

News from Brussels

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#2

- OECD: Declaration on building better policies for more resilient health systems
- Consultation on the Professional Standards Authority's good practice guidance documents in support of regulatory reform
- European Parliament seeks harmonized approach to health data sharing
- EU Global Health Strategy: European Council approves conclusions
- Opening Speech by Commissioner Stella Kyriakides at the Belgian Presidency Conference on Mental Health and Work

OECD: Declaration on building better policies for more resilient health systems

The 23rd of January, the **Organisation for Economic Co-operation and Development** (**OECD**) adopted a Declaration addressing global healthcare systems and their capacities. This Declaration acknowledges the need for both efficiency and resilience build-up in the health sector in order to face modern issues such as climate change, pandemics or aging of the world population. As the **Belgian Minister of Public Health and Chair of the 2024 OECD Health Ministerial Meeting, Mr. Frank Vandenbroucke** put it, "in the coming years, social, environmental and technological changes will exert continuous pressure on healthcare systems, which were already weakened by the COVID-19 pandemic".

Such challenges require global solutions, as they threaten worldwide healthcare systems and populations' mental health. Thus, the Declaration highlights the following **priorities of action** for the OECD:

- further strengthening, and improving access to, health systems in particular primary care, end of life care, mental health and digital services, and supporting prevention, preparedness, detection, surveillance, risk assessment, early warning, and response to future health threats to help building health system resilience
- addressing health workforce shortages by concerted action to **train**, **retain**, **and improve the working conditions of health and care workers**, and introducing new working approaches such as task sharing and task shifting
- reorienting health systems towards health promotion and disease prevention, following a **One Health approach**, including by means of health and digital literacy, addressing wider health determinants through a whole-of-government approach, and working to reduce health inequalities
- addressing gaps in the resilience of our healthcare systems identified, notably, by **regular testing and systematic reviews** that take into account economic, social and health impacts
- improve outcomes in the **mental health of populations** and the performance of mental healthcare systems, including community-based mental healthcare, prevention, and integration of mental health needs in public health and primary care, aiming to reduce unmet needs for mental healthcare services
- tackling **gender inequalities** in the delivery of health and care, and within the health and care workforce
- underpinning its commitment to **climate-neutral**, and **environmentally sustainable health systems**, **including their supply chains and medicines manufacturing**, by undertaking regular monitoring, to track and drive progress
- strengthening trust in the use of **AI and digital technologies**, including improving health data governance globally by strengthening the dissemination and uptake and improving health literacy

These concrete measures should pave the way for better resilience, but also for an innovative, people-centered and intelligent healthcare, and consequently, for healthier populations. Finally, for **Mr. Vandenbroucke**, the Declaration's objectives is a matter of long-term engagement.

For further information about this Declaration, please click <u>here</u>.

Consultation on the Professional Standards Authority's good practice guidance documents in support of regulatory reform

In Britain, the Professional Standards Authority (PSA) is consulting on two draft guidance documents to support healthcare professional regulators in using their new powers around rulemaking and fitness to practice. These new powers will be introduced after the roll-out of the Department of Health and Social Care's regulator legislation reform programme, based on the model outlined in the recently laid Anesthesia Associates and Physician Associates Order 2024.

Context

The changes the Government intends to roll out will give regulators greater freedom to decide how they operate, including introducing the flexibility to set and amend their own rules. There will also be changes to regulators' powers and governance arrangements.

The changes will also create an entirely new process for handling fitness to practice (the process by which concerns about healthcare professionals are dealt with). Under the new system, more cases are expected to be dealt with on paper through a process called an 'accepted outcome' rather than going to a formal hearing.

The PSA produced two sets of guidance to help regulators use their new powers effectively:

- Guidance on the use of Accepted Outcomes in Fitness to Practice: identifies key factors
 for regulators to consider when developing their own guidance on the use of
 accepted outcomes, includes factors to consider when deciding whether a case is best
 resolved by an accepted outcome or a fitness to practice panel (the disposal route) as
 well as factors for regulators to consider to ensure the accepted outcomes process is fair
 and transparent, and to promote effective decision-making.
- Guidance on Rulemaking: aims to help regulators make effective use of their new rulemaking powers in a way which prioritizes public protection, includes some principles to guide what good rules should aim to do or be, and the rulemaking process.

Why a consultation?

The PSA supports the reforms to healthcare professional regulation but has also identified certain risks that may arise from the new ways of working. Developing the guidance that PSA is now consulting on is one of the steps it is taking to help make the reforms a success mitigate any potential risks and realize the opportunities of the reforms.

The objective is to make sure that reformed regulation is as effective as possible at protecting the public. PSA is therefore seeking views from everybody with an interest in healthcare professional regulation, including patients, the public, registrants, regulators, professional bodies and employers.

To respond to this consultation paper, please complete the online survey available in English here before 5pm the 15th of April 2024.

For further information about this consultation, please click <u>here</u>.

European Parliament seeks harmonized approach to health data sharing

The 9th of January, Science Business published an article stating that trilogue negotiations are underway on the **European Health Data Space (EHDS)**, which will enable cross-border sharing of data, including for research. Standardisation will be key to the plan's success.

Finding a compromise on EU pharmaceuticals reform before June's European elections may prove to be impossible, but there is still hope for another key piece of health legislation: the European Health Data Space.

The plan is to set up a secure infrastructure and common standards for sharing health data across the Union. This would facilitate the primary use of data, supporting data exchanges between healthcare providers within countries and across borders and the secondary use of data by researchers and policymakers. Researchers and companies will require a permit from a national health data access body, to be set up in each Member State, granting access to non-identifiable data for approved research projects.

During debates in Parliament, both opt-in and opt-out possibilities were weighed up as a way to give patients more control over their health records. Shadow rapporteurs proposed requiring patients to give consent each time their data are used, but this "would destroy the whole system", co-rapporteur Mr. Tomislav Sokol (EPP) said following the vote in December.

MEPs finally settled on an opt-out option, requiring explicit consent only for certain sensitive types of data, such as genetic and genomic information. The **European Council also backs an opt-out system**. The question of whether each Member State can define how it implements that option will be a major issue during negotiations. It is believed a harmonised approach is necessary to ensure the pool of data available for research is representative of the EU as a whole.

Rare diseases & drugs

However, the issue of consent further needs more discussion around security safeguards when it comes to de-identifying data, says **Ms. Jelena Malinina, data director at the rare diseases patient group EURORDIS**. "These are just buzzwords. For the moment, there is no clear methodology on what is considered strong anonymisation or pseudonymisation," she said.

Surveys by EURORDIS show rare disease patients are overwhelmingly in favour of data sharing, but they are less willing to share their data for commercial purposes. "A better balance is needed between innovation and patient rights", Ms. Malinina said. Rare disease patients or their parents are often willing to do anything to promote research.

Despite these reservations, the proposal represents a great advancement. Common standards for data processing should increase data quality and make it more accessible for a variety of purposes. This is particularly important in the case of rare diseases, where the small patient populations mean there is limited expertise and often people wait years for a diagnosis. It also means there could be enough patients to run properly powered clinical trials of drugs and devices. The main issue currently is that the way data is encrypted and processed is not harmonised across the EU, making cross-border data sharing difficult.

Increased data sharing could make drug development more efficient, by reducing the need to replicate failed clinical trials, said **Alexander Natz, secretary general of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)**. "A lot of those failures are also due to the fact that we were not able to learn from the mistakes of others," he said. Data protection rules need to provide more flexibility for research purposes, he added, while the EHDS should provide a solution to a lack of infrastructure and interoperability when it comes to sharing data.

Implementation

The Council wants to allow five to seven years for registering data after a two-year implementation period, meaning the **EHDS would only be fully operational nine years after its adoption**, which is too long in the Parliament's view. Ms. Malinina though argues nine years is not so long for such an "enormous change to the system", which will require significant time and resources and changes to national laws as countries adapt to the new standards. She says practical details such as which third party will certify the electronic health record systems, and whether they have the resources to do so, will make or break the EHDS.

The Council's text also includes a provision allowing Member States to impose additional limitations on the primary use of data in cross-border situations, which Mr. Sokol claims is contrary to freedom of movement and which could stand in the way of a quick agreement.

For further information about this article, please click here.

EU Global Health Strategy: European Council approves conclusions

The 29th of January, the European Council approved conclusions on the "EU Global Health Strategy: Better health for all in a changing world", in which it reaffirms the leading role of the EU and its Member States in advancing global health. The Council acknowledges that physical and mental health is a human right and that health is a prerequisite for sustainable development.

The Council welcomes the communication of the European Commission on the EU Global Health Strategy and further emphasises that the EU and its member states must play a leading role in ensuring that global health remains at the top of the international agenda. **Global health requires effective multilateralism and inclusive multistakeholder partnerships**, and is an essential pillar of EU external policy.

Recognising that efforts should be guided by the EU Action Plan on Human rights and Democracy 2020-2024, the Council conclusions on the Youth Action Plan in EU external action and the Strategy for the Rights of Persons with Disabilities, the Council calls for increased ambition, a **comprehensive approach to health** including the promotion of health and well-being, mental health, fighting discrimination and stigma and tackling inequalities.

The three complementary priorities of the EU Global Health Strategy, as pillar of Global Gateway and the European Health Union, should guide these efforts:

- **deliver** better health and well-being for people across their life course
- **strengthen** health systems and advance universal health coverage
- **prevent** and combat health threats, including pandemics, applying a One Health approach

The Council calls on the European Commission, the High Representative and the Member States to apply these guiding principles and implement as appropriate the lines of action and initiatives proposed, in a Team Europe approach. This includes taking concrete action to promote global health across relevant sectors, strengthening capacity and enhancing coordination, taking a proactive and constructive role to strengthen multilateral cooperation with the **World Health Organization (WHO)** at its core, and by filling existing gaps in global governance and ensuring complementarity and coherence of action, expanding equitable and mutually-beneficial bilateral, regional, trans-regional and global partnerships.

It also includes promoting equitable access to health services and products, including through local manufacturing, collectively enhancing financing for global health at global, regional and national level, supporting domestic resource mobilisation in partner countries, developing a coherent EU global health diplomacy with augmented capacity in EU Delegations and regularly taking stock of progress and the impact of the strategy.

Background

The 30th of November 2022, the Commission adopted a communication on a new "EU Global Health Strategy: Better health for all in a changing world", designed to improve global health security and deliver better health for all.

The strategy will guide EU action in the field of global health until 2030 and sets out clear policy priorities, guiding principles and operational lines of action. It also creates a new monitoring framework to assess the effectiveness and impact of EU policies and funding.

For further information about this article, please click <u>here</u>.

Opening Speech by Commissioner Stella Kyriakides at the Belgian Presidency Conference on Mental Health and Work

The 30th of January, the Belgian Presidency Conference on Mental Health and Work brought together experts and decision-makers in the field of mental health and work, with the aim of brainstorming and sharing innovative solutions and best practices to help anticipate and plan

for the future. It addressed the three types of prevention (primary, secondary and tertiary) and highlighted the need for an integrated approach, a strong framework at European level, a better anticipation of future crises and the importance of social dialogue.

The Commissioner for Health and Food Safety Stella Kyriakides delivered a speech focusing on EU initiatives' results:

"Deputy Prime Minister De Sutter, Ministers, Honourable Members, Distinguished Guests, Colleagues, Friends,

Let me start by thanking the Belgian Presidency for bringing us together in this important Conference. I am glad that we are shining a light on **issues around mental health and work,** which will be one of the centre-pieces of this Presidency.

EU citizens clearly need and want us to act. A need becoming even more imperative as a recent Eurobarometer survey, showed that almost half of EU citizens had experienced an emotional or psychosocial problem in the last 12 months. In addition, a recent Occupational Safety and Health Pulse survey by EU-OSHA, the European Agency on Safety and Health at Work, revealed that over a quarter of workers experience stress, depression or anxiety that is caused or made worse by work.

EU workplaces have experienced rapid, constantly evolving digitalisation, which has gathered steeper pace during the COVID-19 pandemic. So, it comes as little surprise that 44% of workers say that the COVID-19 pandemic has raised their stress levels at work.

But there is good news as well. **Half of those interviewed found it easier to talk now about stress and mental health at work**. This confirms that we rightfully included breaking stigma and discrimination as one of our top actions in our first ever Comprehensive approach to mental health, launched last June.

Friends,

With 20 flagship initiatives and 1.23 billion euros in funding opportunities, our mental health strategy approach gives us a blueprint for concrete, targeted action. Here are just four examples of action already underway:

- First, with the World Health Organization, we are helping Member States build capacity to include mental health issues across policy areas.
- Second, we support Member States to use best practice as a basis for reforming their mental health systems.
- Third, in the Expert Group on Public Health we are **developing guidance on stigma** and discrimination.
- And fourth early this month we launched a multi-disciplinary **training and exchange programme.** This will help more than 2 000 professionals learn from different care practices across the EU.

Ladies and gentlemen,

Our comprehensive approach to mental health includes a commitment to look more closely at the psychosocial risks at work and assess the need for further proposals. It is rooted in a commitment to examining psychosocial risks in the workplace and considering further measures as necessary. Recognizing the significant time individuals spend at work, we need prioritise cultivating environments that support both well-being and productivity.

Therefore I am pleased to have collaborated with **Commissioner Mr. Nicolas Schmit** on this initiative who will speak about work related aspects more in detail this afternoon, and as Commissioner for Health and Food Safety I am particularly pleased that we continue in addressing the specific challenges faced by health and care professionals with EU OSHA project for Health and Social Care Sector that aims to provide **evidence based knowledge on the diverse challenges faced by this sector, including psychosocial risks**.

Last but not least, as part of the Health at a Glance report, we have launched **27 country health profiles, with a key section on mental health**. This information will help us better guide our mental health resources and investments in each Member State.

Friends,

I am proud that, just a few months since its launch, the comprehensive approach to mental health is already taking tangible form and delivering results. This conference is a helpful contribution to our discussions around mental health and work. Because it's ok not be ok.

Thank you."

For further information about this speech, please click here.