

The Council of Europe's Underrated Role in Fostering Equitable Access to Quality Health Care in Times of Pandemic

Éloïse Gennet

▶ To cite this version:

Éloïse Gennet. The Council of Europe's Underrated Role in Fostering Equitable Access to Quality Health Care in Times of Pandemic. Health and Human Rights, 2024, 25 (1), https://www.hhrjournal.org/2024/04/the-council-of-europes-underrated-role-in-fostering-equitable-access-to-quality-health-care-in-times-of-pandemic/. hal-04520860

HAL Id: hal-04520860 https://hal.science/hal-04520860v1

Submitted on 12 Jun 2024

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers. L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.







The Council of Europe's Underrated Role in Fostering Equitable Access to Quality Health Care in Times of Pandemic

ÉLOÏSE GENNET

Abstract

Different Council of Europe organs have been attentive and reactive to specific human rights issues in the COVID-19 context, quickly alerting on the risks of inequitable access to quality health care, vaccines, or medicines for vulnerable groups. Yet these reactions have mainly taken the form of nonbinding instruments such as declarations, statements, and recommendations. Although these reactions derive from the interpretation of binding Council of Europe conventions, the observance or implementation of these conventions is not always monitored. Strasbourg judges have on several occasions confirmed that European Convention on Human Rights case law must consider other international instruments, especially those of other Council of Europe organs, in order to interpret the guarantees of the convention. As a consequence, soft law rules can sometimes indirectly acquire binding force when used as an interpretation and implementation tool for binding treaties. In this paper, I examine how Council of Europe organs interpret the principle of equitable access to health care of appropriate quality in the context of a pandemic and whether and how this interpretation is being implemented within the Council of Europe's interpretation of binding treaties such as the Medicrime Convention, the European Social Charter, and the European Convention on Human Rights.

ÉLOÏSE GENNET, PhD, is a junior professor in European health law at Aix-Marseille University, National Center for Scientific Research (CNRS), International, Comparative and European Law (DICE), Centre for International and European Studies and Research (CERIC), Aix-en-Provence, France.

Please address correspondence to the author. Email: eloise.gennet@univ-amu.fr.

Competing interests: None declared.

Copyright © 2024 Gennet. This is an open access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/by-nc/4.0/), which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original author and source are credited.

Introduction

The COVID-19 pandemic has uncovered many health inequalities and exacerbated their consequences. As the world continues to recover from this experience, action is gradually being taken at national and supranational levels to prevent this from happening again. Despite recognizing the importance of finding solutions at the global level, in this paper I choose to emphasize existing instruments of the Council of Europe, which, although often overlooked, could serve as a solid basis for a human rights approach to fostering health equity in the context of a future pandemic. As was noted by the Council of Europe's Committee of Ministers in early 2023, crisis situations only perpetuate or exacerbate preexisting inequities.1 Preventing inequitable situations in the next pandemic thus inevitably implies working on day-to-day equitable health care access, and in that regard the Council of Europe's legal framework already provides for a wide range of instruments and actors.

To begin with, the Council of Europe has almost since its creation—cooperated in the field of public health.2 This (rather scientific) cooperation evolved into the creation of the European Directorate for the Quality of Medicines and Health Care in 1964, together with the adoption of the Convention on the Elaboration of a European Pharmacopoeia.3 No directorate instrument per se enshrines a right to health protection or to health care access. However, some of the directorate's instruments could become powerful tools to fight against inequities. For instance, its 2011 Medicrime Convention on the counterfeiting of medical products might prove a crucial instrument, and its Medicrime Committee a crucial actor, in protecting equitable quality of medicines in contexts such as pandemics or shortages.4 In fact, the unmet medical need created by a pandemic or shortage—because it creates attractive opportunities for counterfeiters to meet that need—increases the risk of being exposed to falsified medicines.

Second, the Council of Europe has adopted the only internationally binding instrument in bioethics: the Convention on Human Rights and Biomedicine (commonly known as the Oviedo Convention), adopted in 1997 and now ratified by 30 member states.5 Interestingly, article 3 of this convention enshrines the principle of equitable access to health care of appropriate quality. This provision does not create an individual right on which each person may rely; it has to be assessed within the framework of national laws, which remain competent for health matters.6 However, it can be used to interpret other Council of Europe instruments in favor of equity in health protection—"equitable" meaning "first and foremost the absence of unjustified discrimination."7 The Committee on Bioethics (previously known as DH-BIO, since January 2022 called CDBIO) is a subsidiary body established by the Committee of Ministers to further promote human rights standards in view of scientific developments.8 Interestingly, observing the increasing disparities in health since the adoption of the Oviedo Convention, the committee has made the question of equity in health care one of its three strategic priorities for 2020-2025.9

Beyond these specialized treaties, the Council of Europe also provides for more general instruments that, directly or indirectly, protect human health as well. In fact, the Revised European Social Charter enshrines the right to protection of health in its article 11, considering this right as a prerequisite for the preservation of human dignity.10 The European Committee of Social Rights (ECSR) insists on state parties taking "practical action making available the resources and the operational procedures necessary to give full effect" to social rights, including the right to health.11 Interestingly, when assessing whether this right is exercised effectively and without discrimination, the ECSR "pays particular attention to the situation of disadvantaged and vulnerable groups."12

Finally, the European Convention on Human Rights (ECHR) does not explicitly protect the right to health, but it protects this right implicitly via the protection of life (article 2), the prohibition of degrading treatment (article 3), and the protection of private life (article 8). European judges are very mindful of the wide margin of appreciation of member states in the field of health, yet they have historically shown more audacity when it comes to

effectively protecting the rights and health of vulnerable groups.¹³

These instruments are at the center of the Council of Europe's legal framework on the question of (equitable) health protection. But how have they been mobilized and interpreted in the context of the COVID-19 pandemic? Are these instruments enough to ensure an equitable response and prevention if a major health event such as the COVID-19 pandemic were to happen again? To answer these questions, in the first part that follows, I will examine the concrete interpretations that different Council of Europe organs have made of the principle of equitable access to health care of appropriate quality as a direct reaction to and in the specific context of the COVID-19 pandemic. These interpretations take the form of soft law that is, normative yet nonbinding instruments such as statements and declarations.14 These nonbinding interpretations are then adopted by Council of Europe organs that are mandated to develop and interpret, if not monitor, the implementation of conventions that, on the contrary, are binding. It is thus tempting to hypothesize that these soft law instruments are likely to influence future interpretations of Council of Europe hard law treaties in the context of COVID-19. In fact, I subscribe to the idea that soft law constitutes at least a material source of international law and that it even impacts how hard law is interpreted and implemented in context.¹⁵ I will thus analyze, in the second part of this paper, whether and how those soft law instruments have been effectively incorporated into the Council of Europe's binding treaties and case law.

Interpreting equitable access to quality health care in times of pandemic

Different Council of Europe organs have been attentive and reactive to specific human rights issues in the COVID-19 context and have adopted soft law instruments targeting issues of equitable access to health care. The DH-BIO (now CDBIO) published a general statement in 2020 on human rights considerations relevant to the COVID-19 pandemic, and in 2021 another statement specific to equitable ac-

cess to vaccination during a pandemic.16 The ECSR was also quick to react in 2020 when issuing a statement on the right to protection of health in times of pandemic.¹⁷ The question of equity has played an important role in these reaction statements and is more formally supported in a 2023 recommendation of the Council of Europe Committee of Ministers regarding equitable access to medicinal products in situations of shortage.¹⁸ Yet in conformity with article 3 of the Oviedo Convention, the question of equitable health care access is inseparable from that of appropriate quality of health care. Especially in times of pandemic, quality is an equity-relevant question for two reasons. First, and as recalled by the DH-BIO, the general quality and safety requirements of a medical product have to be adapted to (and thus tested on) vulnerable population groups despite the situation of emergency.¹⁹ Second, in times of pandemic or shortage, the scarcity of vaccines compared to the global demand creates a market for low-quality falsified vaccines. In fact, such a heightened unmet medical need is a golden opportunity for criminals to take advantage of any despair-driven credulity or crisis-related weakened vigilance in regulatory systems. The Medicrime Committee thus issued an advice in April 2021 alerting member states about increased reports of falsified COVID-19 vaccines and the importance of implementing the Medicrime Convention in the context of the pandemic.20

Equitable access to health care

Pandemics are "inherently disequalizing, disproportionately affecting individuals and groups in vulnerable conditions." One major element in common among the soft law instruments drafted in response to COVID-19 is the acknowledgment of the importance of identifying vulnerable groups. This identification allows for setting up priorities in health care access and thus reestablishing a balance in favor of those who usually are at a disadvantage in accessing care.²²

Who to prioritize? Identifying the vulnerable. Recalling the principle of dignity and article 3 of the Oviedo Convention, the DH-BIO statement

underlines the "critical importance of equitable access to vaccination" and of ensuring "that everyone, without discrimination, is offered a fair opportunity to receive a safe and effective vaccine." In a context of scarce resources, this requires prioritizing people in a vulnerable situation: people with disabilities, older people, refugees and migrants, people with mental health problems, people with learning disabilities, minorities, homeless people, poor people, people with substance use disorders, and people deprived of liberty.²⁴

The 2023 recommendation of the Committee of Ministers also targets individuals or groups that are systematically disadvantaged in relation to health, "including as a result of economic and social conditions, legal status, disability, chronic disease or age," and gives a list of examples of such individuals and groups.²⁵ It notes, however, that prioritization should be based on medical criteria: severity of the health condition, expected effectiveness of the medicine, possible therapeutic alternatives, and the mortality risk consequent to the lack of access.²⁶

Interestingly, the ECSR also recalls the existing protection, in the European Social Charter, of health-related rights targeting specific groups, such as workers, socially disadvantaged people, older adults, and children.27 It highlights, in the case of a pandemic, the need to provide effective and affordable access to health care for groups with "heightened vulnerabilities" who might be at particular risk of discrimination or "on whom falls the heaviest burden in the event of institutional shortcoming."28 In an open list of examples, the ECSR refers to poor, homeless, and older people; people with disabilities; prisoners; and irregular migrants.29 This is in line with its long-standing interpretation of article 11 of the European Social Charter, according to which effectivity of the right to protection of health depends on the particular attention given to disadvantaged and vulnerable groups.30

How to prioritize? Removing concrete barriers to health care access. For this prioritization to be effective during a pandemic, the ECSR invites governments to take all required measures to com-

pensate or erase the unfair or avoidable differences among certain groups. To begin with, it underlines that long-standing shortcomings to secure social rights such as housing or freedom from poverty and social exclusion "feed directly into the vulnerability of particular social groups in a pandemic," who may lack equitable access to health care.³¹ Then, to organize prioritization during a pandemic, states have to take targeted measures for those who are particularly exposed, such as measures to educate people about the risks posed by the disease in question, how to mitigate them, and how to access health care services when needed or to provide for widely accessible immunization programs.³²

Similarly, both the DH-BIO statement on equitable access to COVID-19 and the Committee of Ministers recommendation suggest developing strategies "to ensure appropriate support and the removal of barriers" to access vaccines or medicines in a way for them to "be adapted to meet the needs of these persons," meaning the prioritized groups.33 Adapting to those needs means having actively engaged with representatives of these groups to better understand and overcome the barriers to access, having a range of pragmatic accessibility requirements, and adapting information to people's needs (such as low literacy or speaking a foreign language).34 In that regard, the CDBIO released a guide on health literacy in early 2023 as part of its mandate to further promote equitable access to health care.35 This recurring narrative around equitable health care access is thus not just a reaction to the pandemic but a reflection of a preexisting political will to fight increasing health disparities, as shown in the 2019 DH-BIO Strategic Action Plan on Human Rights and Technologies in Biomedicine.36

Interestingly, what is systematically missing in the identification of vulnerable groups is the global perspective on health care access, including cooperation and solidarity between states. The focus is on what countries should do on their own territories about vulnerable groups. Prioritization strategies do not reflect health inequities between countries or regions of the world. One exception, however, lies in the Council of Europe's fight for the equitable quality of medicinal products.

Equitable quality of health care

As the Medicrime Committee stressed during the COVID-19 pandemic, "until a production capacity is reached that satisfies global demand, there is a risk that the vaccines will be illegally moved from people in need to those who do not wish to wait their turn for vaccination." One of the 13 key messages of this advice is for states to recall that "every COVID-19 vaccine that is falsified is a risk both to vulnerable persons and to healthy persons," as it gives them the mistaken belief that they are protected from infection.³⁸

Medicine counterfeiting represents a threat to public and individual health and to the principle of equitable access to quality health care, as it creates new factors of vulnerability. Counterfeited medicines are of low quality because they do not respect regulatory standards. They may result in patients being untreated (or incorrectly treated) and can cause their condition to (sometimes irreversibly) aggravate, which is particularly dangerous when the condition is life-threatening. They can also lead to adverse effects due to dangerous ingredients, allergic reactions, drug interactions, or high dosage, among other things.³⁹

Moreover, medicine counterfeiters directly target vulnerable groups by tailoring their spamming to current shortages, such as those concerning a specific or rare medical condition.40 However, in situations such as a pandemic, an unmet medical need can be globalized, and the vulnerable factors shift from an individual perspective to a collective one. In fact, the collective vulnerability can be related to the financial inability of certain states to acquire enough medical products to meet the needs of their population. It can also be related to the lack of harmonized and effective regulations at the international level with regard to the pharmaceutical market but also more generally to online trade and cybercrime.41 The falsification of medical products represents a threat to any country, irrespective of the stringency of its border controls, because these illicit activities occur in such a fragmented manner that different elements of a counterfeit medicine (e.g., empty boxes, chemical components) infiltrate the legal supply chain separately, without violating

any laws, and therefore remain undetected.42

But most of all, unequal access to medicines and vaccines inevitably leads to unequal exposure to the risk of obtaining a counterfeit drug or vaccine. The Committee of Ministers, in article 19 of its 2023 recommendation on equitable access to medicinal products in a situation of shortage, underlines the "risk of purchasing products and equipment from unofficial supply channels and of unauthorized use."⁴³ Similarly, in its statement on COVID-19 vaccine equity and more specifically in its section about ensuring appropriate quality of vaccination, the DH-BIO underlines the need to comply with the Medicrime Convention of the Council of Europe.⁴⁴

The Medicrime Convention establishes as criminal offenses the manufacturing, supplying, and trafficking of counterfeit medical products, as well as similar crimes (articles 5, 6, 8). This convention has a wide scope because it covers medicinal products in general, irrespective of whether they are still protected by a patent or trademark legislation, thus including generics (article 3). This is an important added value and originality brought by the Council of Europe to the global legal landscape in this context. In fact, international efforts aimed at curbing the counterfeiting of medical products or promoting equitable access to medicines have traditionally centered around intellectual property issues.45 By contrast, the Medicrime Convention's primary goal is to combat the falsification of medical products for the significant threat it represents for individual and public health—that is, even when no actual damage has occurred (yet) for (potential) victims.46 Not only does it provide for another tool for equitable pandemic response, but through the dissuasive effect of the sanctions it foresees, it offers another tool to prevent negative and inequitable consequences of criminal behaviors on patients' rights during a major health event such as COVID-19. Moreover, it could also indirectly defeat some of the intellectual property regime's negative impacts on medicine prices. The high prices of medicinal products are detrimental to patients' access, especially in poorer countries, as they create an unmet demand and thus a market

for counterfeited medicines. In that regard and contrary to previously mentioned Council of Europe instruments, the Medicrime Convention takes into account a perspective on vulnerability and potential health inequities not only at a national but also at a global scale.

To conclude, when reacting to the COVID-19 pandemic, Council of Europe organs were quick to alert about the risks of inequitable access to quality health care, vaccines, and medicines for vulnerable groups. But not all Council of Europe instruments are binding, nor is their observance always monitored. When observance is monitored, the actual impact of the activities of such committees as the ECSR, CDBIO, and the Medicrime Committee is difficult to assess: the causality between the monitoring or expertise and the evolution of national laws may be difficult to clearly demonstrate because it is rarely direct.⁴⁷

Implementing equitable access to quality health care in times of pandemic

Strasbourg judges have on several occasions confirmed that ECHR case law "must take into account relevant international instruments and reports, and in particular those of other Council of Europe organs, in order to interpret the guarantees of the Convention and to establish whether there is a common European standard in the field."48 This, for instance, includes the European Social Charter, the Oviedo Convention, and the Medicrime Convention, even when they have not been ratified by the member state in question. In fact, Strasbourg judges have established that it can be sufficient if international instruments reflect evolving norms in international law or the domestic laws of most Council of Europe member states, indicating common ground in contemporary societies within a specific domain.49 Moreover, the court uses references to norms emanating from monitoring or expert bodies, such as the ECSR, CDBIO, Medicrime Committee, and others, even when those organs do not represent state parties.50 As a consequence, soft law rules can acquire an "indirectly binding force" when used by the European Court of Human Rights to precise ECHR binding provisions.⁵¹ In this section, I examine how equitable access to quality health care has been implemented within Council of Europe human rights treaties such as the ECHR and the European Social Charter, as well as within more targeted health-related treaties such as the Oviedo and Medicrime Conventions.

Implementation in the Council of Europe's general human rights treaties

Case law of the European Committee on Social Rights. Notwithstanding the difficult justiciability of social rights, the European Social Charter is binding for state parties that have ratified it; this binding nature includes cooperation with the independent monitoring committee, the ECSR, regarding the reporting procedure and, for the states that have accepted it, regarding the collective complaints mechanism.52 The ECSR's aforementioned 2020 statement on the right to protection of health in times of pandemic is not itself binding, but it has already been repeatedly integrated into the latest national reporting procedures on article 11 of the European Social Charter.53 In fact, the ECSR explicitly quotes its own statement in favor of equitable health care access by highlighting that nondiscrimination requires making health care effective and affordable to everyone during a pandemic, especially groups that have a higher risk.54 But even more noteworthy is the fact that the statement made its way into several decisions on the merits.

During the COVID-19 pandemic, questions were raised as to whether certain groups of people should be considered particularly vulnerable. For instance, in *International Commission of Jurists (ICJ) and European Council for Refugees and Exiles (ECRE) v. Greece*, the ECSR considered that because of their prior insufficient access to health care, unaccompanied migrant children in Greece were likely to experience heightened vulnerability as a result of the pandemic.⁵⁵ In *Open Society European Policy Institute (OSEPI) v. Bulgaria*, noting that the vulnerability of older adults was not acknowledged by Bulgarian authorities at the beginning of the COVID-19 pandemic, OSEPI alleged "that the

Government disregarded scientific and credible statistical information indicating the higher morbidity of older persons and persons with specific vulnerabilities." In contrast, being qualified as a "vulnerable group" has sometimes been contested by applicants. In *Validity Foundation v. Finland*, a mental disability advocacy center complained that some COVID-19 restrictions were inadequate considering that not all disabled people were vulnerable. The ECSR "took note" of this argument without further comment, instead directly examining the contested measures deriving from this automatic categorization as a vulnerable group.

In fact, categorizing certain groups as vulnerable is important because it impacts governments' obligations in guaranteeing equitable health care access. In Validity Foundation v. Finland, the complainant contended that the automatic categorization as "vulnerable" had prevented some disabled—yet not vulnerable—persons the chance to move away from residential institutions that had become coronavirus hotbeds (sections 32-34). Whereas these measures could be understood as being protective of vulnerable groups, they could also be viewed as discriminatory because they were disproportionately restrictive for the disabled persons who were not particularly vulnerable to COVID-19 infection. On that question, the ECSR did not find any violation and considered that the restrictions of access to health care were aimed at protecting people's health and "to a large extent ... resembled the ones applicable to the other housing service units and to those in place for the entire population" (section 54). In ICJ and ECRE v. Greece about unaccompanied migrant children, the decision did not examine COVID-19 measures since final submissions were received prior to the COVID-19 pandemic. The ECSR only observed that, as it has concluded on the violation of article 11 of the European Social Charter, these shortcomings "risk being exacerbated/compounded by the COVID-19 situation" (section 229).

Finally, in the case of *OSEPI v. Bulgaria*, the complainant alleged that "the situation as regards distribution of COVID-19 vaccines amounts to discrimination, in particular on the grounds of age

and health, in violation of article E in conjunction with article 11 of the Charter" (section 1). It considered that the failure to acknowledge older adults' vulnerability prevented the government from adopting a proper vaccination strategy targeting older adults. In fact, "Bulgaria has the highest accumulated death rate for COVID-19 in Europe" (section 14), and as of December 22, 2021, only 35.2% of persons over 60 had completed the vaccination process (section 4). Given that the Bulgarian government had meanwhile taken effective measures to palliate this problem, the ECSR rejected the idea of taking immediate measures (sections 14-19), but noted that it would examine the alleged discrimination regarding access to vaccines for older adults in an upcoming decision on the merits.

Case law of the European Court of Human Rights. Although many COVID-19 cases have already been examined by the European Court of Human Rights, only a few of them relate to questions of access to health care or medicines, let alone inequitable access thereto. Strasbourg judges usually show self-restraint in the field of health given that member states retain a wide margin of appreciation. Yet interestingly, in several cases, the court had to assess applicants' vulnerability in the context of COVID-19 in order to determine whether their life and health were particularly at risk. In the case of Fenech v. Malta of March 1, 2022, the applicant, a prisoner with only one kidney, was invoking articles 2 and 3 of the ECHR, complaining that authorities had failed to protect his health and life in prison despite his particular vulnerability to a COVID-19 infection.58 Strasbourg judges examined whether the applicant's life was genuinely at risk, considering the global mortality rate of COVID-19 (section 105), as well as the applicant's individual vulnerability to the infection, which he failed to prove. Although a consultant surgeon had indicated that his lack of a kidney could increase the risk of severe complications from COVID-19, no further studies were provided to support this claim. The court did not exclude the potential applicability of article 2 to COVID-19 cases (section 107)—for instance, to the most vulnerable, such as those with

cardiovascular disease, diabetes, chronic respiratory disease, or cancer (section 137)—but the risks for the applicant himself were not high enough (or not properly demonstrated) to trigger applicability of article 2 of the ECHR on the right to life.

On the contrary, in the case of Riela v. Italy of November 9, 2023, the applicant, a 67-year-old prisoner suffering from several diseases, "including a severe obstructive sleep apnoea syndrome, obesity, type 2 diabetes and hypertensive cardiopathy" (section 3), was considered by the court to be vulnerable because he was "exposed to significant risk of complications in the event of contracting COVID-19" (section 20).59 As a consequence, domestic authorities had to take into account his particular vulnerability when providing health care or protecting the applicant from getting infected. Indeed, the applicant was placed in a single cell and received a vaccine, which successfully prevented him from getting infected (section 20). Judges thus rejected the complaint based on article 2 ECHR on the right to life, because "the applicant [had] not provided sufficient evidence that the domestic authorities [had] failed to protect him from the risk of contracting COVID-19 and that, as a consequence, he [had been] exposed to a serious risk of death."60 Nevertheless, it still found a violation of article 3 of the ECHR—not for COVID-19-related care but for prior and continued delays in providing the applicant with a ventilator for his sleep apnea since 2018 (sections 8, 36).

In the aforementioned case of *Fenech v. Malta*, the applicant had failed to prove that he was among "the most vulnerable" and his life was at risk. Yet judges still observed that it may still not be feasible, due to the practical demands of imprisonment and the unprecedented circumstances, to accommodate and provide for safer quarters to all vulnerable prisoners. They concluded that national authorities did not fail to secure the applicant's health and that there had been no violation of article 3 of the ECHR either (sections 142–143).

Surprisingly, none of the DH-BIO's COVID-19-related statements have been used to identify vulnerabilities, whereas judges have used similar Council of Europe instruments when ruling

on prison-related issues. 61 Referring to the ECSR or DH-BIO statements could have led to considering prisoners as a vulnerable group, instead of having to prove a heightened vulnerability among an already vulnerable group. In the case of Fenech v. Malta, this could, for instance, have facilitated the demonstration of sufficiently high risks to health to trigger applicability of article 2 of the ECHR, or it could have weighed more heavily when assessing the alleged violation of article 3 of the ECHR, in the proportionality analysis of prison measures to prevent and limit the spread of the virus. Yet, as Strasbourg judges have noted in the past, "it is for the Court to decide which international instruments and reports it considers relevant and how much weight to attribute to them," be they binding or nonbinding.62 But interestingly, the recent 2023 Committee of Ministers recommendation has been prepared by the DH-BIO and thus might constitute a more impactful medium to spread its work.63 Although this is soft law, such recommendations to member states falling under article 15.b of the Statute of the Council of Europe benefit from a potentially high level of implementation because their adoption requires a unanimous vote and thus implies a "European consensus" between member states.64

The actual impact of these nonbinding instruments reacting to the COVID-19 pandemic will require further attention from legal scholars in the future, as COVID-19 jurisprudence is likely to grow tremendously in the coming years in view of the progressive exhaustion of domestic remedies and as the implementation of health-related Council of Europe treaties expands.⁶⁵

Implementation in the Council of Europe's health-related treaties

As explained above, the Oviedo Convention is central to the question of equitable access to health care of appropriate quality because it enshrines this principle in its article 3. Both of DH-BIO's previously mentioned COVID-19 statements are nonbinding developments of this article. However, it is not possible to precisely identify how this provision is being implemented in national laws.

The CDBIO (formerly DH-BIO) is not a monitoring committee that examines and reports on countries' implementation of the Oviedo Convention, similar to the way that other committees, such as the ECSR and Medicrime Committee, monitor their respective instruments. Rather, the CDBIO's mandate is to evaluate relevant activities and advise the Committee of Ministers on future priorities in the field of biomedicine and health. Moreover, even if the Oviedo Convention has been used in the past against a member state who has not ratified it, in practice it is only rarely explicitly used as an interpretation tool by the European Court of Human Rights, especially in proportion to the high density of bioethics case law.66 Up to now, article 3 has not been explicitly used in COVID-19 jurisprudence.

The Medicrime Convention has also never been cited in the case law of the ECSR or of the European Court of Human Rights, let alone in a COVID-19 case revolving around equitable access to quality medicines. However, this is less of a problem, for two reasons.

First, this can be explained by the fact that the Medicrime Convention is still relatively new. It was adopted in 2011 and entered into force only in 2016. To date, 23 states have ratified the convention, with a recent and continuous progression (five new signatures since 2023) showing the interest of countries including outside the Council of Europe (eight of the ratifying countries are non-member states). ⁶⁷ Effective implementation and actual efficacy of this treaty will undeniably depend on further ratifications and implementation experiences.

Second, it is interesting to note that the Medicrime Convention promises to be all the more impactful given that the very content of its provisions paves the way for its future effective implementation by ensuring technical cooperation and effective monitoring. In fact, the instrument provides for operational oriented provisions: it very concretely organizes the cooperation between state parties as well as between relevant administrations across sectors such as health authorities, customs, police, and others (article 17). The Medicrime Secretariat is already conducting a research project aimed at assessing countries' needs in effectively

implementing this cooperation and providing technical support to improve and strengthen international cooperation.⁶⁹

Finally, beyond this technical cooperation, the Medicrime Convention provides for the creation of a monitoring body to oversee implementation: the Medicrime Committee (article 23). As underlined by Marten Breuer, "in terms of implementation effectiveness, the existence or non-existence of monitoring mechanisms is of paramount importance," as without such a mechanism, "states are called upon to judge for themselves the conformity of their behavior with the treaty rules" and hence may claim conformity where other states or a monitoring body may claim otherwise.70 This monitoring of the Medicrime Convention started only recently, in 2020, first with a questionnaire to state parties, and then with another questionnaire the following year focusing on the context of pandemics.71 Hence, its effective implementation in favor of equitable access to quality health care for patients may just be a matter of time.

Conclusion

The Council of Europe is without a doubt bringing an added value to discussions on equitable access to health care of appropriate quality. Its relevant provisions are enshrined in specialized binding treaties that are unique in the international legal sphere. Its organs have quickly used their soft law powers to concretely interpret and operationalize the principle of equitable access to health care of appropriate quality in contexts such as a pandemic or major shortage. Its judges, experts, and monitoring committees are acknowledging the particular needs of vulnerable groups in accessing health care of appropriate quality. These actors are encouraged to take into account other Council of Europe soft law tools in their activities, thus guaranteeing a circulation and visibility of COVID-19 nonbinding norms in their case law. However, they remain in control of which instruments they refer to and how much weight is placed on these instruments in their review of an individual case—and, most of all, they remain bound by the obligation to respect national

sovereignty and states' wide margin of appreciation in the field of public health. Yet as COVID-19 jurisprudence continues to emerge, the principle of equitable access to health care of appropriate quality may be attributed more demanding obligations for states to prepare for the unavoidable next pandemic.

Funding

This work was supported by the French National Research Agency (ANR-22-CPJ2-0021-01) and by the France 2030 program as part of the Aix-Marseille University's A*MIDEX Excellence Initiative (AMX-22-CPJ-03).

References

- 1. Committee of Ministers, Recommendation CM/Rec(2023)1: Equitable Access to Medicinal Products and Medical Equipment in a Situation of Shortage (2023), preamble.
- 2. J. Ferrero, «Conseil de l'Europe: cadre institutionnel,» *Répertoire de droit européen* (July 2022), sec. 13.
- 3. Convention on the Elaboration of a European Pharmacopoeia, European Treaty Series No. 050 (1964).
- 4. Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (Medicrime Convention), European Treaty Series No. 211 (2011).
- 5. 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 (Oviedo Convention), European Treaty Series No. 164 (1997); Council of Europe, "Chart of Signatures and Ratifications of Treaty 164," https://www.coe.int/fr/web/conventions/full-list?module=signatures-by-treaty&treaty-num=164.
- 6. Oviedo Convention (see note 5), explanatory memorandum, secs. 26–27.
 - 7. Ibid., explanatory memorandum, sec. 25.
 - 8. Ibid., arts. 29, 32.
- 9. DH-BIO, Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020–2025) (2019), secs. 8, 9, 17.
- 10. European Social Charter (Revised), European Treaty Series No. 163 (1996); *FIDH v. France*, European Committee of Social Rights, No. 14/2003, decision on the merits of November 3, 2004, sec. 31.
- 11. *International Commission of Jurists (ICJ) v. Portugal*, European Committee of Social Rights, complaint no. 1/1998, decision on the merits of September 9, 1999, sec. 32.

- 12. European Committee of Social Rights, Conclusions 2005: Statement of Interpretation Article 11 (2005).
- 13. For a complete overview, see *Lopes de Sousa Fernandes v. Portugal*, European Court of Human Rights, application no. 56080/13, judgment of December 19, 2017, secs. 29–43. For further analysis, see L. Peroni and A. Timmer, "Vulnerable Groups: The Promise of an Emerging Concept in European Human Rights Convention Law," *International Journal of Constitutional Law* 11/4 (2013); É. Paillissé, *Le droit à la santé dans la jurisprudence de la Cour européenne des droits de l'homme* (Perpignan: University of Perpignan Via Domitia, 2018).
- 14. For more on the definition of soft law, see A. Boyle, "The Choice of a Treaty: Hard Law versus Soft Law," in S. Chesterman, D. M. Malone, and S. Villalpando (eds), *The Oxford Handbook of United Nations Treaties* (Oxford: Oxford Handbooks, 2019).
- 15. J. Cazala, "Le *Soft Law* international entre inspiration et aspiration," *Revue interdisciplinaire d'études juridiques* 1/66 (2011), p. 49.
- 16. Committee on Bioethics (DH-BIO), DH-BIO Statement on Human Rights Considerations Relevant to the COVID-19 Pandemic, DH-BIO/INF(2020)2 (2020); DH-BIO, COVID-19 and Vaccines: Ensuring Equitable Access to Vaccination during the Current and Future Pandemics (2021).
- 17. European Committee of Social Rights, Statement of Interpretation on the Right to Protection of Health in Times of Pandemic (2020).
- 18. Committee of Ministers (see note 1), art. 3 and its explanatory memorandum, secs. 6–7.
 - 19. DH-BIO (2021, see note 16), secs. 23-30.
- 20. Medicrime Committee, Advice on the Application of the Medicrime Convention in the Context of Counterfeit COVID-19 Vaccines (2021).
- 21. A. Ruckert, K. Zinszer, C. Zarowsky, et al., "What Role for One Health in the COVID-19 Pandemic?," *Canadian Journal of Public Health* 111 (2020), p. 643.
- 22. Committee of Ministers (see note 1), explanatory memorandum, sec. 21.
 - 23. DH-BIO (2021, see note 16), secs. 2-3.
- 24. DH-BIO (2020, see note 16), p. 2; DH-BIO (2021, see note 16), sec. 9.
- 25. Committee of Ministers (see note 1), art. 5. For the specific examples of vulnerable groups, see Committee of Ministers (see note 1), explanatory memorandum, sec. 29.
 - 26. Committee of Ministers (see note 1), art. 6.
- 27. European Committee of Social Rights (2020, see note 17), p. 4.
- 28. Referring to *International Association Autism-Europe v. France*, European Committee of Social Rights, complaint no. 13/2002, decision on the merits of November 4, 2003, sec. 53.
- 29. European Committee of Social Rights (2020, see note 17), p. 4.

- 30. European Committee of Social Rights (2005, see note 12).
- 31. European Committee of Social Rights (2020, see note 17), p. 6.
 - 32. Ibid., pp. 3-5.
- 33. Committee of Ministers (see note 1), art. 7; DH-BIO (2021, see note 16), sec. 5.
- 34. DH-BIO (2021, see note 16), secs. 9–22; Committee of Ministers (see note 1), explanatory memorandum, secs. 30, 62.
- 35. CDBIO, Guide to Health Literacy: Contributing to Trust Building and Equitable Access to Healthcare (2023), p. 4.
 - 36. DH-BIO (2019, see note 9), pp. 11-12.
- 37. Medicrime Committee (2021, see note 20), appendix, sec. 7.
 - 38. Ibid., sec. 4.
- 39. Medicrime Convention (see note 4), explanatory report, sec. 3.
- 40. S. Negri, "The MEDICRIME Convention: Combating Pharmaceutical Crimes through European Criminal Law and Beyond," *Journal of European Criminal Law* 7/3 (2016), p. 358.
- 41. Ibid., p. 352; A. Lavorgna, "The Online Trade in Counterfeit Pharmaceuticals: New Criminal Opportunities, Trends and Challenges," *European Journal of Criminology* 12/2 (2015).
- 42. As noted by the then director of EDQM: S. Keitel, "The MEDICRIME Convention: Criminalizing the Falsification of Medicines and Similar Crimes," *Generics and Biosimilars Initiative Journal* (2012), p. 138.
 - 43. Committee of Ministers (see note 1), art. 19(1).
 - 44. DH-BIO (2021, see note 16), sec. 27.
- 45. For example, K. Perehudoff, H. Qazilbash, and K. Figueras de Vries, "A Needle in a Haystack? Human Rights Framing at the World Trade Organization for Access to COVID-19 Vaccines," Health and Human Rights Journal 24/2 (2022); J. Kohler, A. Wong, and L. Tailor, "Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders," Health and Human Rights Journal 24/2 (2022).
- 46. Medicrime Convention (see note 4), explanatory memorandum, sec. 42.
- 47. On the subject, see M. Breuer, "Impact of the Council of Europe on National Legal Systems," in S. Schmahl and M. Breuer (eds), *The Council of Europe: Its Law and Policies* (Oxford: Oxford University Press, 2017), secs. 36.03 et seq.; Council of Europe Directorate General Human Rights and Rule of Law, *Practical Impact of the Council of Europe Monitoring Mechanisms in Improving Respect for Human Rights and the Rule of Law in Member States* (Strasbourg: Council of Europe, 2014).
- 48. *Tanase v. Moldova*, European Court of Human Rights, application no. 7/08, judgment of April 27, 2010, sec. 176.
 - 49. Demir and Baykara v. Turkey, European Court of

- Human Rights, application no. 34503/97, judgment of November 12, 2008, sec. 86.
- 50. *Demir and Baykara v. Turkey*, European Court of Human Rights, application no. 34503/97, judgment of November 12, 2008, secs. 74–75.
- 51. Breuer (see note 47), sec. 36.91; see also J.-F. Flauss, "L'effectivité et l'efficacité de la soft law européenne dans la jurisprudence de la Cour européenne des droits de l'homme," in J. Iliopoulos-Strangas and J.-F. Flauss (eds), *The Soft Law of European Organisations* (Baden-Baden: Nomos, 2012), pp. 333–367.
- 52. C. Nivard, *La justiciabilité des droits sociaux* : Étude *de droit conventionnel européen* (Brussels: Bruylant, 2012); European Social Charter (Revised) (see note 10), arts. C, D.
- 53. European Committee of Social Rights (2020, see note 17).
- 54. Latest example: European Committee of Social Rights, Conclusions XXII-2: Czech Republic Article 11-3 (2022).
- 55. International Commission of Jurists (ICJ) and European Council for Refugees and Exiles (ECRE) v. Greece, European Committee of Social Rights, complaint no. 173/2018, decision on the merits of January 26, 2021, sec. 229.
- 56. Open Society European Policy Institute (OSEPI) v. Bulgaria, European Committee of Social Rights, complaint no. 204/2022, decision on admissibility and immediate measures of October 18, 2022, sec. 1.
- 57. Validity Foundation v. Finland, European Committee of Social Rights, complaint no. 197/2020, decision on admissibility of September 8, 2021.
- 58. *Fenech v. Malta*, European Court of Human Rights, application no. 19090/20, judgment of March 1, 2022.
- 59. *Riela v. Italy*, European Court of Human Rights, application no. 17378/20, judgment of November 9, 2023.
 - 60. Ibid., secs. 21-22.
- 61. Fenech v. Malta (see note 58), secs. 19–33. See, for instance, European Committee for the Prevention of Torture, Statement of Principles relating to the Treatment of Persons Deprived of Their Liberty in the Context of the Coronavirus Disease (COVID-19) Pandemic, CPT/Inf(2020)13 (2020), sec. 6. For further analysis, see A. Glazewski, "Le contentieux COVID-19 devant la Cour européenne des droits de l'homme," *RDLF* 39 (2023), p. 6.
 - 62. Tanase v. Moldova (see note 49), sec. 176.
 - 63. DH-BIO (2019, see note 9).
- 64. Article 20.a.i of the Council of Europe Statute, ETS 1, London, 5 May 1949; see also Breuer (see note 47), sec. 36.91; K. Dzehtsiarou, European Consensus and the Legitimacy of the European Court of Human Rights (Cambridge: Cambridge University Press, 2015).
 - 65. Glazewski (see note 61).
- 66. *Bataliny v. Russia*, European Court of Human Rights, application no. 10060/07, judgment of July 23, 2015, sec. 55; European Court of Human Rights, *Research Report: Bio-*

ethics and the Case-Law of the Court (Strasbourg: Council of Europe, 2012), p. 52. See also CDBIO semester reports on ECHR bioethics case law: https://www.coe.int/en/web/bioethics/european-court-of-human-rights.

- 67. Council of Europe, "Chart of Signatures and Ratifications of Treaty 211," https://www.coe.int/fr/web/conventions/full-list?module=signatures-by-treaty&treatynum=211.
 - 68. Keitel (see note 42), p. 139.
- 69. Medicrime Secretariat, *Gap Analysis Report: Needs Assessment Falsified Medical Products (NA-FAMED) of the Medicrime Convention* (Strasbourg: Council of Europe, 2021); Council of Europe, "CRIMFAMED Project: Countering Falsified Medical Products Global Programme," https://www.coe.int/en/web/medicrime/crimfamed.
 - 70. Breuer (see note 47), sec. 36.17.
- 71. Medicrime Committee, "General Overview Questionnaire on the Implementation of the Medicrime Convention" (July 7, 2020), https://rm.coe.int/medicrime-country-profile-questionnaire-en/1680a18a01; Medicrime Committee, "Questionnaire for the 1st Thematic Monitoring Round: The Protection of Public Health through the Medicrime Convention in Times of Pandemics" (May 27, 2021), https://rm.coe.int/t-medicrime-2021-01-questionnaire-1st-thematic-monitoring-round-pandem/1680a3156c.