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Securing safe medical supply chains

Report[1]
Committee on Social Affairs, Health and Sustainable Development
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Summary

Medical supply chains are one of the cornerstones of public health. The Covid-19 pandemic has highlighted the need to address the vulnerabilities of global medical supply chains, from the production of medical products to their use by patients. The Council of Europe has a role to play in preventing and combating these vulnerabilities, in collaboration with the World Health Organization and the European Union.

In the context of the persistent shortages which affect the most vulnerable people as individuals, especially women and persons with long-term and chronic illnesses, the Parliamentary Assembly should call on the national authorities and all health actors to agree on a strategy to make medical supply chains safer in order to guarantee equitable access and necessary prevention against shortages, including by establishing firm legal obligations at national level and inviting member States to ratify the Convention on the counterfeiting of medical products and similar crimes involving threats to public health (the "MEDICRIME Convention").

Finally, to respond to the climate crisis and make the medical supply chains safer, the Assembly should call for the development of uncomplicated and resilient health systems with a high level of integrity and based on human rights.

1. Reference to Committee: Doc. 15191, Reference 4553 of 25 January 2021.

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A. Draft resolution[2]

1. Medical supply chains are one of the cornerstones of public health and contribute to the implementation of the human right to protection of health. Yet the adoption by public authorities and the pharmaceutical industry of a largely financial approach seeking to contain costs increases the risks of shortages. All our health systems suffer the consequences of this, creating the risk that the quality of life, the health or even the lives of people who rely on medical products will be jeopardised. The model which has led to the production of medicines being concentrated in only a few countries has reached its limits. It has failed to provide fair access to protection of health for all, and to medical products across countries.

2. The Covid-19 pandemic has highlighted the need to address the vulnerabilities of global medical supply chains, from the production of medical products to their use by patients. During this crisis, particularly in the early stages, shortages of medical products increased dramatically. Market conditions for supplies were impacted in an unprecedented way. Stockpiling, restrictions on exports, closed borders and lockdowns led to shortages of essential medicines in many member States. Concerns were also raised as to whether the products that reached European markets in the early stages of the pandemic met the necessary standards for quality and safety.

3. The Parliamentary Assembly regrets that the relocation of much of the pharmaceutical industry to India and China has not been of benefit to everyone because technology transfers have been limited. Production of new Covid-19 vaccines was concentrated in Northern countries, vaccine coverage remained highly inadequate in the south, and this made it impossible to remedy this situation in our shared interest, which was to contain the disease as quickly as possible. The Assembly reiterates the conclusions it came to in its Resolution 2424 (2022) "Beating Covid-19 with public health measures".

4. The Council of Europe has a role to play in preventing and combating this phenomenon, in collaboration with the World Health Organisation and the European Union. It reacted rapidly to the Covid-19 pandemic, providing its member States with tools and expertise to ensure that the values and principles at the core of the Organisation were not undermined by the crisis. The Secretary General called on the member States to introduce co-ordinated policies taking a human rights-based approach, including through the European Convention on Human Rights (ETS No. 5), the European Social Charter (ETS No. 35), the Convention on Human Rights and Biomedicine (ETS No. 164, "Oviedo Convention"), the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50) and the Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211, "MEDICRIME Convention").

5. The Assembly welcomes the innovative step which the MEDICRIME Convention represents. It is currently the only binding international instrument in the criminal law field on the counterfeiting of medical products and similar crimes involving threats to public health. In view of the growing risk of counterfeiting stemming from shortages of medicines and medical products, the Assembly regrets that the Convention has only been ratified by 13 member States and 6 non-member States. It calls on States which have not yet done so to ratify this convention.

6. The Assembly encourages parliaments to address the question of the implementation of a human rights-based approach in the health field, ensuring quality, safety and fairness in healthcare for all as proposed by the Oviedo Convention. It deplores the shortages of medical products which is at the origin of differences in treatment and of discrimination. It calls on its members to debate the need to adopt co-ordinated approaches providing a flexible response to unpredictable health crises, requiring unprecedented solutions such as group purchasing of medicines or quick reactions to prevent bottlenecks liable to disrupt the supply chains and have an impact on the health situation. Such responses help to make health systems more resilient.

7. In the context of the persistent shortages which affect the most vulnerable people as individuals, especially women and persons with long-term and chronic illnesses, the Assembly deplores these discriminations and calls on the national authorities and all health actors to agree on a strategy to make medical supply chains safer in order to guarantee equitable access and necessary prevention against shortages. It encourages the authorities to establish firm legal obligations if the risks are not alleviated by concerted action in the near future. The goal of securing medical supplies deserves our full attention until it is achieved. These measures could involve:

7.1. an obligation for laboratories to stockpile sufficient quantities of all medicines of major therapeutic value to cover the needs of health system users;

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2. Draft resolution adopted unanimously by the committee on 21 June 2022.

7.2. strengthening, in law and in practice, sanctions for laboratories that are negligent in their management of supplies for domestic markets;

7.3. establishing that if companies use public funding to relocate production sites to Europe, this should be permitted only for operations concerning medicines of major therapeutic value, and particularly concerning the longest established drugs with demonstrated efficacy which are repeatedly in short supply;

7.4. expanding public-sector pharmaceutical production to ensure manufacturing continuity for products dropped by laboratories.

8. In anticipation of future pandemics, the Assembly calls on the member States to set up comprehensive strategies to secure medical supply chains, guaranteeing quality, safety and fairness between countries. The Assembly also proposes putting into place prevention, contingency and mitigation strategies regarding shortages of medical products.

9. To cater for the adjustments needed in response to the climate crisis, the Assembly calls for the development of an uncomplicated and resilient health system with a high level of integrity and based on human rights. It also recommends:

9.1. cutting emissions of polluting gases linked to purchases of medicines and medical devices;

9.2. cutting emissions of polluting gases linked to all the stages in the energy consumption chain;

9.3. taking action on waste;

9.4. using digital technology to support decarbonisation.

10. Lastly, referring to Resolution 2071 (2015) “Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?”, the Assembly calls on the pharmaceutical industry, including companies and associations, and on wholesalers, to step up their efforts to increase transparency and co-operate more closely with the authorities, and to take into account the individual right to protection of health, as well as fairness between countries. Finally, it calls for professional ethical standards to be enhanced so as to restore patient trust.

B. Draft recommendation[3]

1. The Parliamentary Assembly refers to its Resolution … (2022) "Securing safe medical supply chains" and regrets the increase in disruptions liable to jeopardise the functioning of public health systems and impair the exercise of the right to protection of health, which is intrinsically connected with the right to life.

2. It welcomes the establishment on 1 January 2022 of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) and hails the added value that the Council of Europe's work brings to the health sector through its human rights-based approach, which has been particularly useful during the Covid-19 pandemic. It welcomes the complementarity of the work accomplished and the expertise mobilised by the Council of Europe, the World Health Organization and the European Union.

3. To respond to the climate crisis and make the medical supply chains safer, the Assembly calls for the development of uncomplicated and resilient health systems with a high level of integrity and based on human rights.

4. To meet patients' legitimate concerns, the Assembly encourages the Committee of Ministers to ask the CDBIO to maintain an ever-closer working relationship with the World Health Organization, to develop more synergies, and to work on the principle of equity between patients in the same health system and equitable access to medical products for all countries in order to respond to future health crises.

5. Finally, the Assembly calls on the Committee of Ministers to encourage those member States which have not yet done so, to ratify the Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211, the "MEDICRIME Convention").

3. Draft recommendation adopted unanimously by the committee on 21 June 2022.

C. Explanatory memorandum by Ms Jennifer De Temmerman, rapporteur

1. Introduction

1. The Covid-19 pandemic has highlighted the need to address the vulnerabilities of global medical supply chains. During this crisis and in particular in the early stages of it, shortages of medical products increased dramatically. Market conditions for supplies were impacted in an unprecedented way. Stockpiling, restrictions on exports, closed borders and lockdowns led to shortages of essential medicines in many member States. Concerns were also raised as to whether the products that reached European markets in the early stages of the pandemic met the necessary standards for quality and safety.

2. Shortages in medicines and medical products happen regularly and a multitude of factors are to blame. There are typically a number of combined causes that create situations during which the demand for a medicine cannot be met by an adequate supply. In order to secure supply chains and make them more resilient it is thus important to study and understand the underlying causes of disruptions. I would like to pay tribute to the work of my French colleague, Senator Jean-Pierre Decool, the author of an information report on the shortage of medicines and vaccines in 2018.[4] In this report it was noted that the solution to this problem could not be drawn solely from the legal field and that the real issue was a medicine industry whose main concern was to contain costs.

3. The Council of Europe has a role to play in preventing and combating this phenomenon. Its response to the Covid-19 pandemic was swift on the whole, providing its member States with tools and expertise to ensure that our shared values and principles were not undermined by the crisis. The Secretary General[5] called on the member States to introduce co-ordinated policies taking a human rights-based approach, including through the European Convention on Human Rights (ETS No. 5), the European Social Charter (ETS No. 35), the Convention on Human Rights and Biomedicine (ETS No. 164, "Oviedo Convention"), the Convention on the Elaboration of a European pharmacopoeia (ETS No. 50) and the Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211, the "MEDICRIME Convention").

4. On 3 December 2020, the Committee on Social Affairs, Health and Sustainable Development tabled a motion for a resolution[6] entitled "Securing safe medical supply chains". This initiative came following a public hearing on this topic held by the Sub-Committee on Public Health and Sustainable Development on 7 October 2020 with the participation of Ms Nathalie Colin-Oesterlé, Member of the European Parliament (France, EPP/CD); Mr Thomas Senderovitz, Director General of the Danish Medicines Agency; Ms Susanne Keitel, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM); Mr Sergei Glagolev (Russian Federation), Chairperson of the Committee of the Parties of the Council of Europe MEDICRIME Convention; and Mr Allal Amraoui, member of the Moroccan partner for democracy delegation to the Parliamentary Assembly.

5. The hearing was broken up into two sessions. The first session focused on how to build resilience to future crises by making the medical supply chains more sustainable while ensuring that they meet the requirements of safety and quality. The second part of the hearing was dedicated to the MEDICRIME Convention and possible ways to prevent counterfeit medical products (namely, medicinal products and medical devices) from entering the supply chains.[7]

6. The motion for a resolution proposed that the Assembly look into how to strengthen the medical supply chains to ensure an uninterrupted supply of essential medicines, medical devices and other health products that are safe and meet standards for efficacy or performance. Moreover, the motion invited the member States to step up action to prevent falsified medical products from entering the supply chains, and ratify the MEDICRIME Convention as soon as possible. The motion was referred to our committee for report and I was appointed rapporteur on 16 March 2021.

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4. Senate fact-finding group on the shortage of medicines and vaccines.
5. Secretary General's Report, 24 September 2020, "A Council of Europe contribution to support member states in addressing healthcare issues in the context of the present public health crisis and beyond", SG/Inf(2020)24.
6. Doc. 15191.
7. Public hearing on "Securing safe medical supply chains", held by videoconference on 7 October 2020.

2. The causes of supply chain disruption

7. The Covid-19 pandemic has destabilised all goods supply chains and has been a factor in reigniting inflation which is now impacting household budgets through price rises and shortages of varying durations. The war in Ukraine will bring with it even more damaging consequences, entailing substantial rises in prices of energy and essential goods. In the health sector, this succession of crises has exacerbated the disruptions to medical supply chains that were already known prior to it. On top of people being made poorer, their right to protection of health is also in jeopardy, including the right to equitable access to appropriate quality healthcare.

8. The scope of this report is not limited to the supply of retail pharmaceuticals which, according to the OECD,[8] account for a substantial share of health spending (one-sixth of overall health expenditure).[9] It covers the entire supply chain, including pharmaceuticals used in hospitals and clinics whose prices have shown a particularly marked increase partly because of their highly technical nature. These price issues have ramifications for solidarity-based national health systems and threaten their financial balance. In OECD countries, the bulk of health costs is covered by compulsory health insurance and government spending (56%). This figure reaches more than 80% in countries such as Germany and France. The consumption of medicines has risen strongly in recent decades as a consequence of populations growing older and higher living standard. Consumption of anti-hypertensive drugs has increased by 65% since 2000, nearly quadrupling in Estonia. The use of other drugs such as antidiabetic medications or antidepressants has also grown dramatically. That said, generic drugs account for 24% of the entire pharmacy market by value and 53% by volume. The pharmaceuticals sector represents 13% of all research and development, which is as much as the aeronautical sector. In 2020, the American Food and Drugs Administration registered 43 new pharmaceuticals, and the average for recent years is around 50. The Covid-19 pandemic does not appear to have halted the steady growth in the consumption of pharmaceuticals.

9. This report follows up the discussion launched by Resolution 2071 (2015) “Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?” in which the Assembly spoke out about the increase in the number of new medicines marketed without a real therapeutic benefit or satisfying genuine health needs. Beyond the aspect of pharmaceutical development, it is also the supply chain which is problematic and affects the resilience of health services.

10. A key factor which leads to disruption of medical supply chains is the limited number of production sites that supply the world with the active substances (also known as Active Pharmaceutical Ingredients – APIs) used in medicines, which for generic medicines with low profit margins come from low- and middle-income countries. Many products are formulated and packed or repacked in other third countries. Experts have pointed out that it is likely that the world will soon be fully dependent on India and China as main API manufacturers, and are also significantly involved in the manufacturing of generic medicines and biosimilars. Additionally, there are indicators that more third countries could become players in the global supply chain.

11. This is a trend that we have seen for more than 25 years, as production sites have been closed or moved out of Europe – often in order to reduce costs. For example, the last production site for paracetamol in Europe, located in France, discontinued its production in 2008.[10] Since then, all active substance of paracetamol entering into the European market comes from outside our continent. Likewise, most medicinal products such as antibiotics and most vaccines are produced outside European borders. Thus, the globalisation of supply chains has made regional and international co-operation even more necessary. European manufacturing has specialised in more advanced products with higher added value. Industrial actors have often opted for narrower specialisations, abandoning whole swathes of their traditional business. By way of illustration of this trend, according to the pharmaceutical industry, even after the succession of numerous mergers and acquisitions in 2020, the five leading players in the sector accounted for only 22% of the global market.

12. In November 2020, the French consumers association UFC/Que choisir[11] published an alarming survey, drawing the attention of the authorities to the problem of shortages of pharmaceuticals. Compared to 2016, when the authority responsible for supervising the market recorded 405 shortages or possible risks of shortages, there were 2 400 in 2020. It highlighted the poor alternatives to the pharmaceuticals in short

8. OECD report, “Health at a Glance 2021: OECD Indicators”.
9. In the OECD member countries, health accounted, in 2019, for 8.8% of GDP on average (minimum expenditure: Turkey with 4.4% and maximum expenditure: United States with 16.7%), OECD, Health expenditure and financing.
10. *Le Monde*, 12 March 2008, “Rhodia ferme la dernière unité de production de paracétamol en Europe”.
11. *UFC Que choisir*, 9 November 2020, “Pénuries de médicaments – Les laboratoires et les pouvoirs publics responsables”.

supply, but above all the fact that 12% of manufacturers were pushing health professionals towards lower dosages or, in 18% of cases, offered no solution at all, which risked leaving patients completely stranded. The survey revealed that the breakdown of supply related above all to medicines that had been on the market for many years and were cheap and preferred by users. In 2020 and 2021, the French national agency for the safety of medicines and health products (ANSM) and the French association for the prevention of allergies regularly alerted patients and professionals that adrenaline pens were in short supply and recommended that they hang on to their pens until the expiry date before getting new ones from the chemist.[12] Similar shortages affected the United States, the United Kingdom and Australia. It stemmed from the difficulties encountered by the manufacturer of the world's most commonly prescribed treatment in its one and only factory near Saint Louis (Missouri) in the United States. Associations of patients welcomed the fact that direct competitors stepped in to make up the shortfall in supplies.[13] At the time of writing this report, supplies of Spasfon, a symptomatic treatment used against functional disorders of the digestive tract, widely used by women to treat painful digestive tract spasms of gynaecological origin, had been disrupted in France for the last eight weeks. Supply chain malfunctions give rise to inequalities, often gender-linked, affecting people who need care. The United Kingdom is also currently experiencing severe disruptions to the supply of hormonal replacement therapy drugs for one million premenopausal women.[14]

13. The causes of shortages also include structural weaknesses in the supply chain. The British National Pharmacy Association (NPA)[15] thus deplores the quota system applied by some manufacturers to control the European market and the excessive stocks required by certain wholesalers. Patients' access to treatment is delayed, if not impossible.

14. To tackle supply shortage issues, the NPA: co-operates with the health authorities to ensure the supply of medicines to pharmacies within 24 hours; protects the reputation of pharmacies by countering misleading media reports, commissioning independent research into the medicine shortage problem and its impact on patients; provides advice to its members on how to deal with medicine shortages; raises their concerns through international bodies; promotes the capability to trade stock between pharmacies, lobbies MPs on this problem; and contributes to dialogue with national authorities, wholesalers and manufacturers. It has made a "toolkit" available to its members.

15. The UK body promoting the interests of the National Health Service community pharmacists[16] has revealed, in survey findings published on 25 April 2022, that pressures on pharmacists are strongly impacting teams, business and patients. Pharmacists are now experiencing shortages of staff, who had to work very long hours during the pandemic. There has been a huge rise in the number of staff off sick. The mental health and well-being of pharmacists and pharmacy teams have suffered. They can no longer spend the necessary time with patients, they deplore the fact that prescriptions now take longer to dispense and are unable to provide new services. They are also increasingly exposed to abuse from patients who are angry about supply shortages.[17]

16. As argued during the hearing on 7 October 2020, in the short- and mid-term, supply chains can be made more resilient through a co-ordinated approach between stakeholders. In the mid- to long-term a diversification of API production across different global regions is a critical factor to increase the resilience of supply chains. Evidently, being overly reliant on one country or one region makes supply chains vulnerable to disruptions. Following the public health crisis and the disruptions in medical supply chains that were sparked by the Covid-19 pandemic, pharmaceutical company Seqens is set to start its production of paracetamol as of 2023 in Roussillon in Isère, France.[18]

17. Commercial interests and the choice of supply chain management methods, such as just-in-time production, are other factors that make supply chains more vulnerable to disruptions and thus impact the availability of life saving medicines and medical products. A way to strengthen medical supply chains could be to only buy medical products from companies that can demonstrate that their supply chain is resilient to a variety of shocks, including by not being overly reliant on one country or region.[19] In the report on "Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health

12. ANSM press release on the short supply of adrenaline pens, (French only) published on 3 July 2020 and reissued on 16 March 2021.
13. *Reuters*, 10 May 2028, In Europe, "Mylan's rival try to plug EpiPen shortages".
14. *The Guardian*, 25 April 2022, "What is HRT and why are there shortages in the UK?".
15. National Pharmacy Association, "Medicines supply chain".
16. Pharmaceutical Services Negotiating Committee (PSNCE).
17. "Pharmacy Pressures Survey confirms impact on teams, businesses and patients", April 2022.
18. *Le Figaro*, 29 June 2021, "La France va recommencer à produire du paracétamol dès 2023".
19. Centre for European Reform, 20 May 2020, "Securing Europe's medical supply chains against future shocks".

interests?" our former colleague Ms Liliane Maury Pasquier (Switzerland, SOC) pointed out that measures should be taken with a view to gearing the pharmaceutical industry system to public health needs, including by adopting stricter marketing authorisation policies and by ensuring full transparency regarding the real costs of research and development.[20]

18. Globalised supply chains and markets underline the need to optimise supervisory oversight, especially for the manufacturing of active substances, through international co-operation and collaboration based on both new and already existing initiatives, such as with the EDQM. Efforts should be focused on gathering more data on supply chain risks and embedding deeper regulatory co-operation with key countries. More detailed studies looking into the vulnerabilities in supply chains are necessary in order to have a better understanding of the actions needed to avoid future disruptions. Increased regulatory co-operation with pharmaceutical producers is also needed so as to ensure that products imported during an emergency situation meet safety and quality standards, as was rightly done at the beginning of the Covid-19 pandemic.

19. The EDQM, a directorate of the Council of Europe, plays a significant role in protecting public health in Europe and beyond, and ensuring the safety of medical supply chains. It does so by enabling the development, supporting the implementation, and monitoring the application of quality standards for safe medicines and their safe use. At the beginning of the pandemic, the EDQM introduced its business continuity plan to anticipate and mitigate any risks of disruption to its activities, so that the standards necessary for the production and release of medicines by pharmaceutical manufacturers and for market surveillance testing by Official Medicines Control Laboratories remained available. Additionally, the EDQM compiled a list of substances that are used in intensive care units and in clinical trials that they constantly monitor to avoid any disruption,[21] as well as information on products and extemporaneous preparations of paediatric formulations that may be useful in the treatment of Covid-19.[22] Over 80 % of the active ingredients used in the preparation of the medicines available in Europe are produced outside Europe and the United States. The EDQM ensures the good quality of medicines in all the States parties to this Council of Europe partial agreement. On this basis, it guarantees that branded medicines and generic medicines sold in any of the countries covered by the partial agreement will be of the same quality.

20. In response to the lessons to be learned from the Covid-19 pandemic and as a deliverable for 2025, the EDQM is to prepare a Methodological guide for selecting medicines at risk of shortage during public health emergencies, providing guidance on how to address these shortages via the optional and temporary use of standardised pharmacy preparations in hospital and community pharmacy settings. This publication is part of the terms of reference of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), which is one of the EDQM's steering committees. It provides support to authorities for dealing with the challenges of making the medication process safer, more responsible, and accessible to all who need it, at a time of ever greater social gaps and financial constraints. It is tasked with defining strategies to minimise the impact of shortages of medicines during public health emergencies with a view to ensuring continuity of care and safeguarding timely access to safe and effective quality medicines.

21. The European Medicines Agency (EMA) together with the Heads of Medicines Agencies (HMA) have since 2016 provided strategic support and advice to tackle disruptions in medical supply of human and veterinary medicines and ensure their continued availability.[23] The key priorities of the HMA/EMA Task Force include looking at ways to minimise supply disruptions and avoid shortages by facilitating approval and marketing of medicines using the existing regulatory framework; developing strategies to improve prevention and management of shortages caused by disruptions in the supply chains; encouraging best practices within the pharmaceutical industry to prevent shortage; improving sharing of information and best practices among EU regulatory authorities to better co-ordinate actions across the European Union; and fostering collaboration with various stakeholders and enhancing communication of supply problems to EU citizens.[24]

22. Many have pointed out that the European Union should expand its stockpile of medical equipment. At the Council of Europe, we need to think bigger, as our Organisation includes 19 member States from outside the European Union. Furthermore, an important lesson from the pandemic is that nobody is safe until everyone is safe. Medical shortages in other parts of the world could consequently have a negative impact on

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20. Doc. 13869 "Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?" (rapporteur: Ms Liliane Maury Pasquier, Switzerland, SOC).
21. www.edqm.eu/fr/covid-19-sauvegarder-activites-fondamentales-par-plan-de-continuite-activites-de-ledqm.
22. www.edqm.eu/fr/actualites/informations-sur-produits-et-preparation-extemporanee-de-formulations-pediatriques.
23. www.hma.eu/522.html.
24. www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines.

our continent as well. Member States should therefore support the World Health Organization (WHO) in maintaining global stockpiles. This would enable the release of essential medical supply to those countries that need it the most and their fair and efficient distribution.

23. Counterfeit medical products are another danger to public health and can violate the right to life enshrined in the European Convention on Human Rights, the right to protection of health, enshrined in the European Social Charter, and the right to equitable access to healthcare of an appropriate quality enshrined in Article 3 of the Oviedo Convention. As the supply was outstripped by demand, in particular at the beginning of the Covid-19 pandemic, concerns were raised over counterfeiting of medicines and medical products, and existing pressures and risk of corruption on procurement were amplified.

24. The Covid-19 pandemic has also destabilised the illegal drugs market. British experts have expressed alarm over the risk of some heroin users turning to Fentanyl,[25] an opioid analgesic medication which is 50 to 100 times stronger. I refer the reader in this connection to the work by our colleague Mr Joseph O'Reilly and Resolution 2335 (2020) "Drug policy and human rights in Europe: a baseline study".

25. Finally, the Covid-19 pandemic has also put pressure on veterinary medicines, to the point of endangering not only animals but above all humans. Shortages of Ivermectin,[26] one of the world's most widely used deworming drugs in veterinary care, have bumped up the price of treatments meant for animals. The hopes raised by a study in a lab setting that did not involve humans took a nightmarish turn when people were hospitalised with major complications brought on by self-medication.

3. Making medical supply chains more efficient and resilient

26. Under the MEDICRIME Convention, intentionally manufacturing, supplying, offering to supply, and trafficking of counterfeit medical products is considered a criminal act. This convention was the first and is currently the only binding international instrument in the criminal law field on the counterfeiting of medical products and similar crimes involving threats to public health. This innovative treaty calls for multilateral collaboration across nations, disciplines, and sectors, and lays the groundwork for co-operation with and between international bodies such as the International Criminal Police Organization (INTERPOL), the European Union Agency for Law Enforcement Cooperation (Europol), the United Nations Office on Drugs and Crime (UNODC), the World Customs Organization (WCO) and WHO, in order to put a stop to this international threat to public health. This multilateral co-operation approach is also taken within the Council of Europe with the work programme run with health regulatory authorities of the 39 States parties to the Convention on the elaboration of a European Pharmacopoeia gathered in the intergovernmental Committee of Experts on Minimising the Public Health Risks Posed by Falsification of Medical Products and Related Crimes (CD-P-PH/CMED). This committee also raised the alert over the increasing risks of falsification created by shortages of medicinal products and medical devices.[27] Only 13 member States and 6 non-member States have ratified the MEDICRIME Convention. This innovative instrument deserves the parliamentarians' support to boost its sphere of influence.

27. At its plenary meeting held in May 2021, the MEDICRIME Committee took note that a working group had been set up to draft a report on criminal activity resulting in leakages in the medical product supply chain. The working group is composed, *inter alia,* of police authorities, Europol and the European Anti-Fraud Office (OLAF).[28][29] It has also adopted two key documents: the Advice of the Committee of the Parties of 8 April 2020 on the application of the MEDICRIME Convention in the context of Covid-19[30] and the Advice of 27 April 2021 on the application of the MEDICRIME Convention in the context of counterfeit[31] Covid-19 vaccines, and notably the explanatory report thereto.[32]

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25. *The Guardian*, 12 April 2020, "Price for drug that reverses opioid overdoses soars amid record deaths".
26. *New York Times*, 21 September 2021, "How Covid Misinformation Created a Run on Ivermectin".
27. www.edqm.eu/fr/actualites/repercussions-de-crise-de-covid-19-autorites-nationales-europeennes-signalent-penuries-de.
28. https://rm.coe.int/t-medicrime-2021-ld-f/1680a2fd02.
29. Concept note, "Leakages and theft from the supply chain of medical products", T-MEDICRIME(2021)10.
30. Advice of 8 April 2020 on the application of the MEDICRIME Convention in the context of Covid-19.
31. The term "counterfeit" used in the MEDICRIME Convention is consistent with the meaning of the term "falsified", which has become the most commonly used term.
32. Advice of 27 April 2021 on the application of the MEDICRIME Convention in the context of counterfeit Covid-19 vaccines.

28. One of the weaknesses observed in the sector lies in its actual functioning and the allowance made by professionals for entropy, namely, the ability to cater for uncertainty, which is exactly what characterises the state of disorder in a system. The decision-making process for clinical testing should, as far as possible, be evidence-based, which means mobilising concerted efforts at the level of biologists, practitioners and care staff, but there is often a lack of sufficient evidence to overcome uncertainty. Medicine remains both an art and a science. In an article which is already two decades old, the clinicians Isaacs and Fitzgerald[33] sought to analyse the essence of their profession, noting that, in the absence of sufficient evidence, no decision was a clear winner. Medicine could be eminence-based when more senior colleagues benefiting from the "halo effect" could make mistakes over the years with increasing confidence. There is also vehemence-based medicine where the substitution of volume for evidence is an effective technique for convincing more timorous colleagues. Eloquence-based medicine distracts from the need for evidence, while diffidence-based medicine does not look for an answer to a problem but merely sees a problem. Finally, nervousness-based medicine merely responds to a stimulus, generating ever more hesitation, over-investigation, and over-treatment. In conclusion, the authors stress the need to forge deep levels of confidence between the players in the sector. And without confidence, there must be no lack of transparency in a system where science does not provide the right answers. In addition to the information passed on by pharmaceutical companies, we should note the importance of peer review and the decisive contributions of the European Pharmacopoeia and Cochrane organisation.

29. Since 1974 the European Pharmacopoeia[34] has made a regulatory contribution to the protection of public health through the development of recognised common specifications relating to the quality of medicinal products and their components. It is a unique reference for the quality control of medicines in the countries that have signed up to the convention underlying it. Together with the European Pharmacopoeia, the US Pharmacopoeia and the Japanese Pharmacopoeia form the three works of reference making up the integrated international system of standards harmonisation. Other pharmacopoeias, although they do not have the same legal status, are published by different States around the world (Brazil, India, China, etc.).

30. Since 1983, the UK-based not-for-profit organisation Cochrane has succeeded in forging a network extending across more than 220 countries and territories, bringing together researchers, health professionals, patients, carers, and other people passionate about improving health outcomes for everyone, everywhere, based on evidence from clinical testing. In this connection, it promotes transparency in the medical supply chain. Its goals[35] are to: produce trusted evidence; advocate for evidence and; inform health and care decisions. It publishes public statements on the Cochrane community website.[36] "Cochrane strongly supports efforts to ensure the availability of data from all clinical trials. To assess the effectiveness and safety of healthcare interventions, we need to know what trials were done, how they were conducted and what their findings were."[37]

31. The question of medicinal sovereignty has returned to the forefront of national debates. The idea that supply chains can dry up as a result of logistical problems on the other side of the world, as was the case during the health crisis and could continue to be the case owing to the war in Ukraine, calls for an industrial policy response from the authorities for the entire supply chain, from precursors to essential medicines. The climate crisis, entailing higher transport costs that impact end users and the balance of health systems, is a further reason for reviewing how the sector is organised.

32. A recent study funded by the TEVA pharmaceuticals group[38] shows that patients attach increasing importance to the origin of medicines, in the same way that they want to know where their food comes from. They care more about where their drugs are made, and 71% of them want to see Europe remain as competitive as other regions in the production of medication for chronic conditions. They are also concerned that every region around the world should have equitable access to vital medicines.

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33. David Isaacs, clinical professor, and Dominic Fitzgerald, "Seven alternatives to evidence based medicine", *The BMJ*, 1999; 319:1618.
34. European Pharmacopoeia, Background and Mission.
35. Cochrane, Strategy for Change.
36. Cochrane Community, "Policies".
37. Dr Karla Soares-Weiser, editor-in-chief of the Cochrane Library, "Les autorités nationales de réglementation des médicaments en Europe ne protègent pas les intérêts des patients", Transparency International France.
38. Study involving 3 000 people aged over 25 receiving treatment for a chronic or long-term illness in Croatia, France, Germany, Netherlands, Czech Republic and Spain, available in Pharma Business International, 4 October 2021, "Research shows the origin of medicines becoming more important".

33. Under arrangements for co-operation with WHO, the EMA can provide scientific opinions on a number of high priority human medicines, including vaccines. This procedure is known as *EU-M4all*[39] and is not linked solely to the Covid-19 pandemic. It has existed, previously under another name, since 2004. The programme makes it possible to share rigorous scientific assessment by EMA experts, in collaboration with those of WHO and the target country. It cuts down on duplication of efforts, provides a means of sharing EU methodologies, takes account of the benefits and risks for a population outside the European Union, strengthens pharmacovigilance capabilities and facilitates marketing authorisations in target countries.

34. At the 2014 Global Forum on Competition, the OECD[40] noted the following lessons where distribution of pharmaceuticals was concerned: health policy makers and enforcers need to understand the distinctive features of the sector thoroughly to be able to intervene in it; the enforcement of the regulation over the incentives provided by manufacturers to doctors should be improved; mechanisms used to regulate prices must comply with the rules laid down by the competition authorities; generics must be given a stronger role; integration by manufacturers and pharmacy must be supervised; and finally the specific characteristics of national organisations must be respected.

4. Making strong codes of ethics a formal requirement from development onwards, right up to the end user

35. In the United States, the Martin Shkreli case shook public opinion. This former hedge fund manager made the headlines with his handling of the US sales of the Daraprim, an antiparasitic drug on WHO's list of essential medicines, hiking its price from 13.50 to 750 dollars in 2015. In January 2022 he was convicted of practising a monopoly and banned for life from the health sector.[41] He is currently serving a seven-year prison sentence. In 2011, President Obama[42] demanded that the Food and Drug Administration (FDA) directly communicate to the Department of Justice any findings proving market manipulation or collusion. Crude manipulation of this kind should not be possible.

36. The opioids crisis has been another feature of this controversial sector. Their consumption, whether prescribed or bought illegally, has sky-rocketed in some OECD countries to the extent of causing addictions and deaths by overdose, not to mention social and economic consequences.[43] Their low cost made them attractive, but their use has had damaging effects on the health of patients who have failed to comply with dosage levels. Their effects have served as a reminder of just how much the health sector remains a risk sector for the whole of society. Any wrong step can have serious public health implications but above all it can be capitalised on by organised crime. This crisis underlined that professionals were lacking in continued training on the effects of certain treatments and that they had a responsibility for prevention and market organisation.

37. While the Covid-19 pandemic provided an opportunity to restore confidence in vaccines, it has done nothing to alleviate patients' suspicions regarding the pharmaceutical industry.[44] The sector remains particularly exposed to structural weaknesses and the risks of corruption, whether at the level of manufacturing or the supply of medical products to end users. The question of ethics codes for professionals in the medicines sector requires efforts on the part of those professionals to restore public confidence. Prosecutions linked to Mediator, Levothyrox, Dépakine, breast implants and so on are ongoing in the courts.

38. The lack of ethics of some manufacturers and distributors has resulted in them being held criminally liable. Transparency International sees health as one of the sectors most exposed to corruption. In 2016, TEVA Pharmaceutical Industries received the fifth highest fine ever imposed by the United States authorities for corruption[45] (283.2 million US$) for bribing public officials in Russia, Ukraine and Mexico. Novartis was convicted twice and had to pay 347 million US$ to the American Department of Justice and the Securities and Exchange Commission (SEC)[46] in 2020. Other groups brought to book include Pfizer for scandals in China and Croatia, Eli Lilly for its conduct in Poland or Sanofi in Kazakhstan and in the Middle East, as well as AstraZeneca, Bristol-Myers, GlaxoSmithKline, Johnson and Johnson, Schering-Plough. More recently, in July

39. EMA, "Medicines for use outside the European Union".
40. OECD, 2014, Global Forum on Competition.
41. *New York Times*, 14 January 2022, "Martin Shkreli Barred From Drug Industry and Must Repay $64.6 Million".
42. *New York Times*, 31 October 2011, "Medicine Shortages Addressed in Obama Executive Order".
43. OECD report, 16 May 2019, "Addressing Problematic Opioid Use in OECD Countries".
44. *The Guardian*, 9 February 2022, "Covid vaccines deserve our trust – but big pharma doesn't".
45. International Compliance Association, 17 May 2017, "Top Ten FCPA Fines".
46. The American stock exchange is policed by this American authority tasked with ensuring compliance with the Foreign Corruption of Public Officer Act (FCPA, 1977).

2020, the SEC ordered Alexion Pharmaceutical to pay a fine of 21 million US$.[47] With the rise in scandals and in connection with Sustainable Development Goal 3 "Good health and well-being", Transparency has undertaken to map corruption risks throughout the health sector, from research to care provision, and demonstrate how procurement transparency can reduce waste and inefficiencies, promote fairness, and strengthen health systems.[48]

39. Health Action international (HAI) deplores the constantly escalating prices of certain molecules in Europe to the point where the right to protection of health is endangered and views these increases as being the direct product of a narrow interpretation of copyright law, which paves the way for dangerous monopolies. At the same time, it notes that some new medicines have little or no therapeutic value compared to treatments already available. For HAI, the necessary acceleration of the licensing procedure would mean that there are fewer clinical trials and would create major uncertainty as to the proven effects of treatments. Consequently, it calls on the EU authorities to ensure fair market access for cheap drugs. It calls for increased safety of medicines through the promotion of the therapeutic benefits and rational use of medicines. Finally, it seeks the democratisation of drugs policies via good governance of the pharmaceuticals sector.[49]

40. In the United States, the SEC has pointed to the pharmaceuticals sector as being particularly exposed to corruption risks. It encourages whistle-blowers by offering them a substantial share of the fines collected. The Pharmaceutical Integrity Coalition[50] helps professionals to report price fraud involving medicines, defective equipment, problems of information regarding medicines, misrepresentation, and licensing procedure violations.

41. We are beginning to see a sense of awareness taking hold. The big companies in the sector have managed to introduce procedures for strong prevention. The OECD observes that prevention efforts are beginning to reach small and medium-sized businesses. Pharmaceutical manufacturers and distributors have obligations in the prevention of corruption. The OECD published due diligence guidance for responsible business conduct[51] in 2018 so that they take social, human rights and environmental considerations into account. In December 2019, the World Economic Forum launched the Davos Manifesto for a stakeholders' capitalism instead of a shareholders' capitalism.[52]

42. Transparency France deplores the fact that the national authorities regulating the pharmaceuticals sector in Europe do not always protect patients' interests.[53] Transparency is not practised in line with undertakings, and the authorities are overwhelmed. The reliability of the European Register of Clinical Trials is disputed owing to missing or inaccurate information. The study carried out expresses concern over the markedly poor performances of the French, Italian and Dutch regulators. Those involved call for closer harmonisation of working techniques and greater transparency for clinical trials between European countries. They also suggest sanctions that are enough of a deterrent for those who breach the obligation of transparency.

43. The players in the supply chains are both private-sector and public-sector. In some cases public services are delegated to private-sector players in some highly regulated professions (pharmacists and doctors). Confidence in all the players must be reinforced in order not to jeopardise overall sector balance. Following a revolving doors scandal involving supervisory authorities and the private sector in 2011[54], the European Medicines Agency has introduced preventive procedures to control and limit the risks of similar incidents.

44. At a time when several pharmaceutical companies wield more financial power than some of the country where they are operating, when those companies have radically changed their focus after a period of heavy market concentration marked by the destruction of know-how and de-industrialisation in Europe, when prices of innovative medicines are sometimes reaching peaks, when the production of certain essential treatments is

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47. US Securities and Exchange Commission, 2 July 2020, "SEC Charges Alexion Pharmaceuticals With FCPA Violations".
48. Transparency International, Our priorities/Health.
49. Health Action International (HAI), "Medicines in Europe". HAI is an independent non-profit organisation based in Amsterdam (Netherlands) advocating to advance policies enabling access to safe, effective, affordable and quality-assured medicines and rational medicine use for everyone, everywhere.
50. Pharmaceutical Integrity Coalition, "False Claims Act Medicare Schemes".
51. OECD, "Due diligence guidance for responsible business conduct".
52. World Economic Forum, 2 December 2019, Davos Manifesto 2020: "The Universal Purpose of a Company in the Fourth Industrial Revolution".
53. Joint study by Health Action International, Melanoma Patient Network Europe, TI France and TranspariMED, 5 July 2021, "Les autorités nationales de réglementation des médicaments en Europe ne protègent pas les intérêts des patients".
54. *Le Monde*, 14 November 2011, "Quand un ex-directeur de l'AEM part «pantoufler» dans les laboratoires".

concentrated in countries on the opposite side of the world, and when shortages are jeopardising health and well-being, repeated calls should be made on the sector to review how it is organised in order to restore confidence, before sweeping changes are demanded.

45. The climate crisis will exert an increasingly strong impact on the supply chains. Beyond the responsibility of the manufacturers, account must also be taken of the agents who represent the manufacturers; the wholesalers; the dispensaries and pharmacies; and also, the suppliers of hotel services for hospital patients as well as the transport companies who take people to out-patient services. According to the Shift Project,[55] the health sector accounts for between 7.5 and 8% of French carbon emissions, equivalent to 46 million tonnes of CO^2.[56] The first carbon constraint will be to take account of climate change as well as the increasing scarcity of energy resources. The first of these aspects was described by our colleague, Ms Edite Estrela, in her report "Climate crisis and rule of law".[57] The Shift project recommends cutting emissions linked to purchases of drugs and medical devices; cutting emissions linked to energy consumption; taking action on transport movements; taking action on waste; and using digital technology to support decarbonisation, the aim being to pave the way for the emergence of an abstemious and resilient health system.

5. Conclusions

46. Confidence is one of the pillars of our societies. In the sphere of health, it enables care staff to rely on their peers and other care sector players to discharge their front-line duties. It is also important for patients, who expect everything to be done to care for them. But in a sector that lurches from crisis to another, the sincerity of the players involved has to be verified. The scandals that taint them must be avoided. The question of the effectiveness and safety of the medical supply chains is also posed, not least because uncertainty remains despite the willing attitude and sincere efforts of health sector players. The right to healthcare requires a very high level of ethics to advance general well-being.[58] The Covid-19 pandemic had a particular impact on the resilience of the health sector, already badly affected by recurrent scandals and also by sweeping reforms and liberalisation.

47. The problems of securing the medical supply chains stem from a combination of systemic factors in the health sector. They are the result of malfunctions that can be observed throughout the chains, ranging from the development of medical service to its provision, and to a lack of transparency and accountability. They concern manufacturers, distributors, wholesalers, pharmacies, hospitals, health professionals and patients. The sector is particularly exposed to issues of governance but also of corruption. Prevention efforts and the introduction of warning systems and means of prosecuting transgressions should be reinforced.

48. The right to protection of individual's health is key to the enjoyment of every other fundamental right. As counterfeiting medical products is a transnational crime which does not recognise boundaries, more States should sign and ratify the MEDICRIME Convention to strengthen their power to combat this scourge. To mark the MEDICRIME Convention's 10th anniversary, the Committee of Ministers of the Council of Europe recently adopted a Declaration reaffirming the key roles of the MEDICRIME Convention in which was underlined its importance in guaranteeing and promoting the protection of public health and of its Committee of the Parties as the sole and steering committee to monitor the implementation of the convention. The Declaration invited States to sign and ratify the convention, in line with the suggestion made at the 131st Ministerial Session.[59]

49. The strengthening of medical supply chains must be a public health priority. If the fragilities of our supply chains are not quickly addressed, we risk having future crises in which our global supply chains are severely affected once again. The Covid-19 pandemic had an unprecedented impact on the world, but it will not be the last of its kind. The war of aggression inflicted by the Russian Federation on Ukraine and the waves of sanctions decided are likely to have adverse consequences in terms of medical supplies. In addition to the provision of substances used by the pharmaceuticals industry, the EMA notes that the continuation of clinical trials in the region is already threatened for the foreseeable future.[60] Other threats to our global medical

55. The Shift Project, November 2021, "Décarboner la santé pour soigner durablement".
56. The average per capita carbon footprint in France was 9 tonnes of CO^2 in 2021 as compared to a target of 2.4 tonnes.
57. Doc. 15354 (2021).
58. Lawrence O. Gostin, Georgetown University Law Center, "Public Health, Ethics, and Human Rights: A tribute to the Late Jonathan Mann".
59. Declaration by the Committee of Ministers on the occasion of the 10th anniversary of the MEDICRIME Convention, "Protecting public health through criminal law measures" (adopted by Committee of Ministers on 10 November 2021 at the 1417th meeting of the Ministers' Deputies).
60. EMA, 30 March 2022, "Advice to sponsors on managing the impact of the war in Ukraine on clinical trials".

supply chains include events such as climate change and natural disasters, shifting global economic and geopolitical conditions, or the threat of cyberattacks.[61] Medical supply chains must therefore be carefully studied in order to better identify vulnerabilities and focus on making them more robust, so as to minimise the risks for future disruptions.

50. No single country is able to manage supply chain challenges by itself. More than ever, international co-operation is needed to secure safe medical supply chains. Member States must ensure that the right to protection of health is always guaranteed, as provided notably by Article 11 of the European Social Charter.

51. The French consumers association UFC concluded its 2020 survey by demanding: an obligation for laboratories to stockpile sufficient quantities of all medicines of major therapeutic value to cover the needs of health system users; the strengthening, in law and in practice, of sanctions for laboratories that are negligent in their management of supplies for the French market; that if companies use public funding to relocate, this should be permitted only for operations concerning medicines of major therapeutic value and that the longest established drugs recurrently in short supply should be treated as a priority; and finally that public-sector pharmaceutical production be developed to ensure manufacturing continuity for products dropped by laboratories.

52. In efforts to ensure safe supply chains, the right to protection of health as defined by WHO should be emphasised. This objective is further refined by the Oviedo Convention, which establishes an additional specific requirement of equitable access to healthcare of an appropriate quality in Article 3. To achieve this goal, it would be useful to be able to benefit from reinforced expertise geared to that very definition of health. However, the Council of Europe's European Health Committee and Health Division ceased to exist in 2011, which is regrettable. That said, under the auspices of the Committee of Ministers, the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) replaced the Committee on Bioethics (DH-BIO) in January 2022, one of its missions being to ensure that priorities in accessing scarce health resources are set consistently and with respect for human dignity and the protection of human rights. This is both a public health requirement and an individual right. The approach of the Council of Europe is through its human rights-focus to guarantee quality, safety, and fairness. It must be capable of initiating a transparent dialogue with the member States where the preservation of human rights is concerned.

53. If confidence is to be restored, the right to protection of health must be positioned as the sector's sole reason to exist. The functioning of the supply chains is clearly problematic. We must learn the necessary lessons, including from the succession of scandals that have damaged the reputation of manufacturers as well as from the shortages of useful and inexpensive drugs and from the marketing of new products. Faced with these incidents, it is necessary to optimise the functioning of the consultation and debate bodies where the authorities can also exchange good practices and take part in a constructive debate with all the players in the sector and their representatives on all the health related topics. In addition to the pragmatic management of the supply chain issues described and in discussion by European regulatory bodies (EMA, OECD, EDQM), these bodies could set themselves the overall aim, drawing on past proposals from Jonathan Mann, former WHO administrator and a pioneer of the fight against AIDS, of assisting the sector's players in the drawing up of a code of ethics for public health and adoption of a classification of violations of the right to health. This operation would comprise three phases, reinforcing: public health ethics at the professional level, applicable individually to practitioners; public health ethics applied in specific cases where moral judgements are to be made, particularly where arbitration is needed between the management of society's assets and individual interests; and public health ethics which must serve the interests of communities, especially where the most vulnerable are concerned.

61. Communication by the Swiss company Zircon in *Forbes*, 1 June 2021, "Building Resilient Supply Chains For Healthcare".