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Addiction to prescribed medicines

Report[1]
Committee on Social Affairs, Health and Sustainable Development
Rapporteur: Mr Joseph O'REILLY, Ireland, Group of the European People's Party

Summary

Addiction to prescribed medicines is a worldwide problem, which has dramatic consequences for the well-being of the people concerned, as well as that of their families, and comes with a high social and economic cost for society. A holistic and multidisciplinary approach is required which strikes a careful balance between ensuring effective access to prescribed medicines and preventing nefarious addiction to them, both of which constitute an integral part of the right to the highest attainable standard of health.

It is thus recommended that the Council of Europe and its member States work in concert with the World Health Organization, including on the possible drafting and issuance of guidance on prevention, identification, management and treatment of addiction to prescribed medicines at all levels.

The Committee of Ministers of the Council of Europe should consider issuing a recommendation on the rights of patients in relation to the use of prescription medicines, containing, *inter alia*, the right to effective access and availability of essential medicines, including those that contain controlled substances under international law, as well as the right to the enjoyment of the highest attainable standard of physical and mental health, free of dependency or addiction.

1. Reference to committee: Doc. 14646, Reference 4415 of 21 January 2019.

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A. Draft resolution[2]

1. Addiction to prescribed medicines is a worldwide problem, which has dramatic consequences for the well-being of the people concerned, as well as that of their families, and comes with a high social and economic cost for society. It has reached epidemic proportions in the United States of America, and is a growing problem in Europe, where it unfortunately, however, remains largely under-researched and under-reported. The Covid-19 pandemic seems to have further exacerbated the problem worldwide, disrupting treatment services, multiplying and worsening mental health problems, and bumping the topic further down on public health priority lists.

2. According to the European Monitoring Centre for Drugs and Drug Addiction, addiction is "a repeated powerful motivation to engage in a purposeful behaviour that has no survival value, acquired as a result of engaging in that behaviour, with significant potential for unintended harm". In the case of addiction to prescribed medicines, addiction is usually the result of an insidious and gradual process of giving up control of one's own life for the sake of relief provided by the prescribed medicine, typically to counter physical or psychological pain, sleep and anxiety disorders, impulse control disorders, or attention deficit hyperactivity disorder.

3. Addiction to prescribed medicines is highly complex and a systemic social problem that requires a holistic and multidisciplinary approach. A careful balance must be found between ensuring effective access to prescribed medicines – as an integral part of the right to health – and preventing nefarious addiction to prescribed medicines. On one hand, regulations should not limit distribution of prescribed medicines for those in need, so that patients do not become hostage to restrictive national regulations (which can be the case for patients in end-of-life situations who need access to strong narcotic painkillers as part of cancer or palliative care, for example, or for patients prescribed similar medicines as part of the treatment of substance-abuse disorders). Indeed, the Single Convention on Narcotic Drugs of 1961 recognises that the medical use of narcotic drugs is indispensable for the relief of pain and suffering and requires that the availability of such medicines is assured and not unduly restricted. On the other hand, regulations must ensure that prescribed medicines with an addictive potential are not prescribed too easily or for longer than necessary and are part of an appropriate and holistic treatment plan for the patient, with a view to preventing misuse of prescribed medicines.

4. The Parliamentary Assembly welcomes World Health Organization (WHO) guidelines which include recommendations on the proper use of prescribed medicines with addictive potential, such as the 2021 Guidelines on the management of chronic pain in children. It encourages WHO to continue its work in this area, including the drafting and issuance of specific guidance on prevention, identification, management and treatment of addiction to prescribed medicines.

5. The Assembly recommends that Council of Europe member States follow WHO's evidence-based guidance and, inspired by European good practice examples, if they have not already done so:

5.1. develop national guidelines on the proper use of prescribed medicines with addictive potential, which carefully balance the competing needs of ensuring effective access to prescribed medicines as an integral part of the right to health, and preventing nefarious addiction to prescribed medicines as an integral part of the same right to health, free of dependency or addiction; involving all relevant stakeholders in the drafting process, including prescribers, pharmacists, patient groups and academics;

5.2. include guidance on prevention, identification, management and treatment of addiction to prescribed medicines in these guidelines, and make them available and accessible to the relevant health professionals (prescribers, pharmacists) as well as to patients and the general public, and train professionals in their use;

5.3. allocate the necessary funds to ensure holistic treatment of patients' illnesses (particularly, non-malignant chronic pain, depression, sleep and anxiety disorders), which are traditionally treated with prescribed medicines with addictive potential, in particular by making non-drug interventions (such as counselling, rehabilitation, etc.) accessible to all who need them, in as timely a manner as possible;

5.4. in accordance with the Single Convention on Narcotic Drugs of 1961, ensure effective access to internationally controlled essential medicines to meet the medically indicated demand, and make every effort to combat shortages;

5.5. pay particular attention to the social determinants of health in preventing and fighting nefarious addiction to prescribed medicines;

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2. Draft resolution adopted unanimously by the committee on 1 December 2021.

5.6. systematically collect and monitor the relevant data on the use of prescribed medicines with addictive potential, with a view to rapid intervention as necessary;

5.7. keep the issue of addiction to prescribed medicines high on the public health priority list, in view of the large number of persons affected and the high social and economic cost for society;

5.8. monitor the effect of the Covid-19 pandemic on addiction to prescribed medicines and adjust national guidelines as appropriate.

B. Draft recommendation[3]

1. The Parliamentary Assembly refers to its Resolution … (2022) "Addiction to prescribed medicines". The Assembly is convinced that this topic should be given a higher priority in Europe. It considers that the Council of Europe with its different specialised bodies (such as the Council of Europe's Co-operation Group to Combat Drug Abuse and Illicit Trafficking in Drugs (Pompidou Group), the European Directorate for the Quality of Medicines & HealthCare, and the Steering Committee for Human Rights in the fields of Biomedicine and Health) is well-placed to contribute to preventing and fighting nefarious addiction to prescribed medicines.

2. The Assembly thus recommends that the Committee of Ministers:

2.1. consider issuing a recommendation on the rights of patients in relation to the use of prescription medicines, containing, *inter alia*, the right to effective access and availability of essential medicines, including those that contain controlled substances under international law, as well as the right to the enjoyment of the highest attainable standard of physical and mental health, free of dependency or addiction;

2.2. encourage the relevant Council of Europe bodies to work closely with the World Health Organization in this area, including on the possible drafting and issuance of guidance on prevention, identification, management and treatment of addiction to prescribed medicines at global and/or Council of Europe level.

3. Draft recommendation adopted unanimously by the committee on 1 December 2021.

C. Explanatory memorandum by Mr Joseph O'Reilly, rapporteur

1. Introduction

1. Addiction to prescribed medicines is a worldwide problem, which has dramatic consequences for the well-being of the people concerned (and that of their families), and a high social and economic cost for society. It has reached epidemic proportions in the United States, where in pre-pandemic 2017 an estimated 18 million people had misused prescription medications at least once[4] and on average, 130 people died of opioid overdoses each day – more than doubling during the pandemic, to more than 270 a day.[5] The problem is extending rapidly in other parts of the world,[6] including Europe, where it is evidenced, for example, by the growing number of people entering treatment services for non-medical use of pharmaceutical opioids.[7] However, while such addiction was among the leading public health issues in the United States before 2020, it remains largely under-researched and under-reported in Europe. The Covid-19 pandemic seems to have further exacerbated the problem worldwide,[8] disrupting treatment services, multiplying and worsening mental health problems, and bumping the topic further down on public health priority lists.

2. Finding the right terminology to use in this report has not been easy. The motion for a recommendation which started off the work of our committee on this topic was entitled "Involuntary addiction to prescription medicines." The term "involuntary addiction" was originally used to stress the lack of choice/control on the part of the person addicted to prescription medicines, in contrast to persons "choosing" to engage in "recreational" drug use or self-medicating. Fundamentally, however, no-one chooses to become an addict: all addiction is involuntary. According to the European Monitoring Centre for Drugs and Drug Addiction, addiction is "a repeated powerful motivation to engage in a purposeful behaviour that has no survival value, acquired as a result of engaging in that behaviour, with significant potential for unintended harm". In the case of addiction to prescription medicines, it is usually the result of an insidious and gradual process of giving up control of one's own life for the sake of relief provided by the medicine, typically to counter physical or psychological pain.

3. I have decided to use the term "prescribed medicines" rather than "prescription medicines" in this report,[9] in order to focus on the prevention, identification, management and treatment of addiction to prescribed medicines. Dealing with addiction to prescription medicines in general, many of which are acquired illegally and/or on the black market, and thus are also often falsified, would require a slightly different focus.[10] I have also used the term "addiction to" rather than "dependence on" throughout the report;[11] this has been criticised as stigmatising,[12] in particular for patients (physiologically) dependent on prescribed antidepressants. My aim has not been to stigmatise anyone, but the submissions have come too late for me to re-write my whole report, though I am preparing an amendment to paragraph 2.2. of the draft recommendation.

4. Addressing addiction to prescribed medicines is essential for human rights protection and sustainable development. According to the World Health Organization (WHO), "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being".[13] Such enjoyment is clearly

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4. The term "misuse" is used in this report only to denote the non-medical use of prescription drugs, in line with the policy of the United Nations Office on Drugs and Crime (UNODC), DrugBase.
5. "Overdose Deaths Reached Record High as the Pandemic Spread", *New York Times*, November 2021.
6. The Covid-19 pandemic has exacerbated the deadly overdose crisis in Canada, for example. According to Canada's public health agency, the number of opioid-related deaths climbed from less than 4 000 in 2019 to 6 213 in 2020. https://bcmj.org/blog/covid-19-and-opioid-epidemic.
7. "Global overview of drug demand and supply", UNODC, 2018.
8. "Study explores whether Nordic countries could head towards opioid crisis like the US", *News-Medical*, 2019.
9. The reason for the change in the title of the report.
10. A report on "Securing safe medical supply chains" (Rapporteur: Ms Jennifer De Temmerman, France, ALDE), which is of relevance to the question of addiction to prescription medicines, is currently in preparation in our committee.
11. Definitions of Dependence and Addiction from Public Health England's Evidence Review into Dependence and withdrawal associated with some prescribed medicines (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/94 0255/PHE_PMR_report_Dec2020.pdf).

    Dependence: An adaptation to repeated exposure to some drugs and medicines usually characterised by tolerance and withdrawal, though tolerance may not occur with some. Dependence is an inevitable (and often acceptable) consequence of long-term use of some medicines and is distinguished here from addiction.

    Addiction: Dependence plus a compulsive preoccupation to seek and take a substance despite consequences.
12. Submissions from Mr Danny Kruger MP, Chairperson, All-Parliamentary Group for Prescribed Drug Dependence, United Kingdom (dated 1 February 2022), and Professor John Read, International Institute for Psychiatric Drug Withdrawal, London, United Kingdom (dated 2 February 2022).
13. "Health is a fundamental human right", WHO, 2017.

undermined by any kind of addiction. Target 3.5 of the United Nations 2030 Agenda for Sustainable Development which is devoted to strengthening the prevention and treatment of substance abuse, needs to be used as a global framework and impetus for stronger action in this area – now, at the (hopefully) tail-end of a global pandemic, more than ever before.

5. Effective access to prescribed medicines is also an integral part of the right to health. Indeed, the Single Convention on Narcotic Drugs of 1961 recognises that the medical use of narcotic drugs is indispensable for the relief of pain and suffering and requires that the availability of such medicines is assured and not unduly restricted. Thus, regulations should not limit distribution of prescribed medicines for those in need, so that patients do not become hostage to restrictive national regulations (which can be the case for patients in end-of-life situations who need access to strong narcotic painkillers as part of cancer or palliative care, for example, or for patients prescribed similar medicines as part of the treatment of substance-abuse disorders).[14]

6. In short, dealing with addiction to prescribed medicines is all about balancing the competing needs of ensuring effective access to prescribed medicines as an integral part of the right to health, and preventing nefarious addiction to prescribed medicines as an integral part of the same right to health, free of dependency or addiction. My aim in drafting this report has been to explore the current situation in Europe with respect to addiction to prescribed medicines, examine examples of good practice – in particular thanks to a fact-finding visit to Denmark – and make recommendations on how to ensure that patients who need the medicines get them; unnecessary or inappropriate use is prevented; alternative treatments are used as much as possible; risks are minimised; and relevant support is provided to the victims of addiction.

2. Aim and scope of the report

7. A prescription medicine is a pharmaceutical product that legally requires a medical prescription to be dispensed. In contrast, over-the-counter medicine can be obtained without a prescription. The aim of this limitation is to ensure that the medicine is used by the patient concerned for a specific purpose and in accordance with the instructions (for example duration, dosage) of a qualified health professional.

8. The following types of medicines are most susceptible to creating addiction: 1) stimulants, which are prescribed to control impulse control disorders, for example attention deficit hyperactivity disorder; 2) opioids, which are prescribed mostly against pain and 3) tranquilisers / sedatives and anti-depressants, which are prescribed to treat anxiety, depression, sleep disorders, etc.[15]

9. There are many cases when the addiction to prescription medicines has its origin in the intake of such medicines as part of a treatment prescribed by a health professional.[16] Different pathways towards and out of addiction have been identified for different groups of the population (young people, women, older generation, children). In Denmark, for example, some patients' pharmacological dependence on prescribed medicines is treated via a tapering-off regimen with their general practitioner, while other patients present more complicated addiction quandaries (including psychological dependence, multi-co-dependencies, or other problems) and are treated in specialised pain or withdrawal centres.

10. Addiction to prescription medicines has skyrocketed in the recent decades,[17] due to the availability and marketing of new forms of medicines, such as opioids (for example OxyContin, or tramadol). In 2018, globally, the production of opium and manufacture of cocaine was at the highest levels ever recorded.[18] At the same time, global opium production in 2020 has stabilised.[19] While increasing use of their derivatives by pharmaceutical industries helps immensely to reduce the suffering of many people across the world, it also raises some serious concerns.

11. The pharmaceutical industry has a vested interest in generating sales to cover ever growing expenditures on research and development and marketing.[20] The Assembly raised the issue of the compatibility of public health and the interests of the pharmaceutical industry in its Resolution 2071 (2015)

14. See Resolution 2249 (2018) "The provision of palliative care in Europe".
15. This last class of medicines is sometimes wrongly given to women suffering from hormonal imbalances in perimenopause or menopause, the symptoms of which can be misdiagnosed as depression or sleep disorders.
16. Riggs P (2019). Editorial: "Prescription for Addiction", *JAACAP* [Accessed on 7 September 2021].
17. Richard C. Dart et al., "Trends in Opioid Analgesic Abuse and Mortality in the United States", *NEJM*, 2015.
18. "Global opium and cocaine production at record highs, UN report says", *France 24.*
19. "The World Drug Report 2021", UNODC, 2021.
20. Taylor D., "The Pharmaceutical Industry and the Future of Drug Development", *Issues in Environmental Science and Technology*, 2015.

"Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?". This is without doubt an important area to consider in the present report as well, in particular in view of the conviction of Insys Therapeutics – a pharmaceutical company in the US – found guilty of racketeering charges in a rare criminal prosecution,[21] and the US$270 million settlement by Purdue Pharma over its powerful narcotic prescription painkiller, OxyContin.[22] Many more cases against the companies alleged to have fuelled the opioid epidemic in America are still being litigated. On 26 August 2019, a judge in Oklahoma ruled that Johnson & Johnson had intentionally played down the dangers and oversold the benefits of opioids and ordered it to pay the State US$572 million; however, the ruling was overturned by the Oklahoma supreme court in November 2021.[2324]In any case, lack of regulation in the field, leads to a low level of accountability, thousands of lives lost, and long-term losses for the pharmaceutical industry, as the case of the Purdue Pharma bankruptcy in 2021 illustrates.[25] The US Congress is currently investigating the role of the global consulting company McKinsey & Company over its role in the opioid crisis, related to its business practices, conflicts of interest and management standards.[26]

12. Furthermore, such medicines are sometimes prescribed too easily and for longer than necessary. In fact, it is not always possible for doctors to assess the level of distress of the patient and to recognise a possible addiction. Relevant training, guidelines or standards are not always consistent or sufficient. Also, "shared decision making" is part of the culture in some countries, and patients can ask for a specific medicine that has worked well for them in the past.

13. Once addiction has set in, when medicines are not available from doctors, they are often procured from friends, family, or through "pharmacy hopping" or "pharmacy tourism". The Internet is becoming a new additional source of medicines which is easily accessible and difficult to control. Addiction to prescription medicines is thus often likely to result in the subsequent use of falsified medicines and/or illegal drugs.

14. I am convinced that the "war on drugs"-approach is not appropriate to address this issue. I also feel that addiction to prescribed medicines is highly complex, and a systemic social problem that requires a holistic and multidisciplinary approach. In this report, I will 1) highlight the main challenges, including the impact of the Covid-19 pandemic; 2) explore the current policies and strategies in this area; 3) examine to what extent they consider the specific needs of various groups of people and whether they address the root causes of addiction to prescription drugs. I will then propose policy recommendations on how a public health model could be developed and strengthened, to prevent and address addiction to prescribed medicines. I also hope that this report will allow to promote public debate and raise awareness of the scale and gravity of this problem in Europe.

15. I have analysed the available research, including reports of the United Nations Drug Control Programme, the World Health Organization, the European Monitoring Centre for Drugs and Drug Addiction and the Council of Europe's Co-operation Group to Combat Drug Abuse and Illicit Trafficking in Drugs (Pompidou Group). I have also based my report on the Assembly's work on "Drug policy and human rights in Europe: a baseline study,"[27] in which I was involved as rapporteur for opinion and have updated it on the basis of recent media reports. Finally, I visited Denmark, a country with well-developed policy in this area, on 11-12 October 2021, to explore the perspectives of public health officials, academics, and organisations representing patients' interests, as well as the existing channels for policy dialogue and possible ways to improve them.

3. The main challenges

3.1. Understanding the addictive potential of prescription medicines

16. The act of prescription of a medicine as such has several reasons. In some cases, the intention is to entitle a patient to either free or subsidised drugs;[28] in other cases, the reason is to control the consumption of medicines that lose effect if consumed in an uncontrolled manner, as in the case of antibiotics and the related antimicrobial resistance issue;[29] while in some cases prescription is a matter of care for the patient's health in order to avoid a "prescription" overdose.[30]

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21. "Top Executives of Insys, an Opioid Company, Are Found Guilty of Racketeering", *New York Times*, 2019.
22. "Purdue Pharma and Sacklers Reach $270 Million Settlement in Opioid Lawsuit", *New York Times*, 2019.
23. "Johnson & Johnson Ordered to Pay $572 Million in Landmark Opioid Trial", *New York Times*, 2019.
24. "Oklahoma court overturns $465m opioid ruling against Johnson & Johnson", *The Guardian*, 2021.
25. "Purdue's bankruptcy deal shields Sackler family owners from future opioid liability", *Financial Times*, 2021.
26. "Congress Is Investigating McKinsey Over Its Role in the Opioid Crisis", *New York Times*, 2021.
27. Resolution 2335 (2020).

17. Another aspect to pay attention to in this context is withdrawal syndrome. Such an iatrogenic syndrome often appears as a consequence of withdrawal of opioid and benzodiazepine medicines.[31] For example, opioid withdrawal syndrome may be defined as the occurrence of dysphoric mood, nausea, vomiting, diarrhea, or fever up to several days after cessation of opioid therapy.[32] While short courses of certain medicines are not generally associated with withdrawal syndrome,[3334] it has been known for decades that long courses do. A natural outcome of lasting withdrawal syndrome, be it physical or psychological, is dependence.[35]

18. Even though the above-mentioned medication classes are highly valued for their therapeutic effect, their misuse may cause dependence or even addiction.[36] Addiction arises when the organism's endogenous receptor system that these drugs target, cannot function properly anymore without external stimulation by certain medicines.[37]

19. Moreover, while antidepressants play an important role in treating depression and anxiety, it is essential to address how people will ultimately stop treatment. People may suffer withdrawal reactions after stopping antidepressants, as well. Discontinuation problems vary according to dose, treatment duration, and the individual antidepressant. They may be mild or non-existing, but also disturbing and unpleasant or even severe, including dizziness, nausea, anxiety, panic, mood changes, sweating, agitation, insomnia, nightmares, and electric shock sensations as common symptoms. The dose of antidepressant needs to be lowered very gradually, usually over several months or longer, with the final stages of withdrawal requiring particularly small reductions.[38] Steroids also need to be tapered off gradually.

20. Prescribers and retailers, in general, must increase their vigilance when prescribing or supplying medicines[39] in order to prevent and control drug diversion behaviours, and thereby reduce the negative impacts of their misuse. They must give clear information about the effects that medications may have and provide advice about any possible drug interactions. They can create drug records in order to prevent consultations with multiple doctors and subsequent duplicate prescriptions (so-called "doctor shopping") for a drug with misuse potential. Patients should be informed on how to stop their treatment.

3.2. The impact of the Covid-19 pandemic

21. Since the start of 2020, the world has been confronted with an unprecedented public health threat with the emergence of the Covid-19 pandemic. In response to the outbreak of this disease, a range of containment measures has been implemented in order to reduce the spread of the virus. One of the impacts of these measures has been a widespread worsening of mental health, including anxiety, depression, stress, self-harm, suicide attempts, and suicides.[40] Lingering symptoms after infection with the virus, often called "long Covid", can also include pain, fatigue, anxiety, depression and "brain fog".[41]

22. Having a substance use disorder has been shown to increase the risk of becoming infected by Covid-19, of more adverse Covid-19 outcomes, and of death from Covid-19.[42] Indeed, both stimulants and opioids negatively impact immune functions: white blood cells do not function properly. The use of opioids can

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28. "Prescribed drugs and medicines", *Citizens Information*, 2020.
29. Marston HD, "Antimicrobial resistance", *JAMA*, 2016.
30. Kay C, "Prescription Opioids, Time to Rethink How We Assess Risk", *Journal of General Internal Medicine*, 2020.
31. Arroyo-Novoa CM et al., "Opioid and Benzodiazepine Iatrogenic Withdrawal Syndrome in Patients in the Intensive Care Unit", AACN Adv Crit Care, 2019.
32. Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 5th ed, American Psychiatric Association. Arlington, VA, American Psychiatric Publishing, 2013.
33. Hyun DG et al., "Iatrogenic Opioid Withdrawal Syndrome in Critically Ill Patients: a Retrospective Cohort Study", Journal of Korean Medical Science, 2020.
34. A peer-reviewed study of the Danish Medicines Agency did, however, identify the development of addiction during treatment with the opioid tramadol in a treatment period of less than 14 days, at normal doses of below 400 mg, in a small number of cases.
35. Petursson H, "The benzodiazepine withdrawal syndrome", *Addiction*, 1994.
36. O'Brien CP, "Benzodiazepine use, abuse, and dependence", *Journal of Clinical Psychiatry*, 2005.
37. Valentino RJ, Volkow ND, "Untangling the complexity of opioid receptor function", *Neuropsychopharmacology*, 2018.
38. Mark Abie Horowitz, PhD, Prof David Taylor, PhD, "Tapering of SSRI treatment to mitigate withdrawal symptoms", Published: March 05, 2019 DOI.
39. "Misuse of prescription and over-the-counter drugs to obtain illicit highs: how pharmacists can prevent abuse", *The Pharmaceutical Journal*, 17 November 2020.
40. "Covid has led to record levels of antidepressant use", *The Guardian*, 17 May 2021.
41. See the minutes of the public hearing on "Long Covid", held by the Committee on Social Affairs, Health and Sustainable Development on 9 September 2021.

impact breathing by slowing it or making it ineffective. This can lead to decreased oxygen in the blood, brain damage, or death. The use of stimulants can cause acute health problems such as stroke, heart attacks, abnormal heart rhythm, and seizures, as well as more chronic conditions such as heart or lung damage. In general, it is acknowledged that individuals with substance use disorder may be especially susceptible to Covid-19.[43] The vaccines against Covid-19 do not interfere with the treatment of substance use disorder. On the contrary, people with substance use disorder should get vaccinated. It is thus important to have the community actively engage in order to build trust in vaccination.[44]

23. The effects and implications of the pandemic are concerning. Studies have already revealed the impact of the Covid-19 pandemic on drug markets, use, harms, and services.[45] There were supply shortages of numerous street drugs, such as opioids, price increases for consumers on the black market, and reductions in purity. These issues, in combination with general economic stress, may have encouraged shifts to different, and sometimes riskier, drug-using behaviours.

24. Indeed, whether it is tobacco, alcohol, cannabis or psychotropic drugs, consumption since the beginning of the pandemic has increased. Psychotropic drugs, such as anxiolytics, antidepressants, and hypnotics (sleeping pills), have been massively prescribed. These increases likely reflect the significant psychological impact of the Covid-19 outbreak – with emotional changes such as increasing worry, sadness, fear, and loneliness –, its social, professional, and economic consequences, and the restricted availability of talking therapies during lockdowns.

25. Since early 2020, Europe's drug-related challenges, including drug supply, consumption, and related harms, have been heavily impacted by the Covid-19 pandemic. Today, some assessments have shown the impact of Covid-19 on prescription drug use in the short term, but also highlighted the limitation of data, notably regarding the long-term impact of the pandemic. It is necessary to pay attention to the psychological and socioeconomic impacts of the pandemic, as well as to possible changes in drug consumption patterns and related harms. Nonetheless, studies provide a valuable first glimpse into the new developments emerging from the pandemic. For instance, the shift to the greater use of online platforms for drug supply and clinical management of drug problems may persist beyond the Covid-19 pandemic and may likely lead to innovations in monitoring and research methods in the drugs field to capture the "online dimension" of the European drug situation.[46]

26. This is because one of the early effects of the pandemic outbreak was the disruption in access to medication and other support services, due to physical distancing, lockdowns, quarantines, and other public health measures. In response, States have taken steps to expand access to needed medications during the pandemic. Policy changes facilitating "telehealth" or "telemedicine" were carried out.[47]

27. Since the first lockdowns, there was an increase in the use of remote counselling by treatment and harm reduction services. Telemedicine, by phone or video, has made it possible to expand access to medications during lockdowns: this significantly improved the ability of providers to give treatment for opioid use disorder and also helped retain patients in treatment.[48] People with opioid use disorders were able to begin treatment with buprenorphine without an initial in-person doctor visit, which used to be the rule. Methadone treatment previously required daily supervised dosing with tightly controlled take-home options, but patients deemed stable were able to obtain 28 days of take-home doses. In terms of the criminal justice system, many prisons and jails have been proactive and implemented policy changes because of the pandemic.[49]

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42. "Covid-19 Questions and Answers: For People Who Use Drugs or Have Substance Use Disorder", Centers for Disease Control and Prevention, 29 March 2021.
43. Volkow ND, "Collision of the COVID-19 and Addiction Epidemics", Annals of Internal Medicine, 2020.
44. Addiction Policy Forum, "Addiction and COVID 19: A conversation with Dr. Anthony Fauci and Dr. Nora Volkow", 23 March 2021.
45. European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), "Impact of COVID-19 on drug markets, use, harms and drug services in the community and prisons", Results from an EMCDDA trendspotter study, April 2021.
46. Ibid.
47. National Institute of Drug Abuse, "Addressing the Unique Challenges of COVID-19 for People in Recovery", 14 September 2020.
48. Results from an EMCDDA trendspotter study, op. cit.
49. For example, some have allowed people to immediately have access to insurance when they leave the prison so that they can seek out treatment and be kept in treatment.

28. Telemedicine has brought a more equitable way to access to treatments into the communities.[50] It proved beneficial in reaching individuals and new patients that needed treatment by extending service coverage, especially to remote areas where physical services were limited. It was also reported as an efficient way to connect with other professionals and relevant health and social services, thereby improving client referral.

29. However, many challenges were highlighted. Not everybody has access to the Internet. Some groups have difficulties using the technology, such as older drug users, clients referred by the criminal justice system or clients with severe mental health issues and complex comorbidities. In addition, there are inequalities in accessing the Internet between urban and rural areas. For these reasons, not everyone can access telehealth adequately or at all. Some of these challenges have resulted in a yet unknown number of clients having to gradually drop out from treatment. While the benefits of the use of remote interventions are evident, the cost of risking losing or neglecting certain patient groups should not be underestimated.[51]

30. In this respect, it is necessary to provide access to the web for everybody. Without proper internet access, health disparities will remain and continue to grow. Everybody should benefit from the advantages that come through the internet, which includes telehealth, but also education and information.

31. Since the question of access to the internet is out of the scope of the mandate of the Committee on Social Affairs, Health and Sustainable Development, I would urge the competent Assembly and intergovernmental committees to join forces to further develop recommendations on electronic health (eHealth) and mobile health (mHealth) based on evidence and good practice. Development of a framework for pan-European implementation of eHealth and mHealth is one of the paths to take. The World Health Organization has developed a set of Digital Health Country Vignettes illustrating the continued importance of digital health across WHO's European Region during the Covid-19 pandemic.[52] Europe has boosted its eHealth and mHealth usage, while the Covid-19 pandemic became a trigger for even greater uptake of mHealth. These case studies showcase innovative digital health tools, technologies, and actions that countries in WHO's European Region have implemented to strengthen the health system response to Covid-19.

32. Nevertheless, there is still work to be done. With the lessons learnt from different member States, the Council of Europe may replicate good practices by incorporating these into recommendations. The focus of such recommendations should be on both, the availability of digital infrastructure, and accessibility and acceptability of that infrastructure by end-users, be it patients or healthcare practitioners. Such actions are also in line with the Global strategy on digital health 2020-2025, where member States, individually or in co-operation, propose actions to assess and promote digital health solutions that are aligned with country-defined needs and health related to the United Nations' Sustainable Development Goals.[53] Granting access to the Internet is vital for sustainability and the up-scaling of the above-mentioned strategies.

33. The application of Electronic Healthcare Records ensures that those in need of prescribed medicines do receive them, while those who are already receiving medication, consume these in a technology-enhanced supervised manner: this way, over-prescription is minimised and the same prescription cannot be used twice, thus minimising also the pharmacy-hopping possibility. Telemedicine, especially by means of mobile apps (mHealth) allows individuals to control their intake of medicines, consult healthcare professionals at distance regarding the preferred mode of medicines consumption, as well as to seek help in overcoming withdrawal syndrome and dependency issues.

3.3. Lessons from the experience of Denmark

34. I would like to thank wholeheartedly the Danish delegation to the Assembly, in particular its Secretariat, for organising such a productive fact-finding visit to Copenhagen for me in October 2021. My thanks also go to all the interlocutors who took the time to meet me, from the Ministry of Health, the Health Authorities, the Medicines Agency, the Health Committee of the Danish Parliament, academia, and the Danish Rheumatism Association. The visit to the Interdisciplinary Pain Center at Gentofte Hospital was especially insightful.

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50. "Addiction and COVID 19: A conversation with Dr. Anthony Fauci and Dr. Nora Volkow", Addiction Policy Forum, 23 March 2021.
51. Results from an EMCDDA trendspotter study, op. cit.
52. "Digital Health Country Vignettes", WHO, 2021.
53. "Global Strategy on Digital Health", WHO, 2021.

35. The Danish health system serves 5.7 million inhabitants. It is financed by general taxes and characterised by universal coverage, free and equal access, and a high degree of decentralisation. General practitioners act as a gateway for access to hospital and specialised treatment. In Denmark, the Medicines Agency approves new medicines, the Health Authority assesses whether medicines should be recommended in daily use in the primary sector, and medical doctors have a free right of prescription and may prescribe off label, as well. The Danish Medicines Council assesses whether medicines should be recommended in the secondary sector. In 2020, funding from the Danish Ministry of Health was made available for three specific initiatives addressing addiction to prescription medicines[54].

36. Denmark realised in the mid-2010s that the consumption of prescribed opioids (including tramadol[55]) was high, especially compared to the other Nordic countries[56]. Waiting times for consultation when referred to the highly specialised pain management units for other than pharmacological treatment with opioids was long, as was the waiting time for consultation when referred to a psychiatric specialist, leading to longer treatment with antipsychotics with an addictive potential. Documentaries on addiction to prescription medicines aired on Danish TV in 2017 raised the awareness of the general public and led to a higher sense of urgency. Doctors, hospitals, NGOs and health authorities worked together to address the problem, for example by making it mandatory to report all suspected adverse reactions to tramadol from September 2017 to September 2018.[57]

37. On 1 January 2018, new dispensing regulations came into force, requiring that prescribers, as a general rule, have a face-to-face consultation with their patient when prescribing the opioids, including tramadol or codeine[58] in addition to stronger opioids, and making it impossible to refill a prescription. National recommendations on the pharmacological treatment of pain were updated, including guidance on how to taper off such treatment. National Clinical Guidelines on opioid treatment of chronic non-malignant pain were published in 2018, on rational use of medicines for treating attention deficit hyperactivity disorder in children and young people in 2021, on treatment of anxiety disorders in adults in 2021, and new Guidelines on sedatives (including low-dose quetiapine) are planned for 2022. An article on how to prescribe small quantities of addictive prescription medicines when only large package sizes are marketed was published in the magazine on rational pharmacotherapy in August 2020 and distributed to all doctors in Denmark. A pocket-size pain management guide was created and distributed to general practitioners (first free, but as demand rose from other specialties of medicine at 70 cents-cost of printing), and an awareness-raising campaign on the subject was aired on TV and made available on the internet.

38. Before the Covid-19 pandemic started, these measures successfully lowered the consumption of prescribed opioids, in particular – with the consumption of tramadol alone decreasing by 37% from 2015 to 2019. The Danish Health Authorities are, however, remaining vigilant, and continuing their monitoring with a view to responding to changing consumption patterns of other medicines that may replace the consumption of opioids and other addictive medicines (for instance, off-label use of low-dose quetiapine). Our interlocutors at the Health Authorities stressed the importance of maintaining a holistic approach with a view to identifying improved options to treat symptoms/conditions with other interventions than addictive medicines. They also emphasised the importance of striking the right balance between adequate availability and necessary restrictions on medicines with an addictive potential. Thus, the requirement for the doctor to see the patient in person could pose a problem for people in medically well-indicated long-term treatment with addictive medicines.

39. What struck me is that even in such a good practice example as Denmark, there does not seem to be an easy solution to the problematic use of prescribed medicines, in particular opioids for non-malignant chronic pain. The fact is that opioids are not a good choice for such pain conditions, because they lead to addiction and tolerance (requiring ever higher doses for the same pain-relief effect), thus also increasing negative side-effects. But it is also a fact that there is no effective, non-addictive, pharmacological alternative to opioids. Non-pharmacological pain management should thus be given a much higher priority. Reducing

54. *Benzorådgivningen* – a project that provides counselling regarding addiction to sleep and nerve-medicine, as well as downsizing of antidepressants; *Dansk Smerteforum* – an organisation that works to promote knowledge of pain, pain treatment and research in Denmark; and *Smertelinjen* – a free counselling service for people with pain or for relatives of a pain patient. The counselling can be used regardless of the pain being acute or chronic.
55. There was a popular misconception that tramadol is less addictive and less dangerous than other opioids, even though tramadol is metabolised to morphine in the body.
56. This was despite several initiatives in the preceding years (starting in 2007), including guidelines and educational courses directed at Danish physicians.
57. Another such mandatory reporting period is underway for 2020-2021.
58. Other opioids were already submitted to this regimen before.

waiting times to see specialists or enter alternative residential treatment programmes (such as the specialised programmes of the Danish Rheumatism Association) is thus of primary importance. The cost of funding such holistic treatment may seem high at the outset, but is quickly recouped, including in quality of life for patients.

40. Another recommendation that the Danish authorities are considering, and which could be a useful consideration also in other countries, is how to prescribe and dispense small quantities of addictive medicines, for example how to prescribe and dispense the medically indicated dose of 2 tablets when the smallest package of tablets available in retail is 100 tablets. Indeed, our parliamentary interlocutors also emphasised that the possible contribution of pharmacists to addressing addiction to prescribed medicines is not fully used in Denmark, despite the shortage of doctors in the country – which sometimes leads to general practitioner secretariats preparing prescriptions in practice, with the general practitioner only signing off on them, due to shortage of time and work overload. In this context, the transitions from hospital to out-patient care seem to be particularly problematic.

41. The academics we met, Mr Anton Pottegård and Ms Anne Mette Skov Sørensen, provided us with several valuable "take-home" messages. First, they emphasised that timely registry data on drug use is necessary to guide interventions (including policy changes). This is particularly acute during and after the Covid-19 pandemic, which may have affected prescription drug use. They also, like our parliamentary colleagues on the Danish Health Committee, raised the alarm on high consumption of addictive medicines in psychiatry, especially in child and adolescent psychiatry, and on adult psychiatric and geriatric wards. Second, they emphasised that if one addictive medicine is phased out, another one is bound to go up (for example replacing benzodiazepines with other antidepressants). They considered that the use of gabapentinoids (gabapentin/pregabalin) would likely constitute an issue in the near future, due to the crushing down on medical opioid use. Third, they emphasised that Electronic Healthcare Records are not the panacea, since there are often discrepancies between what is listed in the record and the patient's actual use of the medicine. They believed that the type of supervision needed was not digital, but rather in-person, patient-centred.

42. Our interlocutors at the Danish Rheumatism Association informed us that every fifth Dane complained of chronic pain, mostly due to rheumatic musculoskeletal diseases, leading to a very high consumption of strong painkillers (opioids). With the pain itself having many side effects (discomfort, sleeping problems, a negative influence on one's mood), 46% of their members who had answered a recent questionnaire had taken opioids within the last year, of which 78% had not been offered alternatives, 18% had acquired painkillers outside the healthcare system and 19% had considered doing so. 58% considered that their life with pain was overwhelming and unaffordable, and 11% had had suicidal thoughts. The Association tried to support its members, *inter alia,* with counselling services, pointing them towards non-pharmacological interventions such as physiotherapy, weight loss, out-patient pain centres, and their own in-patient holistic treatment centres, called *Sanos*. Their members complained that waiting lists were too long (6-10 months for pain centres, 5-8 months for *Sanos*), and it was still too easy to get prescriptions for opioids, while medical cannabis was largely inaccessible.

43. Our discussion with Ms Anne Hansen, the Chief physician at the out-patient Interdisciplinary Pain Center at Gentofte Hospital, summed up all the lessons I believe we can learn from the Danish good-practice experience. Patients with non-malignant chronic pain need to have access to appropriate opioid pain treatment, but as part of a holistic, multidisciplinary treatment plan which takes into account their individual situation (including the social determinants of health). They need to be properly informed and enabled to make their own choices in how to best handle their condition. The stigmatisation of patients with opioid treatment has to end. We all need to learn to listen to our bodies more – before we develop severe and/or chronic pain. Physicians need to be properly informed and educated on how to deal better with pain (including surgeons), and their workload needs to be reduced so that they can devote more time to patient care. For that, adequate funding is needed.

4. Conclusions and recommendations: finding the right balance

44. In 2021, the number of citizens of the European Union using prescribed medicines reached 38%.[59] It is doubtful that numbers for the whole Council of Europe area would differ significantly. This indicates that the threat of epidemics of dependency on prescribed medicines is real. At the same time, guaranteeing adequate availability of drugs for medical purposes must be addressed. Regulations should not limit distribution of prescribed medicines for those in need, so that patients do not become hostage to restrictive national regulations. Access to medicines is an integral part of the right to health. Ensuring the availability and

59. "Self-reported use of prescribed medicines by sex, age and country of citizenship", Eurostat, 2021.

accessibility of medicines by member States is a clear obligation of the competent national authorities.[60] Efforts should thus be made in national laws and policies to ensure that the UN Drug Conventions are not used as an obstructive measure, restricting the access to and availability of prescribed medicines. The medical needs of the population should be met and the right to health should be ensured.

45. I am convinced that the topic of addiction to prescribed medicines should be given a higher priority in Europe. With our different specialised bodies (such as the Pompidou Group, the European Directorate for the Quality of Medicines (EDQM), and the new Steering Committee for Human Rights in the fields of biomedicine and health), we are well-placed at the Council of Europe to contribute to preventing and fighting nefarious addiction to prescribed medicines, as well as to ensure that patients in need of prescribed medicines get their treatment in a timely manner; in particular if we work in concert with WHO, including on the possible drafting and issuance of guidance on prevention, identification, management and treatment of addiction to prescribed medicines at global and/or Council of Europe level.

46. My main recommendations can thus be summarised as follows:

– Council of Europe member States should follow WHO's evidence-based guidance and, inspired by European good practice examples, if they have not already done so, develop national guidelines on the proper use of prescribed medicines with addictive potential, involving all relevant stakeholders in the drafting process, including prescribers, pharmacists, patient groups and academics;

– the Committee of Ministers of the Council of Europe should consider issuing a recommendation on the rights of patients in relation to the use of prescription medicines, containing, *inter alia*, the right to effective access and availability of essential medicines, including those that contain controlled substances under international law, as well as the right to the enjoyment of the highest attainable standard of physical and mental health, free of dependency or addiction.

47. If, in addition, we allocate the necessary funds to ensure holistic treatment of patients' illnesses (particularly, non-malignant chronic pain, depression, sleep and anxiety disorders), which are traditionally treated with prescribed medicines with addictive potential, in particular by making non-drug interventions (such as counselling, rehabilitation, etc.) accessible to all who need them, in as timely a manner as possible, and we pay particular attention to the social determinants of health and learn the lessons from the Covid-19 pandemic, we will succeed to prevent and fight nefarious addiction to prescribed medicines.

60. "Human Rights and Drug Policy: a paradigm shift", Note prepared for the Committee on Legal Affairs and Human Rights of the Council of Europe's Parliamentary Assembly, Amnesty International, 2019.