News from Brussels

Year 2024 – Issue n°3

#3

- **Medical devices: Council endorses new measures to help prevent shortage**
- **Global nurse leaders warn of critical challenges facing nursing professionals worldwide**
- **The European Commission supports two new Health Union Actions with €126 million from the EU4Health Program**
- **European Health Data Space: Council and Parliament strike a deal**

Medical devices: Council endorses new measures to help prevent shortages

The Council has endorsed key updates to the legislation on medical devices that will help **prevent shortages** and permit **greater transparency** and access to information. The Regulation approved by EU member-state representatives today amends the legislation on medical devices, including in-vitro diagnostic medical devices (IVDs), by:

- Further **extending the transition period** for certain IVDs (particularly those that are high-risk).
- Enabling a **gradual roll-out of EUDAMED**, the new electronic database
- Requiring manufacturers to **flag up potential shortages** of critical medical devices and IVDs.

Helping to guarantee the supply of critical IVDs

Around two-thirds of all clinical decisions are based on information provided by IVDs, which include tests for HIV, cancer, pregnancy and COVID-19. In 2017, new rules were introduced to **modernise and update the EU framework** for these products, further guaranteeing their safety and effectiveness.

The far-reaching nature of these changes led to an increased need for scientific, technical and regulatory expertise and capacity, which take time to develop. As a result, **many critical IVDs have yet to comply with the new rules**, leading to a risk that – once the transition deadline has passed – they may be removed from the market without being replaced.

The revision approved today **extends the deadline** for transitioning to the new system under certain conditions, to avoid shortages of critical IVDs without compromising on safety.

Gradual roll-out of EUDAMED

To improve transparency and access to information, the new rules adopted in 2017 provided for the creation of a **European database on medical devices** (EUDAMED), which would ultimately contain comprehensive data about all medical devices available on the European market.

Initially, manufacturers were not required to register their medical devices on EUDAMED until all of its **six elements ('modules')** had been set up. However, while three modules are already available, and two more are expected to become available in 2024, the final module is unlikely to be completed until late 2027.

Therefore, in order to **speed up the process** of registering medical device data, manufacturers will be required under the new rules to provide information about their products via the completed EUDAMED modules. This mandatory registration is expected to take effect as of late 2025.

Flagging up potential shortages

The best way to prevent shortages of key medical devices is to detect them early. Today's revision therefore introduces an obligation for manufacturers to give **prior notice about any interruption of supply** of certain critical medical devices or IVDs to relevant authorities, health institutions, healthcare professionals and economic operators to whom they supply the device.

Background

The **In Vitro Diagnostic Medical Device Regulation (IVDR)** entered into force in 2017 and is applicable since 26 May 2022. It was adopted together with the Medical Devices Regulation (MDR), which has been applicable since 26 May 2021. These two regulations aimed to modernise the rules on medical devices, including IVDs, and improve patient safety.

Due to the far-reaching nature of the changes set out in the IVDR, a large number of IVDs currently on the market have yet to comply with the new rules; the situation is particularly serious for high-risk IVDs such as certain blood tests.

On 23 January 2024, the European Commission published a proposal to update the provisions of the IVDR and MDR in order to mitigate shortages of critical medical devices. The EU Council agreed on its mandate on 14 February 2024.

For further information about this consultation, please click here

Global Nurse leaders warn of critical challenges facing nursing profession worldwide

On February the 28th, **The International Council of Nurses** (ICN), in partnership with the **Joint Virtual Swedish Nurse Organisation**, held the International Workforce Forum (IWF) in Stockholm, Sweden this week. The IWF brought together more than a dozen leading National Nurses Associations (NNAs), representing millions of nurses, with high level members of the World Health Organization (WHO), and Sweden's Ministry of Health.

ICN President Dr Pamela Cipriano

Nursing organizations from Europe, North America and Australia, attending the Forum,

held the view that the nursing profession faced several challenges, which led them to reaffirm a call made by ICN more than a year ago that we are experiencing a global health emergency.

They highlighted a wide range of concerns detrimentally affecting nurses' working environments and consequently creating major risks to public health. These issues included international migration, recruitment and retention, workload, safe staffing levels, violence, and burnout.

ICN President Dr Pamela Cipriano who opened the proceedings, addressed the issue of the deteriorating work environment:

"We saw the serious and sometimes deadly challenges that our nurses went through during the pandemic, but as we fast approach the third anniversary of WHO declaring the pandemic on 11 March, we find that nurses are still being profoundly affected in their daily work by shortages that undermine safe staffing, lack of fair pay, poor conditions and violence in the workplace, all of which were exacerbated by the pandemic and its aftershocks.

"Together we have a responsibility to address these multiple challenges and shift nursing from being invisible to being seen as invaluable and that means ICN will continue to lead and fight for improvements in the nursing working environment."
"We are also calling for a policy shift from a focus on supporting individual nurse resilience to ensuring that all health care systems - providers and employers - meet their duty of care to ensure that nurses are fully supported and can work in safety to provide effective care to their patients. Nurses are some of the most resilient workers in the world, but they should not be expected to do their vital work in isolation, without support."

Sweden's Minister for Healthcare, Acko Ankarberg Johansson, who attended the Forum and echoed Dr Cipriano's words, told the participants of her personal commitment to improve the working environment and conditions of nurses, and underlined their key role as leaders within the health care system.

Sineva Ribeiro, President of JSNO and President of Vardforbundet, and Dr Oili Dahl, Vice President of JSNO and President of the Swedish Society of Nursing said:

"JSNO appeals to responsible ministers and employers to work towards Sweden becoming self-sufficient in registered nurses and frame a national plan for safe staffing. We also urge employers to respect the profession's requirements for development, training, and working conditions."

Nursing organization leaders agreed on the crucial need for countries to implement a package of policy solutions, which target urgent priorities, but also focus on long-term improvements to recruitment policy, domestic production, and retention of nurses.

Many of the nursing organizations present at the Forum came from countries at the forefront of international recruitment, heavily reliant on nurse migration, despite being amongst the richest countries in the world. They were deeply concerned about the impact of increasing global recruitment activity and the damage and potential danger to the source countries' health systems. In response, ICN Chief Executive Officer **Howard Catton** said:

"The picture our NNAs have painted at the Forum is that crisis in nursing amounts to full-scale global health emergency. Governments must not close their eyes to these warnings but act."

"We have heard directly from our NNAs about their very deep levels of concern about over reliance on migration. They strongly support the right of individual nurses to move across borders to improve their careers and their lives, but equally they are highlighting the risks of growing large scale nurse migration."
"ICN has called for strengthening of the WHO's voluntary code on international migration and the need to see tangible mutual benefits for the nursing workforce from the source countries. The current system is unsustainable and is causing real harm in countries that are losing their nurses through emigration. We want to see strengthening to the code that brings mutual benefit to nurses and health systems in all countries that import and export nurses internationally."
"In addition, ICN is calling for the WHO Pandemic Accord, currently being finalized, to strengthen its language on workforce, especially in relation to the WHO's voluntary code on international migration and widening inequalities."

Mr Catton said the Pandemic Accord should also address the lack of accurate data on nurse infections and deaths during any future pandemics:

"The lack of accurate data on nurse infections and deaths during the COVID-19 pandemic and since is unacceptable: it is vital that all countries collect such data because it will help to ensure that nursing staff are fully protected during pandemics and other health emergencies and honour the sacrifice of nurses who lost their lives."

Mr Catton also said that health workers, and especially nurses, should be represented in any governance arrangements that will be established to monitor the Pandemic Accord.Senior representatives from WHO attending the IWF shared early information about the next State of the World's Nursing (SOWN) report, which is due to be published in 2025. They discussed the plan for data collection. It was agreed that NNAs have an essential and critical role to play in ensuring the integrity of the country data to be used to develop the SOWN report.

The European Commission supports two new Health Union action with €126 million from the EU4Health Programme

On February 13th 2024, the Commission launched two major projects to support action on key European Health Union priorities. The first action is focused on **antimicrobial resistance** (AMR) and healthcare-associated infections, one of the key health threats of our times. The project aims at reducing the risk of exposure of citizens to antibiotic-resistant bacteria and is supported with €50 million under the EU4Health programme, making it the **largest EU-funded action on AMR to date.** The action JAMRAI 2 brings together all EU Member States as well as Iceland and Norway to work on areas such as infection prevention and control, surveillance and monitoring, prudent use of antimicrobials, raising awareness, and innovation. In line with the One Health approach needed to tackle AMR, the initiative includes activities related to animal health and the environment.

The second Joint Action focuses on **cancer prevention and other non-communicable diseases** (NCDs), such as cardiovascular diseases, diabetes, as well as **mental health**. It will be funded with €76 million from the EU4Health programme and brings together the national authorities of 22 EU Member States along with Norway and Iceland working to maximise efforts. The Joint Action JA PreventNCD will also build a comprehensive European infrastructure to monitor factors related to cancer and other NCDs, as well as focus on reducing social inequalities.

Stella Kyriakides, Commissioner for Health and Food Safety, said: "*The actions launched today are proof of the positive impact the European Health Union and the actions funded by the EU4Health programme has on EU citizens' lives. Antimicrobial resistance is responsible for over 35 000 deaths every year in the EU alone and cost our health systems €11.7 billion. We need to urgently step-up our measures in Europe and across the world to tackle this threat, which is why we are today launching the largest ever funded EU action on AMR to support countries make a real difference on the ground. Our actions are also helping countries to improve prevention and reduce the disease burden of cancer and other non-communicable diseases, supporting our ambition under Europe's Beating Cancer Plan and other key initiatives.*"

Commissioner for Health and Food Safety Mrs. Stella Kyriakides

For further information about this consultation, please click here

European Health Data Space: Council and Parliament strike a deal

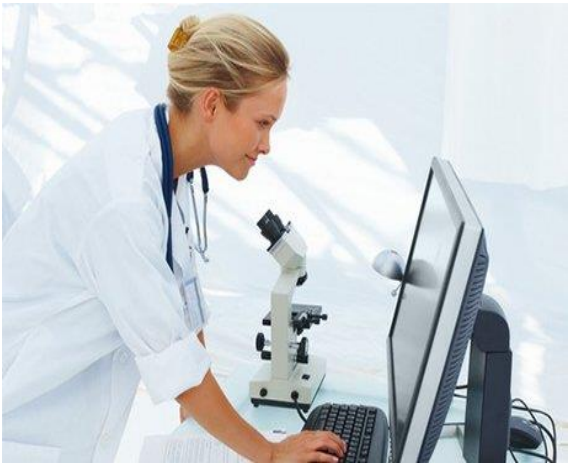
The Council of the EU and the European Parliament have reached a provisional agreement on a new legislation easing interoperability between health databases at the EU level. The agreement remains to be officially adopted by both the Council and the Parliament.

The proposed regulation for a European Health Data Space (EHDS) aims to improve individuals' access and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes. It provides for a health-specific data environment that will help foster a single market for digital health services and products.

Currently, cross-border access to health data varies across the EU. The new rules aim to make it possible for a Spanish tourist to pick up a prescription in a German pharmacy, or for doctors to access the health information of a Belgian patient undergoing treatment in Italy.

At this occasion, Mr. Frank Vandenbroucke, Belgian Deputy Prime Minister and Minister of Social Affairs and Public Health, declared:

"After months of hard work and dedication, we have a deal that will strongly support patient care and scientific research in the EU. The new law agreed on today will allow patients to access their health data wherever they are in the EU, while also providing scientific research for important reasons of public interest with a wealth of secure data that will greatly benefit the development of health policies."



Easier access to health data for individuals

Under the new rules, individuals will have faster and easier access to electronic health data, regardless of whether they are in their home country or another member state. They will also have greater control over how that data is used. EU countries will be required to set up a digital health authority to implement the new provisions.

Greater research potential

The EHDS will also provide researchers and policy-makers with access to specific kinds of secure health data, enabling them to tap into the vast potential provided by the EU's health data to inform scientific research in the public interest.

Ensuring interoperability

Currently, the level of digitalisation of health data in the EU varies from one member state to another, making it more difficult to share data across member-state borders. The proposed regulation requires all electronic health record (EHR) systems to comply with the specifications

of the European electronic health record exchange format, ensuring that they are interoperable at EU level.

Key elements of the provisional agreement

The provisional agreement reached today between the Council and the Parliament amends the Commission's original proposal in a number of key areas, including:

- Opt-out: member states can allow patients to opt out of the use of their health data being accessed, whether by a healthcare professional (primary use) or for further use (secondary use, always under strict conditions), except for purposes of public interest, policymaking, statistics, and research purposes in the public interest.
- Restricted information: if patients choose to restrict information, healthcare professionals will only be able to access restricted health data in situations of vital interest.
- Sensitive data: member states may put in place stricter measures governing access to certain kinds of sensitive data, such as genetic data, for research purposes.
- Trusted data holders: to reduce the administrative burden, member states may establish trusted data holders that can securely process requests for access to health data.
- Clinically significant findings: if researchers inform health data access bodies (HDABs) about findings that may impact the health of a patient whose data was used in the scientific research, the HDAB may inform the trusted data holder who has to inform the patient or the relevant treating health professional about these findings.

Next steps

The provisional agreement has yet to be officially adopted by the Council and the Parliament. After legal-linguistic revision, the Regulation will enter into force 20 days after publication in the EU's Official Journal.

Background

On May 3rd, 2022, the European Commission presented a proposal for a Regulation creating a European Health Data Space (EHDS). The proposal is the first of nine European sector- and domain-specific data spaces set out by the Commission in its 2020 communication, 'A European strategy for data'. The Council agreed on its mandate for negotiations on 6 December 2023.

The EHDS aims to provide easier cross-border access and exchange between health databases, both to support healthcare delivery ('primary use of data') and inform health research and policy-making (re-use of data, also referred to as 'secondary use of data'). It is considered a key pillar of the European Health Union.

For further information about this consultation, please click here