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A Council of Europe contribution to support member states in addressing healthcare issues in the context of the present public health crisis and beyond

Executive summary

The COVID-19 public health crisis has had a devastating effect on individuals, families and communities across Europe and the wider world. It has forced governments to make fast, difficult and often controversial policy choices.

The Council of Europe has been quick to react by providing its member states with tools and expertise to ensure that the crisis does not undermine our common values and principles (see Toolkit, SG/Inf(2020)11). The Secretary General called upon the member states for greater solidarity and better co-ordination in responding to the crisis. There is also a need for the Organisation's programmes and activities to be refocused in order to promote co-ordinated responses, to exchange good practice, and together to learn the lessons of the crisis in the quest for a quicker recovery.

The present document focuses primarily on the crisis-related issues relating to healthcare in the light of relevant conventions of the Council of Europe, in particular the European Convention on Human Rights, the European Social Charter, the Convention on Human Rights and Biomedicine ("the Oviedo Convention"), the Convention on the elaboration of a European pharmacopoeia and the Convention on the counterfeiting of medical products and similar crimes involving threats to public health ("the MEDICRIME Convention"). The issues included are the right to life and the protection against ill-treatment (Articles 2 and 3 of the European Convention on Human Rights (ECHR)), the related right to the protection of health (Article 11 of the European Social Charter), and the principle of equitable access to healthcare (Article 3 of the Oviedo Convention).

These unique instruments must be better employed to review and strengthen member states' capacities to comply with our common standards. Special attention must be paid to the situation facing vulnerable groups, including the gravely ill, people in extreme hardship, older persons, migrants, people with drug addiction problems and those deprived of their liberty.

Member states are encouraged to take an active part in the implementation of the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) of the Committee on Bioethics. It is also important that states support the MEDICRIME Convention including the co-operation project – which has been launched and is open to financing – aimed at providing technical assistance and support to States Parties to the Convention and to other interested countries.

Furthermore, the Council of Europe must enhance its co-operation activities regarding national practices to address pandemics. A new multilateral and multidimensional co-operation project is currently being prepared, which will identify the most acute issues and the effective solutions to be adopted or to be considered at national level. It will be open to all interested member states. Subject to budgetary support, the project, alongside other existing projects on offer, should enable member states to realise their potential to fully employ relevant Council of Europe mechanisms with a view to strengthening their preparedness to protect human rights during public health crises. It should be instrumental in enriching the Organisation's standard-setting activities in those critical areas.

Introduction

The situation of the COVID-19 pandemic demonstrates the fundamental importance of everyone's right to health protection. Governments must be assisted in obtaining the right tools, restoring confidence and advancing in healthcare. Whether we are considering the provision of appropriate healthcare, access to resources, or the development of tracing applications, the common standards of the Council of Europe must apply.

This situation makes it all the more important to achieve greater unity between member states, to foster international co-operation and to uphold the rights and responsibilities of all members of society. The COVID-19 pandemic requires urgent and co-ordinated action to support member states in their efforts to protect public health.

The Council of Europe will continue to make every effort to support its member states during the current crisis and its aftermath. The Organisation's wide array of effective legal instruments, technical expertise and extensive networks of national experts provide valuable tools for governments and citizens to find the best and most sustainable responses to protect public health, maintain the democratic fabric of our societies and mitigate the social consequences of the crisis. The statutory bodies, institutions and Secretariat of the Council of Europe are being mobilised and will strive to use the tools and resources of the Organisation to share information, good practices and lessons learnt among all stakeholders, including authorities, civil society and citizens, in order to find appropriate responses to the challenges we face.

As suggested by the Toolkit for member states issued at the beginning of the crisis (9 April 2020), the programmes and activities of the Organisation (including, upon request, co-operation programmes with member states and non-member states) are being refocused to include components that will make the Organisation's contribution as relevant, timely and concrete as possible. The new multilateral and multidimensional co-operation project referred to in the present document will represent an important step in this direction, for which we will seek further support.

Right to life (Article 2 of the European Convention on Human Rights) and the Prohibition of torture and inhuman or degrading treatment or punishment (Article 3 of the European Convention on Human Rights)

Right to life

The right to life is a core right under the European Convention on Human Rights and cannot be subject to any derogation, even in times of public emergency such as the COVID-19 pandemic. This right has consistently required the positive obligations of states to protect people in their care against deadly diseases and the ensuing suffering. States have a duty to inform the population about the known risks related to pandemics and about behaviours or measures to avoid spreading disease.

The right to life may be invoked in respect of severely ill patients and other vulnerable groups such as people with disabilities or older persons. Their exposure to disease and an extreme level of suffering may be found incompatible with the state's positive obligations to protect life. This obligation is further confirmed by Article 11 of the European Social Charter (below). States' increased attention to vulnerable groups is also consistent with the principle of equitable access to healthcare (see below, Article 3 of the Convention on Human Rights and Biomedicine, "the Oviedo Convention").

¹ See the factsheet "Prisoners' health-related rights" published by the Court's Registry.

² See European Court of Human Rights, *Guerra and Others v. Italy*, judgment of 19 February 1998, Reports of Judgments and Decisions 1998-I, p. 227, § 58; *Öneryildiz v. Turkey [GC]*, no. 48939/99, 30 November 2004.

Prohibition of torture and inhuman or degrading treatment or punishment

The prohibition of torture and inhuman or degrading treatment or punishment is also a core right under the European Convention on Human Rights and cannot be subject to any derogation. Member states have an ongoing obligation to ensure that there is an adequate level of medical care for people deprived of their liberty³. The Committee of Ministers is exercising enhanced supervision over the execution of some judgments of the European Court of Human Rights revealing structural deficiencies in the medical care provided to prisoners or to migrants in detention.⁴ In this connection, the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) issued a Statement of principles relating to the treatment of persons deprived of their liberty in the context of the COVID-19 pandemic. The CPT is monitoring the situation and continues to do so during the crisis.⁵

On a practical level, in the framework of the revised European Prison Rules⁶ which contain key legal standards and principles related to prison management, staff and treatment of detainees, the Council of Europe is supporting member states in their legislation, policies and practices. This includes several co-operation projects concerned with assisting national authorities in reforming healthcare provision and human rights for sentenced persons. Attention is given to areas such as enhancing regulatory and operational framework, improving prison healthcare services through the introduction of new technologies in healthcare services, ensuring the protection of healthcare rights of mentally ill persons in penitentiary institutions, improving preventive healthcare, particularly sanitary-epidemiological and hygienic conditions and control mechanisms, and modernising hospital / specialised medical care and services in penitentiary institutions. In response to the COVID-19 pandemic, the Council of Europe donated and continues to donate urgently needed protective materials to inmates and prison staff in several member states. These donations aim to support the commitment of member states, including their national prison administrations, to adhere to the CPT statement of principles for the treatment of persons deprived of their liberty, in accordance with the World Health Organization quidelines in relation to the COVID-19 pandemic.

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³ See *Khudobin v. Russia*, no. 59896/00, 26 October 2006; As the CPT detailed in its Statement of principles relating to the treatment of persons deprived of their liberty in the context of the coronavirus disease (COVID-19) pandemic, "an inadequate level of healthcare can lead rapidly to situations falling within the scope of the term "inhuman and degrading treatment". See also relevant cases referred to in https://www.echr.coe.int/Documents/FS_Prisoners_health_ENG.pdf.

⁴ For prisoners, see notably *Ashot Harutyunyan v. Armenia*, (No. 34334/04); *L.B. v. Belgium* (No. 22831/08) – mental healthcare; *Kehayov v. Bulgaria* (group), (No. 41035/98); *I.D. v. the Republic of Moldova* (group), (No. 47203/06); *Bragadireanu v. Romania* (group), (No. 22088/04); *Dorneanu v. Romania*, (No. 55089/13) – terminally ill prisoners and *Ticu v. Romania* (group), (No. 24575/10) – mental healthcare; *Kalashnikov v. Russia* (group), (No. 47095/99) and *Ananyev and Others v. Russia* (group), (No. 42525/07); *Gömi v. Turkey*, (No. 38704/11) – mental healthcare; *Nevmerzhitsky v. Ukraine* (group), (No. 54825/00). For migrants in detention, see *M.S.S. v. Greece* (group), (No. 30696/09).

⁵ See news on CPT website, section "Latest visits".

⁶ On 1 July 2020, the Committee of Ministers adopted the revised European Prison Rules. These Rules are a global reference in this field to guide the 47 Council of Europe member states in their legislation, policies and practices.

The European Social Charter – A central instrument to protect social rights

The European Social Charter⁷ is crucial for building sustainable and prosperous democracies, especially when confronted with pandemics. States Parties to the Charter must ensure the best possible state of health for the population according to existing knowledge. This includes better preparedness for pandemics, such as COVID-19, to enable health systems to respond appropriately to avoidable health risks. Taking stock of these situations and learning the lessons are an important part of the recovery from them.

Article 11 of the European Social Charter enshrines the right to the highest possible standard of health and the right of access to healthcare. In other words, health is a state of complete physical, mental and social well-being and not merely the absence of disease or disability, in accordance with the definition of health in the Constitution of the World Health Organization (WHO), which has been accepted by all Parties to the Charter. To comply with Article 11, States Parties must demonstrate their ability to cope with infectious diseases, such as arrangements for reporting and notifying of diseases and by taking all the necessary emergency measures in case of epidemics.8 In its Statement of Interpretation on the protection of the right to health, adopted on 21 April 2020, the European Committee of Social Rights, the monitoring body of the European Social Charter, emphasised that "States Parties must take all necessary emergency measures in a pandemic. This includes adequate implementation of measures to prevent and limit the spread of the virus. Such measures may include, as in the present COVID-19 crisis, testing and tracing, physical distancing and self-isolation, the provision of adequate masks and disinfectant, as well as the imposition of quarantine and 'lockdown' arrangements. All such measures must be designed and implemented having regard to the current state of scientific knowledge and in accordance with relevant human rights standards." Furthermore, States Parties must operate widely accessible immunisation programmes. This includes maintaining high coverage rates not only to reduce the incidence of disease but also to neutralise the reservoir of the virus and thus achieve the goals set by the WHO to eradicate a range of infectious diseases. Vaccine research should also be promoted, adequately funded and efficiently co-ordinated across public and private actors.

In concordance with the Oviedo Convention (see below), Article 11 underlines that access to healthcare must be ensured to everyone without discrimination. Groups at particularly high risk, such as older persons, persons belonging to minorities, the homeless, the poor, and those living in institutions, must be adequately protected by the measures put in place. This implies that health equity as defined by the WHO should be the goal: absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification. Ideally, everyone should have a fair opportunity to attain their full health potential and no one should be disadvantaged from achieving this. New policies and measures should be put in place addressing the specific needs of vulnerable groups.

To support member states in the aftermath of the COVID-19 pandemic, the Council of Europe has an effective working tool – the European Social Charter – which is the most comprehensive international treaty in the field of social rights and is sometimes qualified as the "social constitution of Europe". It is the legal responsibility of our Organisation, as the depository of the Charter, to ensure that this treaty and its functioning is up to the challenge.

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⁷ European Social Charter, ETS No.163, Turin, 18 October 1961: see https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/163/signatures?p auth=1aBN6v1L.

⁸ ECSR, Conclusions XVII-2 (2005), Latvia.

As measures to improve the protection of social rights in Europe are rolled out in light of the proposals made by the Steering Committee for Human Rights (CDDH), member states should be encouraged to accept further commitments under the Charter and use it as a guideline in their policies and practices. Most importantly, our Organisation should take concrete steps to enable the organs of the European Social Charter to address the problems and social challenges of the post COVID-19 era in a concerted, coherent and above all timely manner. It is important for the Council of Europe and the States Parties who bear a collective responsibility to guarantee human rights, including social and economic rights, to engage in a genuine dialogue with a view to identifying practices and tools that will enable the competent authorities to adopt appropriate measures based on a common understanding of the need to preserve the solidarity and cohesion of our democratic societies. Based on this dialogue, the Council of Europe could provide additional support via co-operation projects to align national policies, legislation and practices to the requirements and standards provided under the Charter and other Council of Europe instruments. This would enhance the capacities of national authorities in delivering, protecting and promoting social rights and services, as well as raising awareness among target groups and populations in general regarding their human social rights. Finally, as the Council of the European Union acknowledged in its 13 July 2020 "Conclusions on EU priorities for co-operation with the Council of Europe 2020-2022", the European Social Charter constitutes an important reference for the Pillar of Social Rights of the European Union. In view of those priorities, the Council of Europe will work jointly with the EU and the European Commission "on guaranteeing economic and social rights in line with [member states'] international obligations".9

The Oviedo Convention – Protecting human rights in the field of biomedicine

On the occasion of the launch of the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025), organised in June 2020, under the auspices of the Greek chairmanship of the Committee of Ministers, Miltiadis Varvitsiotis, Alternate Minister of Foreign Affairs of Greece stated that "Following the COVID-19 pandemic, we have to look at the human rights through a new perspective. Therefore, a closer view on the area of biomedicine is imperative. Now more than ever".

The COVID-19 pandemic is greatly affecting healthcare systems. The number of severe cases raised major ethical challenges that professionals and competent authorities must address in the healthcare of patients. This results in difficult decisions being taken at collective and individual levels in a context of uncertainty and scarce resources. Anticipating these challenges and assessing the capacities needed to deal with them requires efficient management in line with ethical principles and respect for human dignity and human rights.

The fundamental and indissociable link between human rights, solidarity and responsibility in this time of crisis is underlined by the Oviedo Convention. This is a unique legally binding instrument at international level which addresses, *inter alia* emergency and health crisis management, and guides decisions and practices in the clinical and research fields. The Oviedo Convention addresses important ethical challenges such as equitable access to healthcare (Article 3) in concordance with the European Social Charter (see above) which asserts that access to existing resources must be guided by medical criteria in order to prevent discrimination in the provision of healthcare. This is certainly relevant for the care of COVID-19 patients, but also for any other type of care potentially made more difficult with confinement measures and the reallocation of medical resources to fight the pandemic. The protection of the most vulnerable individuals and groups is at stake, such as persons with disabilities, older persons, refugees and migrants.

⁹ Annex to the Council conclusions on EU priorities for co-operation with the Council of Europe 2020-2022, approved by the Council of the European Union (Foreign Affairs) on 13 July 2020, 9283/20, COSCE 7, COPS 239, CFSP/PESC 606.

¹⁰ Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine ETS No.164, Oviedo 4 April 1997.

The impact of the Oviedo Convention can be seen far and wide in the national legislation and practices of many member states. With 29 member states having ratified the treaty, 6 having signed but not yet ratified, and a number of others aligning with its principles, it is considered to be the "European patient's rights treaty". The Convention is an instrument of reference for judgments of the European Court of Human Rights, and it has been reasserted by others, namely the EU in its Charter of Fundamental Rights and in certain directives. At the global level, the Oviedo Convention is cited in UNESCO's Declaration on human rights and bioethics. Non-European countries, notably Mexico, have expressed their interest in acceding to the treaty.

Responsibility for the Oviedo Convention lies with the Committee on Bioethics (DH-BIO), the leading intergovernmental platform for exchanges of information, expertise and analysis on the protection of human rights in biomedicine also during the pandemic. This platform strengthens the resilience of member states to address health-related threats, including issues of transparency and trust in healthcare systems and the authorities responsible for the management of the COVID-19 pandemic.

To optimise reflection and action on health-related threats and ethical challenges, the DH-BIO has expressed its commitment to effective and efficient co-operation with other organisations and bodies. The Committee seeks out active partnerships with members of the UN's Interagency Committee on Bioethics, including WHO, UNESCO International Bioethics Committee (IBC), World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), and European Group on Ethics in Science and New Technologies (EGE). In doing so, the Committee will be able to harness the offer of co-operation activities to member states.

At national and local levels, the Council of Europe's capacity building programmes help member states to align themselves with human rights principles in the biomedical field. This includes the preparedness of their national institutions / bodies to protect human rights during public health crises. At a practical level, this comprises good practices in relation to, for example, informed consent for medical intervention, protection of private life and right to information, protection of participants in biomedical research both in emergency clinical situations and in complex and acute situations encountered during healthcare crises. Under the HELP programme, an online course on key human rights principles in biomedicine provides strong and structured support for health and legal professionals alike.

Such support will increasingly be needed during and in the aftermath of the pandemic, especially support to national authorities in their efforts to bring the law and legal implementation practices in the biomedical field in line with European human rights and ethical standards. There will also be a need to promote societal dialogue between the public, scientists and policy makers in order to build trust in the management of the crisis. The Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) will play a key role in channelling the support needed and in helping national authorities to make decisions in addressing the pandemic we face today in a way

¹¹ Committee on Bioethics Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025).

¹² See WHO guidance on managing ethical issues in infectious disease outbreaks (2016).

¹³ See joint Statement on COVID-19: Ethical consideration from a global perspective.

¹⁴ See Statement on European solidarity and the protection of Fundamental Rights in the COVID-19 Pandemic.

¹⁵ As underlined by the President of the European Committee of Social Rights in his statement "If...there is no opportunity to rebuild trust, the damage will persist and ripples will destabilise communities and countries, and possibly threaten social and democratic sustainability. In order to mitigate these risks, ...there will be a need for some form of social dialogue to enable "reconciliation" after COVID-19."

¹⁶ The Committee on Bioethics has adopted a guide to public debate on human rights in biomedicine for decision makers, government officials, public authorities, national ethics committees and other relevant educational and academic institutions and organisations, in other words, those who usually have responsibility for initiating and/or carrying out public debate.

that maintains our common standards on human rights, democracy and the rule of law. To this end, member states are encouraged to abide by their commitments, to take up the Council of Europe's offer of support where needed and to take an active part in the implementation of this Strategic Action Plan.

The European Pharmacopoeia and other activities to ensure the quality of medicines and healthcare

The right to the highest possible standard of health and the right of access to healthcare enshrined in Article 11 of the European Social Charter require the broad availability of good quality medicines. With the ratification of the Convention on the elaboration of a European Pharmacopoeia (Ph. Eur.), Parties commit to join forces in the establishment of quality specifications for medicinal products and their components that are of general interest and importance to the peoples of Europe, compiled in the form of a common pharmacopoeia, and to make them mandatory on their respective territories.

Since the Convention's adoption in 1964, it has been ratified by 39 Council of Europe member states and the European Union. To date, the Ph. Eur. contains more than 2,400 monographs and 375 general texts which define the quality of medicines and how to test them – the collective outcome of the work of more than 800 experts in pharmaceutical sciences from Europe and beyond, achieved under the leadership of the Ph. Eur. Commission; a success that would never have been possible for one member state alone.

As new products are being developed and approved, as medical practice and technology are ever-evolving, new standards are regularly added to the Ph. Eur. and existing ones reviewed and revised. As a response to the COVID-19 pandemic, the Ph. Eur. Commission and its secretariat, the European Directorate for the Quality of Medicines & HealthCare (EDQM), took a number of additional initiatives to contribute to the protection of public health, e.g. to make freely available targeted information on antiviral medicines and vaccines to support those developing, manufacturing or testing these products and fast-tracking candidate COVID-19 vaccine developers' understanding of regulatory requirements.

During confinement, the EDQM has reached out both to national pharmacopoeia authorities and the pharmacopoeias of the world to exchange on the situation in the different member states and regions and to discuss how and where to join forces.

The activities of the Network of Official Medicines Control Laboratories (OMCLs), co-ordinated by the EDQM and co-funded by the European Union and the Council of Europe, also demonstrate the importance of multilateralism and worksharing in the context of a public health crisis. Examples are the sharing of information on the testing of potential candidate substances used for the treatment of acute SARS-CoV-2 patients or supporting each other in overcoming the challenges posed by the crisis, including the establishment of a business continuity plan to help ensure continuity of important activities such as the Official Control Authority Batch Release (OCABR) of vaccines and human blood- and plasma-derived products as well as veterinary vaccines to safeguard the continued availability of these essential medicines to patients. Most importantly, the OCABR network is currently preparing for the transfer of the potential future batch release tests for COVID-19 vaccine candidates to OMCLs – earlier than in the usual process – to ensure the OCABR system is ready at the time the first vaccine gets market approval in Europe.

In the field of Substances of Human Origin, the European Committees on Blood Transfusion (CD-P-TS) and on Organ Transplantation (CD-P-TO), and their subordinate working groups, have facilitated the exchange of information and fostered co-operation between member states and health authorities to minimise the impact of the pandemic on this public health sector.

In this sector, the COVID-19 pandemic has major implications, notably the reduction in the number of blood, organs, tissues and cells donations, and the loss of crucial staff because of sickness or their transfer to intensive care services. This situation urged professionals and relevant healthcare establishments to implement continuity measures to maintain sufficient stock of blood, organs and tissues and cells to respond to critical clinical needs for transplantation and transfusion, for instance, major trauma or vital transplantation.

In this context, the EDQM organised a series of webinars for the tissue donation and transplantation communities to discuss how the COVID-19 pandemic was affecting national tissue donation programmes and daily activities in tissue establishments, to exchange ideas on the latest recommendations on testing practices and to support forward-looking decisions, in particular, through the application of comprehensive quality management systems and a thorough assessment of the new risks during all critical steps and procedures in tissue establishments. In addition, continuity of the work of these intergovernmental committees was key in ensuring patients all over Europe continued to receive lifesaving transplantation and transfusion treatments during this unprecedented crisis and beyond.

Council of Europe member states Parties to the Convention on the elaboration of a European Pharmacopoeia also work on improving public health and access to good quality medicines and healthcare under the aegis of the European Committee for Pharmaceuticals and Pharmaceutical Care (CD-P-PH). This is done by the means of harmonised good practices for the appropriate use of medicines and promoting the implementation of the pharmaceutical care philosophy and working methods in Europe. Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services has just been published for this purpose and monitoring and co-operation work is starting to ensure its dissemination at national level. Rational use of medicines is one of the multiple ways healthcare systems and the supply chain of medical products can be made more resilient to crises such as COVID-19. In the same framework, committees of experts co-ordinated by the EDQM work at updating existing guidance on "mail order" trade of medicines. This area requires extra caution from authorities, healthcare professionals and patients, as illegal online pharmacies and other vendors try to benefit from the pandemic situation to sell unauthorised, falsified or low-quality medical products.

The EDQM is also active in the fight against counterfeit / falsified medicines via the activities of the European Network of OMCLs and the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED). COVID-19 has led to issues with shortages of both medicines and devices and substandard or illegal/ unauthorised (e.g. traditional Chinese medicines, claimed healing / preventing COVID-19) moving from one country to another because of the exceptional environment. Work is ongoing to develop a guide on good social media practice for communication about falsified medical products.

All these activities illustrate the need to develop or update strong standards for member states and to ensure their implementation via co-operation and monitoring so that healthcare systems are better prepared in case of a next crisis.

The MEDICRIME Convention – A criminal law tool for countering falsified medical products

Criminal networks are introducing into the market falsified medical products which endanger public health and the right to life enshrined in regional and universal human rights instruments.¹⁷ This significant and growing global phenomenon has been made more visible with the pandemic. National authorities contributing to the protection of public health (e.g. judicial, health, law-enforcement and customs) are facing both falsified medicines and falsified medical devices, such as surgical facemasks or COVID-19 testing kits and may also face the risk of falsified vaccins. Every country is vulnerable to the falsification of medical products – regardless of how tightly it controls its borders and supply chain because of the fragmented nature of these crimes. These products may find their way into the legal supply chain. Individual criminals and organised crime groups can take advantage of loopholes and inconsistencies in national legislation to perform their criminal activities by using new technologies, the Darknet and other platforms without being detected by law-enforcement authorities. The lack of a solid legal framework allows criminal networks to act with impunity, putting at risk the health and safety of the most vulnerable people.

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¹⁷ Including, *inter alia* the European Convention on Human Rights (Article 2), the Universal Declaration of Human Rights (Article 3) and the International Covenant on Civil and Political Rights (Article 6). Indeed, as human rights are interdependent, indivisible and interrelated, the violation of the right to health may often impair the enjoyment of other human rights.

The falsification of medical products is a transnational crime which does not recognise boundaries. There is an urgent need for countries to criminalise those activities connected with the falsification of medical products and other similar crimes. Countries have at their disposal the Council of Europe MEDICRIME Convention¹⁸, which was devised partly with public health epidemics and pandemics like COVID-19 in mind. Along with other legal instruments, it may be used as an indispensable tool to surmount some of the obstacles faced by competent national authorities when combating the falsification of medical products and other similar crimes. The Convention safeguards public health through penal measures by criminalising certain acts, protecting the rights of victims, promoting co-operation at national and international level, as well as establishing preventive measures. This allows countries to participate in a global coalition that employs cross-sector co-operation between health, law-enforcement and judiciary authorities. In April 2020, the Committee of the Parties to the Convention issued Advice¹⁹ to support member states in tackling falsified medical products during the pandemic.

With only 13 Council of Europe member states²⁰ and 3 non-European states²¹ having so far ratified the MEDICRIME Convention, it is now time for countries to step up their commitment to fighting the falsification of medical products by signing and / or ratifying. This commitment will enable all our member states and several non-member states to join forces against this scourge at a time when unscrupulous criminals are taking advantage of the pandemic. The Committee of the Parties of the MEDICRIME Convention is an ideal platform to both facilitate the collection, analysis and exchange of information, experience and good practice between states and to make international co-operation happen. Further advances in the different legislative frameworks of certain countries need to be implemented in order to align national legislation with the MEDICRIME Convention, thus allowing more effective international co-operation. The MEDICRIME Convention promotes and facilitates cross-sector and multidisciplinary co-operation between judicial, health,²² customs and law-enforcement authorities.

At a time when the COVID-19 pandemic is posing unprecedented challenges to public health, the Council of Europe calls on governments to be extremely vigilant against falsified medical products. Faced with this threat, states can rely on the MEDICRIME Convention to safeguard public health and target the criminal behaviour of those taking advantage of the vulnerabilities in our systems and of the current crisis. In this connection, member states are called upon to support the Council of Europe co-operation project aimed at providing technical assistance and support to the State Parties to the MEDICRIME Convention, and to other interested countries, which has been launched and is open to financing.

Pompidou Group contribution to meet the challenges resulting from the pandemic for drug policy-related services

To support its member states in meeting the health and human rights challenges arising from the COVID-19 pandemic, the Pompidou Group set up an online platform for the use of decision makers and practitioners. Since its creation in April 2020, the platform offers concrete examples of practices that are aimed at mitigating the adverse effects of the COVID-19 crisis and associated restrictions for people who use drugs as well as those who are in contact with them. Frontline workers use the

¹⁸ Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, CETS No. 211, Moscow, 28 October 2011.

¹⁹ See https://rm.coe.int/cop-medicrime-covid-19-e/16809e1e25.

²⁰ Albania, Armenia, Belgium, Croatia, France, Hungary, Portugal, Republic of Moldova, Russian Federation, Spain, Switzerland, Turkey and Ukraine.

²¹ Benin, Burkina Faso and Guinea.

²² Co-operation with health authorities is ensured through the work of the European Directorate for the Quality of Medicines & HealthCare (EDQM) which actively contributes to the fight against falsified medicines through its network of official medicines control laboratories (OMCLs) and its intergovernmental committees that bring together experts from national health authorities from Council of Europe member states.

platform to upload information to the *SaveLivesProtectPeople.net* website in order to present their ideas and actions in one of the platform's six languages: English, French, German, Italian, Spanish and Russian. A publication summarising contributions and identifying lessons learned for nurturing future discussions on protecting the health of risk groups is under preparation.

Conclusions and next steps

The COVID-19 pandemic has had a devastating effect on individuals, families and communities across Europe and the wider world. It has forced governments to make fast, difficult and often controversial policy choices, especially regarding healthcare. In the difficult choices that lie ahead it is important that our member states can make those decisions in a way that maintains our common standards in human rights, democracy and the rule of law.

In this regard, the relevant legal instruments, as referred to in the previous sections of the document, must be supported and promoted. All member states should sign, ratify and effectively implement the European Social Charter, the European Convention on Human Rights and Biomedicine ("the Oviedo Convention") and the Convention on the counterfeiting of medical products and similar crimes involving threats to public health ("the MEDICRIME Convention").

These unique instruments need to be better employed to review and strengthen member states' capacities to comply with our common standards.

In this respect,

- It is necessary for all member states to take an active part in the implementation of the Strategic Action Plan on Human Rights and Technologies (2020-2025) of the Committee on Bioethics; the Secretariat will spare no effort to facilitate a genuine and result-oriented implementation of this Strategic Action Plan.
- Steps will need to be taken very rapidly to enable the Organisation to react more promptly and to engage in a structured and genuine dialogue with all member states as regards the respect for social and economic rights; specific proposals will be made soon in respect of the role and place of the European Social Charter in this field, including its interaction with other international organisations, in particular the European Union.
- The need for states to support the MEDICRIME Convention is more pressing than ever; a
 co-operation project aimed at providing technical assistance and support to the State Parties
 to this Convention, and to other interested countries, has been launched and is already open
 to financing.
- Finally, we need a new multilateral and multidimensional co-operation project to address healthcare issues and devise effective, tailor-made solutions to be implemented at a national level. The Secretariat has been instructed to prepare such a project open to all those who are interested. Subject to budgetary support, this project should enable member states to fully employ relevant Council of Europe instruments and mechanisms with a view to strengthening their preparedness to protect human rights during public health crises. It should be instrumental in enriching the Organisation's commonly accepted human rights standards in the field of healthcare. It will comprise co-operation activities which serve to align national policies, legislation and practices and enhance the capacities of national authorities in delivering, protecting and promoting social rights and services. Capacity building programmes will help member states align themselves with European human rights and ethical standards in the biomedical field. Cross-sectoral and multidisciplinary co-operation between judicial, health, customs and law-enforcement authorities will also help member states counter the threat of falsified medical products, including those provided during the COVID-19 pandemic. Member states will be duly informed of this novel and timely co-operation project and encouraged to come up with funding initiatives to support it.