NEWS FROM BRUSSELS

European NURSING Council

Word from Senior Policy Advisor Dr. Theodoros Koutroubas

Dear Friends,

This News from Brussels contains, if I may so, quite exiting reading material. Nurses can (soon) prescribe medicines in Belgium, the EU has published the very important regulation on the European Health Data Space (EHDS), and there is (finally) a plan to avoid foreign dependency and shortage of medicines in Europe.

Do come back with feedback.

Kind regards,
Theo

NEWSLETTER HIGHLIGHTS

Nurses Will Be Able to Issue Certificates and Write Prescriptions in Belgium

A recent legislative development has opened new perspectives for Nursing in Belgium. At a time when access to healthcare and reform is on the agenda of countries all over the world, **Belgium has adopted a law giving select nurses the ability to prescribe certain treatments, request medical examinations, refer the patient to another professional and even deliver medical certificates.**

The proposal would not be extended to all nursing professionals but only to a 'certain category of nurses,' such as advanced practice nurses (APN) who will be approved legally by a regulated commission to ensure high standards are maintained.

The criteria are also stringent: **Those nurses have to have 'a master's degree in nursing sciences and have accumulated at least 3000 hours of practice as a nurse in a context specific to healthcare over the course of the five years preceding the request of approval.'** Should the nurse succeed in his/her request to be recognised as an APN, the nurse shall be 'recognised for their practice in a specific sector and shall be therefore approved as an APN in said sector only.'

This widening of options of authorised activities will allow the first approved APNs, in addition to what they can already do now as nurses, certain medical actions which hitherto have been the prerogative of physicians.

However, medical unions have opposed this measure. The possibility of prescribing medication or the issuing of certificates is indeed part of the new decree but its implementation has been reportedly postponed by Minister Vandenbroucke until the start of 2026 owing to trade union opposition and the need to adapt the administration and infrastructure to the new measures for a 'harmonious and efficient transition.'

The Belgian Association of Medical Unions, Absym, is opposed to the idea of allowing some nurses to prescribe medicines, with Luc Herry, the President of Absym, stating **'as trained as they may be, they are not physicians,'** the measures according to him would erode the position of the physician while opening up a conflict of responsibility in addition to the 'distancing' of patients and physicians which 'will not improve the attractiveness of the profession.'

It is clear that this proposal has some hurdles to overcome before being fully implemented, but the breach has been made and owing to the growing need for more access to healthcare services, the Belgian case study may inspire similar changes across Europe.

Pharma Braces for Tariffs as President Trump Threatens to Buck Trade Convention

The following article was adapted from POLITICO

After raising tariffs on steel and aluminum [*sic*], U.S. President Donald Trump had a clear message for the pharmaceutical industry — you're next.

"It'll be 25 percent and higher, and it'll go very substantially higher over [the] course of a year," he said when asked about semiconductors and pharmaceuticals during a press conference at his Mar-a-Lago residency in Palm Beach, Florida on Feb. 18. He later doubled down on his 25-percent tariff plan for Europe on Feb. 26.

Generic drugmakers say that will lead to price increases for American patients, while analysts believe tariffs could also disrupt the delicate drug supply chain at a time when both the U.S. and the EU are trying to boost domestic medicine production after years of relying on cheaper Asian drugs.

"Tariffs would affect both sides of the ocean," Elisabeth Stampa, board chair at Spanish generics and active pharmaceutical ingredients firm Medichem, told POLITICO, underlining that Europe, which is a major supplier of medicines and their ingredients to the U.S., would experience export disruptions.

Analysts also warn that counter-measures from Brussels — which the EU has promised — could end up exacerbating the continent's supply problems.

Whatever the consequences, tariffs on the industry would signify a new frontier in a trade war. Pharmaceutical products are normally excluded from tariffs because of a World Trade Organization agreement that dates back to 1994.

"The general trend of the last decades has been to lower tariffs on pharmaceuticals globally to promote better access to medicines. Pharmaceuticals have not been at the forefront of recent tariff disputes," said Justine Fassion, an international trade lawyer at Sidley.

The threat of tariffs, even if remote would have immediate consequences. For example, the Irish industry is particularly exposed: In 2023, the U.S. was the No. 1 country for Irish goods exports, with the United States buying products worth €54 billion. Of that, some €36 billion related to pharmaceuticals and chemicals.

A spokesperson for Ireland's Department of Foreign Affairs said in an emailed statement that it "will work with EU partners to measure the impact of tariffs across all sectors, and calibrate our response on that basis." "Increased protectionism is not in the interests of businesses or the global economic environment, and would not benefit the EU, Ireland or the U.S.," it added.

Larger pharmaceutical companies with a big presence in Europe have also played down their concerns, saying they would be able to absorb the cost of any tariffs. Novo Nordisk CEO Lars Fruergaard Jørgensen said that while the company was "not immune" to the effects of tariffs, it is "confident" the business could weather the storm despite Novo Nordisk's production of all of its weight-loss drug Wegovy's active pharmaceutical ingredient, semaglutide, in Europe, from where it is exported to the United States.
But smaller companies say they are concerned about the potential impact on their business. "Such uncertainty complicates investment decisions and strategic planning, making it essential to prepare for various scenarios," Jacopo Andreose, CEO at Angelini Pharma, told POLITICO in an email. The Italian firm makes products including eye drops and heat pads. The U.S. is the largest export market for European pharmaceutical products, accounting for 33 percent of the sector's exports, he said, adding that "any trade barriers would impact supply chains, increase costs, and ultimately limit patient access to essential medicines" in the U.S.

"Moreover, tariffs would drive up pharmaceutical prices in the U.S., affecting both patients and the entire U.S. health care sector. The climate of uncertainty is already damaging an EU that is struggling with competitiveness," he added.

The continent's drug shortage problem complicates any decision by Brussels to impose countermeasures on the U.S. The big question is — would the EU retaliate?

The European Commission said earlier this month it would react “firmly and immediately” to any levies, but when it comes to drugs, European patients could end up in the cross-hairs. Both the EU and the U.S. are drawing up measures to bolster their domestic drug production, but both are currently hugely reliant on Asia for medicines and their compounds, especially cheaper generics. The U.S. has one advantage: When supply issues arise in China or India, “pharmaceuticals tend to go to the U.S. over the EU because they pay more,” said Diederick Stadig, health economist at Dutch bank ING.

Medicines for Europe, a lobby group for the continent’s generics sector, wants to use the moment to work together. “Europe or the U.S. (alone) will struggle to build competitive manufacturing,” its Director General Adrian van den Hoven said in an email. “We would be happy to work with the U.S. industry and government to tackle jointly concerns over dependence.” He added that Europe is a “major supplier” of generic medicines and active pharmaceutical ingredients.

Nevertheless, the continent’s drug shortage problem complicates any decision by Brussels to impose countermeasures on the U.S. “I assume the Commission is thinking about this, thinking ahead and preparing counter-tariffs,” Belgium’s Health Minister Frank Vandenbroucke said at a Polish presidency event in Brussels this month.

He cautioned: “I think we should be very careful because of unintended impacts on the supply chain.” In many European countries the price is fixed, so if a tariff is levied the product may simply disappear, he said. “I think we should be very careful.”

Aging populations in Europe are creating increasing demand for medicines, and cheaper medicines in particular, said Stadig, the ING economist. But tariffs generally drive prices up. “This, and shortages, may inform the EU response when it comes to tariffs. This poses many complex questions to policymakers,” he said.

“I wouldn't want to be the person making that decision.”

Regulation on the European Health Data Space Published

The Regulation on the European Health Data Space (EHDS) has been published in the Official Journal of the EU. The Regulation is an important milestone in the EU's efforts to build a secure and efficient digital health ecosystem as part of the European data strategy.

The EHDS will provide a comprehensive framework for the access to and use of electronic health data across Member States. It will enhance innovation and competitiveness in the health sector for the benefit of all EU citizens.

The EHDS benefits are:

- **empowering citizens, giving them better control over their personal health data and enabling seamless access to their medical records across the EU, whenever and wherever they need healthcare (primary use).**
- **strengthening the re-use of health data in anonymised or pseudonymised form, for research, innovation, public health, and policymaking, with safeguards fully in line with EU data protection and cybersecurity standards (secondary use).**

EHDS is a game changer for healthcare in Europe. The EHDS represents a major leap forward in strengthening the resilience of Europe's health systems, ensuring they can tackle today's most pressing challenges such as an aging population and workforce shortages.
The EHDS supports the health sector to provide high-quality, accessible, and sustainable healthcare. By fostering a more interconnected, patient-centred, and data-driven healthcare system, the EHDS will enhance efficiency, reduce administrative burdens, and support the long-term financial sustainability of health services.

Citizens will have the right to access and share their health records, such as e-prescriptions, medical images, or test results securely across borders, ensuring better-informed medical decisions and continuity of care. At the same time, researchers, public health authorities, and policymakers will be able to leverage health data in a secure and privacy-preserving way to accelerate the development of new treatments, improve disease prevention, and strengthen Europe's crisis preparedness.

Next steps

The EHDS Regulation will enter into force on 26 March 2025 and will become applicable in different phases according to data types and use cases.

The most significant milestone will happen in four years' time, on 26 March 2029, when data exchanges for the first group of priority categories (including patient summaries) under primary use will go live. At the same time, the rules on secondary use will begin to apply to most data categories. Two years later, on 26 March 2031, the EHDS will expand to additional data categories.

Over the next four years, the focus will be on developing and adopting more than twenty Implementing Acts, as well as establishing the EHDS governance bodies, which will be essential for the effective functioning of the system. The Commission will work closely with Member States, healthcare providers, researchers, and industry stakeholders to ensure a smooth and effective implementation.

Medicines - A European Plan to Avoid Shortages

The shelves of Belgian pharmacies are sometimes emptying faster than they can be restocked: nearly 800 medicines are currently unavailable or permanently missing, according to the PharmaStatut database which records these unavailabilities. Among them are painkillers or anti-inflammatories as common as Dafalgan or Ibuprofen. Last year, some 3,000 notifications of unavailable medicines were recorded.

This situation is not only due to an increase in demand. It is also a symptom of a structural problem: the growing dependence of Belgium, like other EU Member States, on Asian imports of active ingredients (key substances that give medicines their therapeutic effects). Whereas Europe was once the world's pharmacy, 70 to 80% of European pharmaceutical products now depend on China and India.

A question of health... and strategic security

To address these shortages, the European Commission is preparing to unveil a legislative act on critical medicines. The objective: to protect the supply of vital treatments, including antibiotics, anaesthetics and thrombolytics, which are essential for both civilian care and emergency interventions... in the event of war, for example.

In view of growing geopolitical tensions, the Belgian Minister of Health, Frank Vandenbroucke (Vooruit), and ten of his European counterparts have signed a platform calling on Europe to act as quickly as possible to deal with any crisis situation. In the current context, ignoring the issue of medicine safety would be "a major strategic error", warn the eleven health ministers.

"Several medicines, including antibiotics, anaesthetics and thrombolytics, are not only essential for civilian health care but also for military and emergency scenarios," they remind. The threat is serious, especially in this unstable period: "In the event of an escalation of the conflict, a disruption in the supply chain of certain medicines could have dramatic consequences, making certain operations impossible," warns Frank Vandenbroucke.

Drug shortages: a persistent problem in Europe

As worrying as it is, the problem is not new. At the height of the COVID crisis, shortages of essential medicines, including muscle relaxants needed for emergency intubation, paracetamol and active pharmaceutical ingredients for vaccines, revealed with a bang the state of dependence of the Old Continent on Asian supplies.

In five years, things have unfortunately not changed much... Supply disruptions still affect essential medicines such as insulin, antibiotics or thrombolytics (used in particular in cases of ischemic stroke or myocardial infarction to prevent the formation or spread of blood clots) or anticancer treatments that are just as fundamental for survival or improving quality of life, such as hormone therapy or chemotherapy.

Identifying supply chain gaps

Faced with these risks, the EU is trying to structure a response. It all started in 2023 with the publication of an informal note at the initiative of Belgium, co-signed by 23 Member States. During the Belgian Presidency of the EU in 2024, Frank Vandenbroucke emerged as one of the driving forces behind the European Critical Medicines Alliance, a consultative mechanism bringing together Member States, the pharmaceutical industry, civil society and researchers, which published its first report at the end of February.

Supported by the Health Emergency Preparedness and Response Authority (Hera), the Alliance is continuing and deepening measures taken by the Commission in 2023, in particular the organisation of a solidarity mechanism between Member States and a list of molecules that are critical from a public health perspective. In total, 276 molecules that are essential for survival or quality of life and for which there is no alternative have been listed.

"It is a question of identifying both the vulnerabilities in the supply chains and the risks that weigh on the critical medicines that have been listed. Several levers of action are possible: either diversify the offer (in the situation where there are several producing countries) or create or recreate the production capacity in Europe, which obviously requires a legal framework that allows financing, without which it is not possible. This is the crux of the problem," explains Frank Vandenbroucke.

Storage and solidarity: avoiding competition between Member States

It is also necessary to create a market that now takes into account the security of supply and not just the attractiveness of prices. "For 20 years, public procurement has favoured the lowest prices, particularly for generic medicines, to the point that it has become almost impossible to produce these treatments in Europe. It is a paradigm shift that must now be made," believes the Belgian Minister of Health.

Without forgetting the principle of solidarity that must prevail between Member States, insists the Flemish socialist: "There must be tangible coordination of medicine stock strategies between Member States. Currently, each country tends to protect its own stocks, which can deprive other States of vital treatments in times of crisis. However, we are touching here on a principle that must really be anchored in European legislation: the needs of a patient must take priority over the stock obligations of a Member State ."

Europe must act quickly. Securing access to medicines is no longer just a matter of public health policy, it is now also a question of strategic security.