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Committee on Social Affairs, Health and Sustainable Development

Sub-Committee on Public Health and Sustainable Development

Minutes

Public hearing on "Securing safe medical supply chains", held by videoconference, on Wednesday 7 October 2020

In the framework of a draft motion on the topic of securing safe medical supply chains, the current Covid-19 pandemic and the resulting disruptions in medical supply chains, the Sub-Committee held a public hearing on the topic of "securing safe medical supply chains" with the participation of:

- ✓ Ms Nathalie Colin-Oesterle, Member of the European Parliament
- ✓ Mr Thomas Senderovitz, Director General of the Danish Medicines Agency
- ✓ Ms Susanne Keitel, Director, European Directorate for the Quality of Medicines and Health Care (EDQM)
- ✓ Mr Sergei Glagolev (Russian Federation), Chairperson of the Committee of the Parties of the MEDICRIME Convention
- ✓ Mr Allal Amraoui (Morocco), Partner for Democracy, Parliamentary Assembly of the Council of Europe

Mr Leite Ramos, the Chairperson of the Plenary Committee, opened the hearing by stressing that it should be our public health priority to strengthen the medical supply chains to ensure an uninterrupted supply of essential medicines, medical devices and other health products that are safe, meet standards for quality and are beneficial to health. He called for collaboration and solidarity within Europe and globally. In urging more states to join the fight against falsification of medicines by ratifying the MEDICRIME Convention, he referred to the Committee's booklet that provides good and informative answers to relevant questions about the Convention.

Ms Jennifer De Temmerman, the Chairperson of the Sub-Committee, briefly introduced the speakers and welcomed everyone to the hearing.

First part of the hearing –
Securing medical supply chains: Lessons from Covid-19 – Building resilience against future crises

Ms Nathalie Colin-Oesterlé started off as the first speaker referring to a report she had drafted on the lack of medicines within the European Union. She pointed out that although this is a national competency, article 168 of the Treaty on the Functioning of the European Union states that the EU shall co-ordinate co-operation between member States and complement national policies in order to protect the health of European citizens.

Ms Colin-Oesterlé continued by saying that there are multiple causes for disruptions in medical supply chains, including manufacturing problems, supply being outstripped by demand, as has been the case during the Covid-19 pandemic, and of course, the location of production facilities. In fact, for a number of products, she noted, Europe is relying on only two to three suppliers all located in Asia, which may result in shortage of medicines or medical products in the case of the slightest manufacturing problem or any other issue within the supply chain.

[1]The minutes were approved and declassified by the Sub-Committee on Public Health and Sustainable Development at its meeting on 18 January 2021, held via videoconference.

In her conclusions, **Ms Colin-Oesterlé** stressed the need to relocate, harmonise and to strengthen co-operation between member States, with a greater focus on solidarity, in order to regain sovereignty and develop a true industrial strategy for pharmaceutical products in Europe.

Mr Thomas Senderovitz noted that no single country is able to manage supply challenges by themselves, nor are all solutions to those challenges of a local nature. He went on to stress the need for extended supervisory oversight of supply chains, especially for active substance manufacturing, through international co-operation and collaboration. Although the Covid-19 pandemic had illustrated that being overly reliant on just a few countries or a region might pose a risk to continuity of supply, it seemed likely that Europe would remain dependent on India and China as major sources of generic medicines, biosimilars and Active Pharmaceutical Ingredients (APIs). However, he noted that there might be future developments in the regulatory framework encouraging supply chain resilience through measures which might favour manufacturing inside the EU, in order to decrease dependency on third countries, to promote diversity of suppliers and to contribute to the EU's strategic autonomy.

Mr Senderovitz introduced five main areas in the new Network Strategy of the European regulatory Network that focus on:

1) enhancing traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of APIs,

2) enhancing inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing,

3) reinforcing responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries,

4) encouraging supply chain resilience and reviewing long-term risks resulting from dependency on limited number of manufacturers and sites, to ensure continuity of supply and availability of medical products, and

5) analysing the possible implications of new manufacturing technologies in order to regulate the new supply chains needed to manufacture and distribute new types of medicinal products for human and veterinary use.

Ms Susanne Keitel gave an insightful introduction to the work of the EDQM in securing medical supply chains, on how the EDQM had responded to the Covid-19 pandemic and the vision for avoiding shortages in the future. As a response to the pandemic, the EDQM had developed a Business Continuity Plan to safeguard core activities. This had enabled their supply of reference standards to continue uninterrupted. Other measures had included fast-tracking of CEPs (Certification of Suitability to the monographs of the European Pharmacopoeia), which attest that the APIs in a medicine can be suitably controlled by the quality requirements set out in the European Pharmacopoeia, and monitoring of the pandemic's impact on the supply of APIs to Europe, which was essential for market supply.

Speaking about how to make the supply chains more resilient, **Ms Keitel** suggested that in the short- and medium-term, this could be done through a co-ordinated approach between stakeholders. In the mid- to long-term, a diversification of API production across different global regions was a critical factor to increase the resilience of supply chains. Although the EU continued to examine different levers and options around shortages and the production of APIs in Europe, Ms Keitel pointed out that bringing back the production was a complex matter that would have significant impact on the cost of medicines and hence of health-care systems. In addition, she noted that thinking beyond the EU was needed, as the Council of Europe membership is much larger, and concluded by saying that the challenges which lie ahead could only be tackled through international co-operation.

Ms Konul Nurullayeva took the floor to share her perspective on the topic discussed by the panel during the first part of the hearing. Speaking of the impact of the Covid-19 pandemic, she noted that while a number of regions enjoyed the privilege of medical supply during this time, others had suffered from shortages and increasing prices. Thus, Ms Nurullayeva proposed a few specific measures in order to make supply chains more resilient to future crises, while still ensuring that they are safe and meet standards for quality. First of all, she stressed the need for regulatory co-operation with trade partners as one of the priorities. Second, she insisted on ensuring medical supplies to the countries that needed it the most at first, and to lift restrictions that countries had imposed on each other based on the exports of medical products, to ensure inclusivity. Finally, she suggested building datasets and investing in research in order to better track and monitor disruptive events in medical supply chains. In her conclusion she highlighted three components necessary to secure safe medical supply chains, namely multilateral co-operation, visibility / transparency and trust.

Second part of the hearing –
The contribution of the MEDICRIME Convention to securing safe medical supply chains

Mr Sergei Glagolev presented a brief outline of the MEDICRIME Convention's role in securing the legal distribution chain of medical products, and of its significance in light of the Covid-19 pandemic. Stressing that public health is key to the enjoyment of every other human right, the primary goal of the Convention is to combat any threat to public health with a view to protecting individuals, groups and populations through substantive criminal law measures, including protecting people from using falsified medical products. This goal was achieved by prosecuting the falsification of medical products through specific and effective criminal sanctions, protecting the rights of victims and promoting national and international co-operation. During the pandemic, there had been a dramatic increase and change in the pattern of crimes related to medical products. Pointing out that falsified medical products put the health of millions of people at risk, **Mr Glagolev** urged more states to ratify the Convention to help combat this scourge and to protect human life and public health.

Mr Allal Amraoui emphasised that the MEDICRIME Convention was currently the only legally binding instrument in the fight against the falsification of medical products, and thus urged more states to ratify it. He went on to say that in the context of the pandemic, the Convention remained an essential legal tool to protect human life and public health, noting that falsification of medical products was a fact, but indeed in times of crises it might pose an even greater threat. Further to this, Mr Amraoui referred to a study by WHO which had found that 42% of falsified medical products are dispensed in Africa. Another study from 2015 estimated that 122 000 children under the age of five lost their lives in just one year due to falsified antimalarial medication in Sub-Saharan Africa. He thus pointed out that the threat was global, and international co-operation was needed in the fight against falsified medical products. He also noted that it was not enough to only ratify the Convention; above all states had to show political will and invest money to ensure it was properly implemented.

Ms Jennifer De Temmerman, the Chairperson of the Sub-Committee, made some closing remarks and summed up the hearing by reiterating the need for international co-operation, promoting research, exchange good practices among states and to work on new developments. As for the second part of the hearing she joined the two speakers in urging more states to ratify the MEDICRIME Convention. She concluded by thanking the speakers for sharing their expertise, to other participants for their questions and comments, and lastly to everyone that had followed the meeting as viewers.

Committee on Social Affairs, Health and Sustainable Development
Commission des questions sociales, de la santé et du développement durable

Sub-Committee on Public Health and Sustainable Development
Sous-commission de la santé publique et du développement durable

List of participants / *Liste des participant.e.s*

(28 seats / *28 sièges*) ***07.10.2020***

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3.	M.	Simon MOUTQUIN	Belgium / *Belgique*	Ms	Els van HOOF
4.	Ms	Ivelina VASSILEVA	Bulgaria / *Bulgarie*		ZZ…
5.	Ms	Alena GAJDŮŠKOVÁ	Czech Republic / *République Tchèque*		ZZ…
6.	Ms	Minna REIJONEN	Finland/ *Finlande*		ZZ…
7.	M.	Bernard CAZEAU	France		ZZ…
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12.	Mr	Fabio DI MICCO	Italy / *Italie*		ZZ…
13.	Mr	Nikola POPOSKI	North Macedonia / *Macédoine du Nord*		ZZ…
14.	Mr	Andrzej SZEJNA	Poland / *Pologne*		ZZ…
15.	Mr	Bolesław PIECHA	Poland / *Pologne*	Mr	Tomasz LATOS
16.	**Mme**	**Edite ESTRELA**	Portugal		ZZ…
17.	M.	Cezar Florin PREDA	Romania / *Roumanie*	Mr	Valeriu Andrei STERIU
18.	Mr	Sergey KALASHNIKOV	Russian Federation / *Fédération de Russie*		ZZ…
19.	Ms	Carmen LEYTE	Spain / *Espagne*		ZZ…
20.	Mr	Ola MÖLLER	Sweden /*Suède*	Ms	Annicka ENGBLOM
21.	Mme	Sibel ARSLAN	Switzerland / *Suisse*	Mme	Ada Marra
22.	Mr	Halil ÖZŞAVLI	Turkey / *Turquie*	Ms	Selin SAYEK BÖKE
23.	Ms	Olena KHOMENKO	Ukraine		ZZ…
24.	Mr	Oleksandr SKICHKO	Ukraine		ZZ…
25.	**Mr**	**Geraint DAVIES**	United Kingdom / *Royaume-Uni*		ZZ…
26.					
27.					
28.					

ex officio : **Mr Luís LEITE RAMOS** (Chairperson, Portugal*, Président, Portugal)*

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