites both in the EU and outside the EU (not limited to GMP compliance but also other policies such as environment policies).

3. *Reflecting on the possibilities for strengthening the communication between national authorities and stakeholders, would you see added value in establishing an appropriate platform for regular dialogue with stakeholders for specific topics or would you rather build on the mechanisms coordinated by EMA that have been put in place in the context of the COVID-19 crisis?*

It is important to keep the dialogue and exchange of information within the network regardless of the fora.

During the COVID19 crisis, different additional mechanisms (such as the iSPOC) has been put in place which has meant an administrative burden for companies since they have been confronted with a duplication of work and very short timelines. They continued with their mandatory obligation to report shortages to NCAs and at they received a request to collect other information to report it to the EMA. The creation of these alternatives mechanisms do not have an added value and should be avoided over future.

We support the exchange of information through regular channels already established that can be accommodated to different situations, we also have structures in place within the network to escalate problems when there is urgent actions to make or a multinational action is required.

We truly believe that we need to maintain a regular dialogue at the European level with the stakeholders building it on regular mechanisms already in place and strengthening their capacity to be useful for Member States. To achieve this goal, we find it critical to have an homogeneous level of representation in all these fora.

9. (10)(2a)

- Dear Commissioners, Dear ministers,

- First of all, we would like to thank the Presidency for organizing this timely meeting and for proposing these questions.
- The new EU Pharmaceutical strategy is coming at right time. We have a long preparatory work behind us and we all have already learned a lot from the present crisis.
- I believe indeed that long term strategic thinking is needed at European level. The pharmaceutical strategy should encompass the complete scope of medicines (including vaccines) and medical devices, from cradle to grave.
- We can already draw several lessons from this crisis :
- We should be better prepared and we need a roadmap for the availability of medicines and medical devices in case of a pandemic together with management bodies and regular exercises. European coordination must be improved on the issues of medicines, medical devices and PPE and this is true for pandemic as for more local outbreaks and health emergencies.
- It is of utmost importance to better know, control and steer the European market including the production and distribution chains and their weaknesses. Transparency on production capacity, needs, stocks, prices and repartition keys at national and european level is needed. We should also use incentives to foster the diversification of production chains and reshoring. Dialogue with all stakeholders is of paramount importance in this regard.
- For PPE and medical devices, I note that we do not have enough European production and quality control capacities. I retain also that we lack notified bodies and fast track procedures for the certification of new producers of medical devices and PPE.
- I retain that reuse and in house production of medical devices are important issues in crisis time.
- For medicines, in crisis time, complete monitoring coupled with a controlled distribution is needed given the huge impact of stockpiling at all level on the market.
- In this regard, we have to be aware that about 70% of the drugs we need are at least partially produced outside Europe and that there are worldwide monopolies. Maybe should we consider placing new obligations to marketing authorization holders such as rolling stocks or having at least two active production sites ? We should also reflect on the issue of API production. It happens that for certain products only one factory remain worldwide, often far away... This combined with just in time production and limited capacity could cause troubles.
- Finally, we should not forget older challenges such as the fee regulation, the medical device regulation, the financing of common projects, the green deal, the place of real world data and AI in the approval of new medicines, the blood, tissues and cells directive, the anti-microbial resistance challenge, the availability of (older) medicines and the issue of pricing, including possibilities such as pay for value or pay for performance.

10. (10)(2a)

On behalf of (10)(2a) Deputy Secretary of State (10)(2e) drew attention to the fact that we are currently using drugs for the treatment of Covid -19 outside the indication, and it would be important to evaluate the experience with the use of antiviral drugs at the EU level. In addition, there is also a shortage of personal protective equipment and demand for new coronavirus vaccines is also expected to be high. Systemic epidemiological analysis and trend estimates should be part of strategic thinking not only at national but also at EU level. On this basis, our needs for medicines, vaccines and personal protective equipment can be better predicted and access to medicines and, hopefully in the near future, vaccines can be ensured in good time. We recommend the establishment of a partnership defined by health gains, involving all channels of production and wholesale. In addition, we believe that parallel trade regulation needs to be reviewed. The main goal is to achieve health benefits through the availability of the most effective antiviral drugs. Or we need to consider further options to ensure access to medicines at national and international level. We join those Member States that have emphasized the strengthening of autonomy in production and access to active substances. We will do our utmost to engage in dialogue and partnership in this area to better prepare for the potential future epidemic wave.

11. (10)(2a)

12. (10)(2a)

- First, let me thank the Presidency for organising this meeting and for the very relevant discussion paper.
- There is a strong need to discuss whether we have the right mechanisms in place to ensure that medicines, especially the critical ones, are available to all EU citizens when they need them.
- The COVID-19 pandemic has also shown the pressing need to reduce over-dependency on supply from outside the EU.

- We must cooperate with the European industry to ensure that more critical medicines and vaccines are developed and produced in Europe.
- Together, we must build a more resilient infrastructure to deal with unforeseen events, such as future epidemics and pandemics

Q1:

- (10)(2a) agrees that the linkage between the Pharmaceutical Strategy and the newly published Industrial Strategy is important, especially with regard to ensuring resilient supply chains.
- Our efforts should build on a well-functioning single market and sound principles such as free and fair competition, limitations on state aid and open markets.
- We need to strengthen our supply chain, so that the life science industry is not dependent on supplies from single countries or sources. Likewise, we must support efforts to make production more adaptable and flexible.

Q2:

- We need to take both immediate measures and long-term and well-founded initiatives.
- In the first phase, Member States should collaborate closely to:
 - build common European stocks,
 - increase critical pharmaceutical production, and
 - coordinate research efforts to develop an effective vaccine and treatments for the common good.
- In a second phase, these measures must be integrated into a broader strategy aimed at building resilience and general security of supply in the longer term.

Q3:

- Denmark supports transparency, dialogue and stakeholder involvement.
- It would be preferable if the dialogue with stakeholders can build on already established forums and platforms.
- Thank you.

13 (10)(2a)

- At our last meeting, we were blissfully unaware of the major crisis that was looming just around the corner. Today we meet at a distance to reflect on this COVID-19 pandemic, to see how it has impacted our pharmaceutical systems and to discuss how we can improve on our current systems.
- (10)(2a) struggle with securing the medicines that patients in (10)(2a) need, their affordability and prompt access to these medicines is well known from previous meetings and other communications. The COVID-19 pandemic simply highlighted and exacerbated the many flaws within the current EU pharmaceuticals market which had already been identified. Commercial biases, supply chain bias and rigidity as well as a dependence on a mere handful of key players are but just a few of the problems that we've been witness too as an EU throughout this crisis and previous incidents. As a European Union coming together to pool our resources we've been constantly reminded of how the EU is about Solidarity and Equality and the importance of ensuring medicines are available in a timely manner across the EU at an affordable price.
- These ideals do not end with the end of the COVID-19 pandemic nor are the problems of shortages and accessibility unique to this pandemic or any other crisis. They are a constant problem and unless, as a unified Europe, we decide to take firm action to address the root causes we will find ourselves discussing this same matter in the near future. In (10)(2a) accessibility, affordability and shortages continue to be a problem.
- It is important that we, as a European community, implement strategies and policies which would enable the establishment of a robust pharmaceuticals manufacturing market within the EU, especially with active pharmaceutical ingredients. On their own, these manufacturers could not possibly compete with competitors in third countries who have benefited from lower costs and economies of scale. The EU's dependence on a handful of players in one geographical region is just too high a risk to ignore, not to mention that it hinders any hope of growth and innovation within the internal market.
- Equally critical is that medicines must be made available across the ENTIRE EU, at the same time and at a price that ensures the sustainability of health systems. Bad practices need to be eliminated, transparency needs to be enhanced throughout the entire internal market and industry needs to be incentivised to approach the internal EU market as a single market and not the segregated pharmaceuticals market which it is today.
- The COVID-19 pandemic is a wakeup call for all pharmaceutical policy makers and strategists in the EU. We are at the mercy of players outside of the EU and at the whim of commercial

interests. The EU, when acting together, is powerful, it's a market of half a billion citizens! As member states acting alone, we are vulnerable. Together we need to not just discuss the flaws but to take immediate action, to implement strategies and regulations that will ensure the security of medicines supply, for all EU citizens equally and fairly.

14. ^{(10)(2a)}

- ^{(10)(2a)} welcomes the approach of the Presidency to ensure that the fundamentals of security, quality, accessibility and affordability are integrated into the new EU Pharmaceutical Strategy
- The increasing frequency with which we are all affected by medicine shortages, drawn into sharp focus by the current pandemic, means that we must act now to improve the security of supply for European patients. We should integrate real and urgent solutions into the new Pharmaceutical Strategy.
- This should not simply be about repatriating production back into Europe, but taking steps to improve the quality, robustness and resilience of all our pharmaceutical supply chains from source to patient.
- Turning to your questions. Enabling infrastructural and financial supports for sustainable innovation, while addressing access and affordability of medicines, will be essential to promoting and maintaining Europe's collective capability to provide for its citizens and equally contribute to its financial recovery.
- In relation to medicine shortages: medicines are not like any other goods. Therefore, an important fundamental should be that the reliability and resilience of pharmaceutical supply chains in Europe must be founded on quality and quality systems.
- Ireland's ongoing experience in preparing for Brexit has recognised the need for pragmatic solutions to secure medicines supplies within the regulatory framework. However, this has, at times, proven difficult. Through the promotion of regulatory and administrative simplification in a new Strategy, we can increase the availability and continuous supply of medicines to all Member States, in particular smaller ones like Ireland.
- Furthermore, by enabling pharmaceutical companies to embrace risk-based approaches, and the use of technology, we can facilitate suppliers to react more quickly when a medicine shortage is anticipated or has already occurred.
- Recent efforts to address medicine availability at a European level have been encouraging. We need to build on this cohesive and integrated approach by fully embracing the work of the HMA-EMA TaskForce. As a result, there may not be a need to establish new platforms, but rather this and other existing fora, such as the Pharmaceutical Committee, could be better utilised to improve communication and dialogue with stakeholders.
- Through Ireland's engagement with stakeholders in the context of Brexit and COVID-19, we have witnessed the benefits of such open dialogue for Irish authorities, patients and for the stakeholders involved. Ireland therefore sees a role for developing these platforms at national and European level.
- We look forward to hearing the views of other Member States over the course of this meeting.

15. ^{(10)(2a)}

- Dear Presidency, Dear Commissioners, Dear Colleagues,
- We would like to thank the Presidency for organizing this timely videoconference.
- The situation in medicines market remains very dynamic and sensitive to all the measures undertaken by both the EEA, and non-EEA countries. For the time being, we collect information about drug stocks not only from our wholesalers, but also from our hospitals on their needs and shortages. In general, our hospitals have enough medicines for the next two months. Supply disorders have been reported in some groups of medicines. Therefore, we are planning to procure a certain amount of these drugs into the state reserve for the autumn period.
- We believe that the most efficient way to tackle shortages on the internal market would be to address their multiple root causes. We highly support the Pharmaceutical Strategy for Europe and would like to suggest to include such measures as, closer cooperation mechanisms among Member States, information sharing, revision of EU Pharmaceutical legislation. A certain level of regulatory flexibility and legislative measures on pharmaceuticals such as earlier notification of shortages, transparency of quotas and wholesale transactions, or stockpiling requirements for pharmacies could also be considered. Merit could be seen in exploring digital solutions to optimize the implementation of the EU regulatory framework. Another possible measure could be oversight on the global manufacturing and supply chain of Active Pharmaceutical Ingredients. Also I would like to emphasize the importance of creating such market conditions that could potentially secure and bring back production of essential medicines and Active Pharmaceutical Ingredients, as well as manufacturing technology, to the EU.

- Last but not least, we would like to call all Member States for full use of Clearing House that Commission has launched. At least Lithuania, has actively used it and provided information about Lithuanian producers who converted their production to the areas that are needed to fight COVID-19. We believe, that Clearing House could be a first very concrete instrument to collect information at EU level and to see what is missing in our supply chains. We would appreciate more information from the Commission how we could build further on the a very good start that it was made since the beginning of Clearing House idea.
- Thank you.

16. (10)(2a) – geen interventie

17. (10)(2a)

- *1. Recognizing that pharmaceuticals are important for Europe's security and autonomy in today's world, would you agree that there is an important link between the Pharmaceutical Strategy for Europe to both the Industrial Strategy¹¹ and the announced Economic Recovery Plan?*
- We would like to thank the (10)(2a) Presidency for organising this videoconference, which is taking place in a phase aimed at re-starting and planning in different way the social-economic life as a part of health and wellbeing of our populations.
- In this regard, the importance of the Pharmaceutical Sector is absolutely central for the recovery plan as it will imply a consolidation and a rethinking of the best ways to ensure the coupling of solid and transparent evaluation of new treatments and vaccines with the full availability in a sustainable and affordable way. We need to cooperate more and develop new ways to ensure higher production capacity for the new treatments and vaccines once approved.
- We would like to take this opportunity to stress the innovative law that was approved in (10)(2a) during the current Covid19 epidemic. Now all clinical trials on new treatments for COVID 19 are evaluated by the National Regulatory Agency for Pharmaceutical products (AIFA) and, subsequently, by only one Research and Ethics Committee at the National Institute for Infectious Diseases "Lazzaro Spallanzani" (4). This led, as of April 24, to 114 clinical trials having received an assessment. Of these, 26 (22.8%) were approved, 13 (11.4%) suspended for further clarifications, 64 (56.1%) rejected and 11 (9.6%) are under evaluation (5). The centralised procedure allowed the Agency to use the clinical trial approval pathway to reinforce the pivotal role played by best available evidence to inform clinical practice and to support the emergency governance.
- Lessons learnt during this difficult emergency are towards the integration of different streams of work such as:
 - The need to define standard treatment and standard of care with respect to both efficacy (based on very preliminary data and negative findings) and safety to avoid potentially harmful combinations.
 - Progressively define high methodological standards for clinical studies nudging the research community towards randomised pragmatic multi arm and bigger trials.
 - Have a governance role for optimal drug use by providing reliable information based on best available evidence on both efficacy and safety data for various subpopulations.
 - Underscore the need to rapidly scale up intensive care unit capacity and the need for highly trained health care personnel that was the backbone for the response to Covid19.
- These four streams have been integrated, at National level, by simultaneously working on improving clinical trial design, increasing information on drugs and encouraging optimal use of them in a difficult and rapidly evolving emergency environment. Overall, the Italian NHS was the most effective answer to this Covid19 epidemic and we need to strengthen it for the future preparedness.
- *2. Taking into consideration the impact of the COVID-19 crisis on the internal market, which actions would you see fit for inclusion in the Pharmaceutical Strategy for Europe to address shortages on the EU market for medicines?*
- To define actions against shortages it is important to differentiate the different types, requiring different solutions:
 - "medicine shortages due to manufacturing issues" (related to problems of the Marketing Authorisation Holders (MAH companies), which report them to the competent regulatory agency),
 - "unavailability of medicines" (related to distribution problems)

- o "failure of hospital supply" (due to market distortions, possibly falling under the jurisdiction of the Antitrust authority).
- The (10)(2a) approach, which for years has privileged the sharing of actions between administrations, individuals and associations through a dedicated forum (the "Ad hoc technical board for medicine unavailability", also used to manage the crisis), represents a model that is deemed useful to extend to a European level.
- 3. *Reflecting on the possibilities for strengthening the communication between national authorities and stakeholders, would you see added value in establishing an appropriate platform for regular dialogue with stakeholders for specific topics or would you rather build on the mechanisms coordinated by EMA that have been put in place in the context of the COVID-19 crisis?*
- It is important to keep EMA in a coordinating role to accelerate the activities related to new drugs and vaccines approval and availability/shortages.
- However, there are areas such as production and scaling up that would benefit from an involvement of the economic sector with a re-thinking of current approaches in a more collaborative way. Next preparedness plans would benefit from a stronger EU collaboration.

18. (10)(2a)

- Dear (10)(2a) and Commissioner, dear colleagues,
- We would like to thank (10)(2a) presidency for organizing this video conference and bringing this important issue to the attention of Health Ministers. Latvia sees great added value in the efforts to implement measures and find solutions at the European Union level to tackle the problems of access to medicines and shortages.
- Regarding the first question, following the principle of "health-in -all-policies" we should work hand in hand with our colleagues from ministries of economy and finance. We recognise the link between the European Union's Pharmaceutical Strategy, the Industrial Strategy and the Economic Recovery Plan.
- About concrete actions, we are sure that all efforts and initiatives at the European Union level striving to make medicines more accessible and addressing shortages, should be welcomed especially in times of public health crisis. In our view, initiatives to promote the production of critical active substances in the European Union should be considered. Given that production costs in Europe will be higher than in Asian region, European producers should receive comprehensive support to boost their competitiveness.
- Regarding the issue of matching supply and demand, consideration could be given to setting up a centre of excellence at European level to forecast the demand for medicines. These forecasts should consider not only historical consumption data, but also morbidity, mortality forecasts and risk analysis, and a common methodology should be used for data processing throughout the European Union.
- Let us emphasize that differentiated approach to the market for medicines in various Member States should be avoided when supplies to major markets are initially resumed after supply disruptions.
- There must be a debate on the affordability of medicines and possible mechanisms to prevent price speculation, not only at national level but also at European level.
- We believe that support measures should be designed to create cooperation between large and small companies, thus promoting the participation of all EU companies in industrial ecosystems.
- Regarding the third question, we are concerned about setting up additional structures, given that existing forms of cooperation, already offer a good opportunity to address various problems, even in times of crisis. Consequently, the exclusive centralization of communication could delay communication in crisis situations. Therefore, we are more in favour to support the existing communication mechanisms, which could only be supplemented by a centralized communication channel, but not replaced by it.
- We suggest for consideration the development of a single electronic contact database for all manufacturers of medicinal products and authorized marketing holders, as well as manufacturers and importers of active substances.
- Thank you for your attention!

19. (10)(2a)

- Dear Presidency, dear Commissioner, dear colleagues,
- During recent years, access to medicines has been on the agenda in a number of formal and informal fora, including EPSCO councils.
- This issue has been further aggravated due to the current coronavirus crisis.

- Medicine shortages are a European cross-border health threat which must be urgently addressed through a coordinated and coherent European approach.
- Therefore we welcome these timely discussions on the upcoming European pharmaceutical strategy.
- Before turning to your three questions, I would like to raise a point that is particularly close to our hearts: as I have already mentioned at recent meetings of health ministers, I would like to reiterate that the precondition for any action under the European pharmaceutical strategy is that all border restrictions must be lifted in order to keep trade flows open, ensure the free movement of goods and guarantee the integrity of the internal market.

Question 1: Recognising that pharmaceuticals are important for Europe's security and autonomy in today's world, would you agree that there is an important link between the Pharmaceutical Strategy for Europe to both the Industrial Strategy and the announced Economic Recovery Plan?

- (10)(2a) agrees that timely access to high quality and safe pharmaceuticals is important for EU's autonomy and health security.
- In that sense, pharmaceutical development should be accompanied by EU and national investments in capacity-building and support for the transition to sustainability and digitalisation of the sector.
- While aiming at reducing regulatory burden in order to improve market access, one must not forget that EU member states need to keep a fair and appropriate benefit-risk assessment.

Question 2 : Taking into consideration the impact of the COVID-19 crisis on the internal market, which actions would you see fit for inclusion in the Pharmaceutical Strategy for Europe to address shortages on the EU market for medicines?

- Shortages of medicines is a complex issue that needs to be tackled on several fronts.
- One of the reasons for shortages and supply disruptions is that the medicines' supply chain has become longer, more complex and fragmented as companies have delocalised a large part of production of medicines outside the EU.
- It is therefore essential that we make our open and rules-based trade more resilient for our businesses. The EU must provide for a stable and predictable framework in order to avoid any further shortages. We also call upon the Commission to consider the launch of plurilateral negotiations at the World Trade Organisation on the basis of the existing Agreement on trade in pharmaceutical products in order to further facilitate trade in pharmaceutical products. It is important that the EU takes a leading role in restoring global dialogue.
- At the same time we should aim for more "strategic autonomy" by building more resilient supply chains, based on diversification. The EU has to reduce its dependence on supply from certain third countries and we therefore call upon the Commission to analyse and identify weaknesses and dependencies in our current supply chains.
- In addition the industrial and pharmaceutical strategy should include legislative measures, policies and incentives to strengthen the competitiveness of the European market and encourage production of essential APIs and medicines in Europe to guarantee supply at all times.
- In that context, monitoring of available stocks and anticipation of potential shortages of critical medicines need to be transparent and available from all involved parties, including visibility on parallel trading. Information sharing is key in order to avoid unnecessary stockpiling that further stresses the market.
- The pharmaceutical strategy should focus on the establishment of a network - along the lines of the "early warning and response system" used for cross-border health threats - with the aim of enabling early notification of alerts on supply disruptions and sharing of measures envisaged by Member States to prevent and mitigate these events.
- This network could be supported by the establishment of continuous monitoring at European level of events that could lead to disruptions in the supply of medicines.
- In addition, we would call upon the Commission to carry out a periodic assessment of the Union's supply of medicinal products and active substances which would serve as the basis for updating guidelines on good manufacturing and distribution practices while including provisions on minimum production capacity, storage of raw materials and exploring ways to address strategic stockpiling within the EU.

Question 3 : Reflecting on the possibilities for strengthening the communication between national authorities and stakeholders, would you see added value in establishing an appropriate platform for regular dialogue with stakeholders for specific topics or would you rather build on the mechanisms coordinated by EMA that have been put in place in the context of the COVID-19 crisis?

- The EMA has already set up mechanisms that could be built upon. However, we would welcome a common strategy and coordination between the EMA, the European Commission and the

Council in order to avoid duplication and to maximize the outputs of the initiatives already undertaken.

- Moreover, I would very much welcome the knowledge generated from OECD contributions to the COVID-19 crisis as well as other global initiatives for pharmaceuticals (as well as vaccines and medical devices).

20. (10)(2a)

Dear colleagues,

- The Netherlands would like to thank the (10)(2a) Presidency for arranging this video conference.
- Furthermore we thank the European Commission, the European Medicine Agency and the European Center for Disease Control for their good work.
- In the Netherlands we have seen positive developments with regards to COVID-19 patients in hospitals over the last days.
- It seems like we are on the right track. But it is far too early to say we are winning the battle.
- The Covid-19 crisis underlines, more than ever before, the importance of a European Pharmaceutical Strategy.
- Urgent action is needed.
- The publication of the roadmap for the Pharmaceutical Strategy is unfortunately and, at the same time understandably, delayed due to this crisis.
- It becomes clear that we should decrease the vulnerability in the production and distribution process of medicinal products.
- The Netherlands very welcomes a discussion on a and is willing to cooperate intensively with the Commission in preparing the Pharmaceutical Strategy and the resulting Action Plan.
- The Council should provide clear input to the Commission for the Pharmaceutical Strategy, it should become a joint effort of the Member States and the Commission.
- I share the analysis of the Croatian EU-Presidency that there is an important link between the European Pharmaceutical Strategy and the Industrial Strategy as well as the announced Economic Recovery Plan.
- They should not be seen in isolation.
- The Pharmaceutical Strategy should cover many topics, but in relation to shortages, we consider the following issues important:
 - An in depth investigation to the causes of the increased vulnerabilities of the production and distribution. I look forward to the outcome of this study, initiated by the European Commission, on which we hopefully can start a discussion as soon as possible;
 - More coordination at European level in the overview of shortages, demand and supply;
 - Based on the results, a robust consideration on how the supply of medicines in Europe can best be guaranteed; for instance to stimulate more development and production within the EU.
 - An integral approach is necessary, where the interest of public health should be leading.
- We see added value in establishing an appropriate platform for policy discussions with all relevant stakeholders for specific topics, next to the mechanisms coordinated by the EMA.
- The mandate of the EMA is limited to regulatory issues, whereas shortages can not only be solved by regulatory actions, but an integral approach is needed.
- Let me conclude by congratulating and thanking the nurses of Europe on this international nurses day in these difficult times.
- Thank you

21. (10)(2a)

- Firstly, I would like to thank the PRES for organizing this videoconference. Let me also to apologize the absence of (10)(2a) Minister of Health, who was unable to attend this meeting, but sends his greetings.
- Shortages of medicines is a growing problem in Europe, affecting all classes of medicines and has detrimental effects on patient care. The global nature of COVID-19 pandemic has increased the risk of medicines shortages and also showed EU dependency on manufacturing of APIs and finished medicines in the third countries.
- We agree there is an important link between the Pharmaceutical Strategy for Europe to both the Industrial Strategy and Recovery Plan, because they all aim to boost production in the EU.

COM suggests in the Guidelines on the optimal and rational supply of medicines that *Pharmaceutical manufacturing should be seen as an essential activity and Member States should support industry increasing their manufacturing capacity, in particular through fiscal incentives and State aid.*

- We would like to underline that the incentives to pharma industry must reflect the market needs but at the same time be beneficial to patients. We also agree that EU should increase production of pharmaceuticals and APIs in order to be less dependent on supply from the third countries. But it does not mean that pharma industry picks only cherries in the form of incentives and when it comes to delivery, they forget about fair and affordable pricing.
- We are aware, there is no "quick fix" of shortages problem, but we expect the new Pharma Strategy to suggest long-term EU solutions of supply chain problems linked with manufacturing of APIs as well as with manufacturing and fair distribution of vaccines.
- Strategy should also touch the problem of parallel trade, which still persists in many countries. In this respect, we think that Pharma Strategy should cover specific definition of medicine, which is not ordinary good, but good with specific properties- to treat patients. All proposed activities and measures must go hand in hand with respecting national competences.
- Shortages could be better prevented if Member States join forces. On EU level, we can succeed in solving this issue through early dialogue with stakeholders and regular mapping of the situation. In this regard, we do not see any added value in establishing new communication platform. In our opinion, early dialogue can be coordinated by EMA and it should take place in existing foras in order to avoid duplication of activities.
- To conclude, let me emphasize that strong protection of human health is a central objective of the EU public health policy. To guarantee this objective, high standards of quality and safety of medicinal products are essential. Our goal should be to secure accessible treatments for all EU patients.
- Thank you for your attention

22. (10)(2a)

Thank the Presidency for organising this meeting.

(10)(2a) believes that a number of concerns and challenges exist in the EU-pharmaceutical system, in particular in the field of accessibility, availability and affordability. The Pharmaceutical Strategy for Europe needs to take a comprehensive view of both the demand and the supply side and consider the balance of the two. The economic crisis brought about by the pandemic may affect the demand and affordability of medicines being used in the treatment of patients. It is important that the Pharmaceutical Strategy addresses the chronic problems with the current framework and does not focus exclusively on the industrial aspects, thus bringing back the manufacturing back to Europe, which (10)(2a) also supports.

In this respect the issues and priorities identified and under discussion in the pharmaceutical policy area need to be viewed from a broader perspective. Weaknesses in the pharmaceutical framework have further emerged during the current crisis. Common challenges, which need to be addressed holistically, have been identified both from an industrial and strategic pharmaceutical approach.

The critical priorities identified by the Pharmaceutical Committee are a step in the right direction. Keeping in mind the COVID-19 impact, (10)(2a) considers further focus on the following topics:

- Enhance Transparency in the pharmaceutical market, in particular price Transparency. The EU market is fragmented at Member State level and price secrecy further increases this fragmentation
- *Ensure access and affordability while addressing shortages, and unmet needs* - such as improving the market launch of Centrally Authorised Products
- *Ensure security and oversight of the global manufacturing supply chain – such as the reducing dependency on Active Pharmaceutical Ingredients from third countries especially for "strategic" medicines and vaccines.*

Regulatory efforts, actions and flexibilities taken at European level to mitigate the COVID-19 impact on certain critical medicines need to be considered as long term solutions to address shortages on the EU market for medicines:

- The COVID-19 pandemic has brought to light how unilateral, reactionary, protectionist measures affect the availability of medicines and medicine shortages across the EU. The lessons learnt so far from the COVID-19 pandemic should be kept in mind and used for further investigation on the root causes of medicines shortages when identifying solution strategies.
- The COVID-19 pandemic has brought about challenges of medicine shortages which stem both from an increased demand, as well as from a reduced supply. We have also observed an

Increased use of certain drug classes such as anaesthetics, antibiotics, muscle relaxants and analgesics. From a supply point of view, the supply chain has been affected by unilateral export bans and stockpiling which resulted in supply problems. To this end, in a spirit of European solidarity, export bans within the internal market need to be minimized and stockpiling needs to be rational. Supply has also been affected by a decrease in production and reliance on third countries.

- Resilience of the supply needs to be supported while ensuring and increasing production. To this end, measures to support full manufacturing capacity are to be considered, especially with regards to essential products and products at risk of shortages.
 - Flexibility of regulatory measures needs to be increased as it enables adequate supplies, helps maintain manufacturing capacity and ultimately helps prevent medicine shortages. For example, procedures for changes in suppliers,
 - Improvements to communication flows in the context of shortages also need to be considered to enable earlier notifications of interruptions of supply. The onus of responsibility on suppliers with regards to early notification of interruptions needs to be reinforced. EU-wide communication on issues regarding shortages also needs to be supported to enable European approaches, for example, re-distribution of stocks across the EU or joint procurement.
- (10)(2a) agrees with establishing appropriate platform for regular dialogue between national authorities and stakeholders in order to be able to prioritise and address any country specific issues. However, it is still of benefit to maintain and further strengthen on the EMA coordinated mechanisms to tackle common matters related to shortages.

23. (10)(2a)

- We would like to **thank the Presidency** for following up on the December Council meeting and organising a debate on pharmaceutical strategy and shortages at this videoconference.
- Over the past few months, our health systems have been through challenging times, which has taught us **valuable lessons**.
- The COVID-19 crisis has once again **demonstrated the reality of unequal distribution of medicines** in Europe and serious disruptions in supply chains. **This** is why the debate on a common EU pharmaceutical strategy is **timelier than ever**.
- In Estonia, to combat the problem of shortages and to protect our patients we signed voluntary **cooperation agreements with some wholesalers of medicinal products** to secure stocks of essential medicines for 2 months during the state of emergency.
- We agree that excessive stockpiling should be avoided. At the same time, a **reasonable reserve at wholesale level** has proven to be effective to secure continuous supply in cases of unexpected events. We believe this deserves a discussion at the EU level to have common principles.
- In order to **decrease the risks of supply in the EU** we should set **clear obligations to the industry** (manufacturers, marketing authorisation holders and wholesale distributors) to have certain **risk mitigation measures** in place to prevent shortages. These obligations would work best if set at the EU level. For example, manufacturers should have **alternative solutions** to obtain active pharmaceutical ingredients in case of disruptions.
- The **flexibilities in the regulation** available already today should be used fully, for example exemptions from the packaging rules, and should be based on a uniform approach in the EU.
- To make progress, it is essential to **engage all stakeholders** when discussing the way forward in Europe's pharmaceutical policy. We believe that the EU stakeholder forum should **focus on concrete steps and actions** and have result oriented debates.
- Thank you!

24. (10)(2a)

- Thank you also for the opportunity to address today the very sensitive issue of the EU-wide medicine shortages, a long-standing issue that was unfortunately exacerbated by the recent COVID outbreak.
- 1. The health in all policies approach is the guiding principle of our health governance, emphasizing the need to articulate health considerations into policymaking across sectors to improve the health of all communities and people. The COVID-19 pandemic posed unprecedented challenges in ensuring the continuity of supplies of medicines, questioning the sustainability of our healthcare systems, and posing our patients at risk. Therefore, it is essential the pharmaceutical strategy also addresses the economic roots of the shortages and proposes measures to strengthen and extend the existing manufacturing EU base with the aim to provide supply chain resilience. Moreover, these measures must be echoed in both the

Industrial Strategy and the Economic Recovery Plan with measures stimulating investments in both pharmaceutical manufacturing and R&D with a focus on incentivising manufacturers. The linkages between the three strategic frameworks will not only address the Single Market concerns and reduce external dependence and utterly important provide the equitable access to medicines, but also will build on leveraging the impact and EU competitiveness on the global stage.

- 2. The discussion document proposed by the Croatian Presidency already provides for a good starting point for an efficient pharmaceutical strategy. Besides the economic perspective that would focus on creating market conditions that reward security of supply, we may add on regulatory measures, the uniformization of the HTA procedures, pricing policy at EU level, earlier notification of shortages through a unique monitoring mechanism for the single market. It is an urgent need to establish harmonised and accurate ways of reporting shortages. Regulatory reform to reflect the digital transformation and technological progress could be also considered.
- 3. Strengthening the communication between national authorities and stakeholders is essential in the effective management of pharmaceutical issues, so having an appropriate platform for regular dialogue with stakeholders for specific topics is undoubtedly beneficial. We should however pay attention not to duplicate efforts with the mechanisms coordinated by EMA. At the national level, we recognize the importance of an appropriate platform for regular dialogue with stakeholders for specific topics and a cooperation protocol between the National Medicine Agency and the pharmaceutical industry on regular communication is soon to be put in place.

25. (10)(2a)

- Madam (10)(2a)
- dear Commissioner,
- dear Colleagues!
- Many thanks for discussing the problem of pharmaceutical shortages in the context of the actual COVID-19 crisis. Continuous supply with critical pharmaceuticals must be one of the main target of the European Health Policy in the near future. We have to focus on a common European Strategy to ensure availability of medicines in the European Union.
- The global pandemic has clearly demonstrated the dependence of the European Union on supply of Active Pharmaceutical Ingredients and finished products from third countries. Bringing back to Europe the production of critical medicines should be one of our main goals regarding the pharmaceutical policy. From the (10)(2a) point of view, the three questions in the document should be answered as follows:
 - (1) Yes, there is no doubt that there is a connection between the Pharmaceutical Strategy for Europe, the Industrial Strategy and the Economic Recovery Plan. The strategy of a sustainable and safe supply of essential medicines can only be developed in accordance with the industry, in view of the current challenges of global production and supply chains.
 - (2) In principle, increased transparency and interaction on possible supply disruptions between the competent authorities and stakeholders involved is essential to enable an efficient response to market restrictions.
 - The promotion of the production in Europe with incentive measures should be considered within a framework of a broad, overarching Master plan.
 - The mandatory introduction of a transparent reporting system in order to make emerging bottlenecks visible at an early stage and to be able to take countermeasures on a case-by-case basis is a first more important step.
 - These reporting systems should be further promoted with innovative IT solutions at European level.
 - (3) Communication and transparency must be strengthened both on national and European level. In recent months and years, (10)(2a) has already made intensive efforts and intensified communication through the involvement of all stakeholders, including through "round tables" and a task force.
- The Regulation on the supply of medicinal products, which entered into force on 1 April 2020, now obliges marketing authorisation holders to make binding declarations of any restriction on the marketing capacity of prescription-only human medicinal products. This open communication was an indispensable prerequisite for consensual implementation of the national measures that have just entered into force.
- Intensified communication at all levels is therefore seen as the key to an efficient response to supply restrictions. (10)(2a) is ready to continue to support and promote efforts to take action. The communication between the European Network Authorities, the European Commission and

industry associations, which has now been established by the European Medicines Agency (EMA) in relation with Covid-19, is a good starting point for such a cooperation.

26. (10)(2a)

- A key priority of the pharmaceutical policy in (10)(2a) is to protect human health. Apart from that, it is inherently dependent on other goals of the health policy, such as ensuring sustainability of the health system and providing a stimulating environment for a pharmaceutical industry that produces effective, safe and quality medicines at an affordable price.
- In this context is also my answer to the first question: we consider the production of medicinal products of importance both for the national security and for the security and autonomy of Europe. The strategic importance of medicines needs to be fully taken into account by the Industrial Strategy, as well as by the Economic Recovery Plan.
- To your question N° 2:
- A Pharmaceutical Strategy for Europe should first and foremost be based on a transparent approach and equal treatment of MS. It should take into account the interests of all MS, thus safeguarding a solid protection of patients throughout the EU. Its development requires active involvement of the Council preparatory bodies, so as to take into account the inherent differences between the capacities and interests of the individual EU MS.
- At the heart of a health-oriented pharmaceutical strategy should be to ensure a clear perspective, sustainability, trust in the system and proportionate regulatory burden. At this stage I would highlight three points:
- First, Providing safe, effective and quality medicines at an affordable price:
- At EU level, the pharmaceutical policy should prioritise the safety of products over the speed of their placing on the market. This requires solutions that safeguard the availability of proven effective medicinal products on the market. In addition, need to ensure access for patients to treatment by Member states precludes ideas such as price convergence, for example. It also calls into question unilateral measures, such as the introduction of parallel import quotas, leading to lower prices in some MS, at the expense of depriving patients of access in others.
- Second, Ensuring safety and surveillance:
- The availability of sufficient clinical data and effective mechanisms for gathering reliable real world data is key to maintaining patient confidence in the system.
- Third, Sustainable environment:
- Regulatory predictability and the establishment of incentives, including through dialogue with marketing authorization holders, are among the prerequisites for the success of any strategy.
- In this sense is the answer to your third question:
- Strengthening communication between national authorities and stakeholders should not be a purpose in itself; this process should be driven and targeted towards the solution of concrete issues. Such an issue for example is the shortage of medicines, where we hope for solutions from the enhanced monitoring and communication system launched by the EMA, together with the pharmaceutical industry and the EU Member States. The objective assessment of this activity and the need to create additional fora should be a subject of regular discussions in the Council and its preparatory bodies.