NEWS FROM BRUSSELS

European NURSING Council

Word from Senior Policy Advisor Dr. Theodoros Koutroubas

Dear Friends,

There are very interesting evolutions concerning pharmaceutical policy and rules in the EU, and I do believe that we are directly concerned, especially as nurses get the right to prescribe in ever more countries, in a context marked by the need to invest in healthcare systems.

Our member ONI has a new President, elected less than a month ago. Naturally, ENC wishes him a very fruitful term and looks forward to closely working with him and ONI in the year to come.

Warm regards from Brussels,

Theo

NEWSLETTER HIGHLIGHTS

Invest in Healthcare Systems to Improve Europeans' Health and Prosperity, Report Finds

Non-communicable diseases, such as diabetes or cancer, cause most of the preventable illnesses and deaths in the EU. They are increasingly affecting younger people, with more children becoming inactive and obese. A new report on the state of health in the EU identifies addressing this concern as a critical area for improvement.

More broadly, the report shows that Europe urgently needs to invest in its health systems to improve Europeans' healthcare. This would also boost competitiveness, thanks to a healthy workforce. EU countries are already carrying out critical reforms, funded by the EU, to their healthcare systems. The new report outlines four areas where challenges persist, and further action is needed.

Address the major health concern of non-communicable diseases

- **the European Commission will present an EU cardiovascular health plan, targeting diabetes and obesity especially in younger generations**
- continued action under Europe's Beating Cancer Plan, and Healthier Together initiative

Strengthen the backbone of EU health care

- **EU countries should keep improving their systems to attract and retain primary care providers and develop new community-based care models**
- EU Cohesion Funds and Recovery and Resilience Facility already support EU countries in improving access, coverage and continuity of primary care

Improve healthcare through technology

- all EU countries are now providing access to electronic health records and investments in ePrescriptions, AI integration, and digital governance are expanding
- **continued EU investment in health-related ICT**

Support EU competitiveness through affordable access to pharmaceuticals and innovation

- amid rising medicine prices and growing demand, EU countries have managed to carry out important pharmaceutical reforms to improve access and affordability of medicines, aligned with and supported by the reform of the EU's pharmaceutical legislation and the Health Technology Assessment regulation

Alongside the report, 29 Country Health Profiles have also been published, which cover the latest developments in health trends and health systems across all EU Member States, plus Iceland and Norway.

To read the report click here

Deal on Comprehensive Reform of EU Pharmaceutical Legislation

European Parliament

Early morning on Thursday the 4th of December, co-legislators reached a provisional agreement on revamping the EU's pharmaceutical policy framework, to boost competitiveness, innovation and security of supply.

Regulatory data and market protection to support innovation

Parliament and Council negotiators agreed to a regulatory data protection period (during which other companies cannot access product data) of eight years, with one additional year of market protection (during which generic or biosimilar products cannot be sold), following a marketing authorisation.

Pharmaceutical companies would be eligible for additional periods of market protection:

if the particular product addresses an unmet medical need (12 months);
if it contains a new active substance, fulfilling a combination of conditions on comparative clinical trials, clinical trials carried out in several member states, and the obligation to apply for market authorisation within 90 days after the submission of the application for the first marketing authorisation outside the Union (12 months);
if the company obtains an authorisation for one or more new therapeutic indications that bring a significant clinical benefit in comparison with existing therapies (12 months).
The deal envisages a cap of eleven years on the combined regulatory protection period.

Orphan medicinal products addressing a disease with no current available medicinal treatment ("breakthrough orphan medicinal products") would benefit from up to eleven years of market exclusivity.

To support earlier market entry of generic and biosimilar medicinal products, the deal clarifies the scope of the "Bolar" exemption (which allows manufacturers to conduct certain activities during the market protection period of the original product). Patent rights would not be infringed when necessary studies, trials and other activities are conducted for the purposes of obtaining marketing authorisations, conducting health technology assessments, obtaining pricing and reimbursement approvals, or submitting procurement tender applications.

Stepping up the fight against antimicrobial resistance (AMR)

Negotiators agreed to introduce a “transferable data exclusivity voucher” for priority antimicrobials, giving the right to 12 additional months of data protection for one authorised product. The 12-month extension may be used once, for the priority antimicrobial or for another centrally authorised medicinal product of the same or different marketing authorisation holder.

Among new measures to promote the prudent use of antimicrobials, the deal introduces stricter requirements, such as compulsory medical prescriptions for all antimicrobials, specific information requirements to be provided with the package leaflet, and an “awareness card” in paper format in case the leaflet is made available only electronically.
When applying for marketing authorisation for antimicrobials, companies would also need to provide an “antimicrobial stewardship plan” and include an evaluation of the risk for antimicrobial resistance as part of the compulsory environmental risk assessment.

Competitive regulatory framework

The updated rules would simplify the European Medicines Agency’s (EMA) internal functioning, to enable it to treat market authorisation requests more rapidly. Marketing authorisation applications would be submitted electronically in a common format. Marketing authorisation for a medicinal product would be valid by default for an unlimited period, avoiding the unnecessary administrative burden linked to renewals (the EMA would still have the possibility to limit validity, on safety grounds).
Under special conditions, the Commission may set up regulatory sandboxes, to allow the development and testing of new and innovative therapies, under the direct supervision of the competent authorities.

Ensuring the availability of medicines

Companies holding marketing authorisations for medicinal products would be required to put in place and update shortage prevention plans for medicinal products subject to prescription and medicinal products that would require a shortage prevention plan identified by the Commission. Shortages would be monitored at both national and EU levels, and the EMA would establish and update a list of critical shortages in the EU.

Next steps

Parliament and Council have concluded an "early second reading agreement" (negotiation took place after Parliament’s first reading was adopted in plenary). The Council is now expected to formally adopt its position, which can then be endorsed by Parliament in second reading.

Commission Welcomes Political Agreement on Major Reform of EU Pharmaceutical Rules

The European Commission welcomes the political agreement to modernise the EU's pharmaceutical legislation, reached last night by the Council and the European Parliament. The reform is a crucial step in **boosting innovation and investment** in the EU's pharmaceutical sector, while ensuring that **medicines are safe, effective and available for patients throughout Europe**. The reform package revises the current EU rules, which are over 20 years old.

Today's agreement offers a more modern, flexible and competitive framework for the pharmaceutical sector, so that it can better deliver for European patients and compete globally. The new rules will:

- **Expand access and availability of medicines.** The EU's robust, science-based assessment process will continue to underpin all medicine authorisations to ensure the highest safety standards, while streamlined procedures will make it more efficient.
- **Accelerate medicine supply chains**, by cutting red tape for companies, reducing evaluation times for new medicines and reforming the European Medicines Agency (EMA). They will ensure that new medicines get to the market faster and that patients have better access to therapies, especially for unmet needs.
- **Place the EU at the forefront of pharmaceutical innovation**. The reform offers world-leading incentives for innovative products, introduces regulatory sandboxes as a secure testing environment for truly novel medicines and introduces adapted frameworks for certain non-standard treatments, like personalised therapies. In addition, fulfilment of unmet medical needs will receive strong recognition.
- **Enable timely market entry for generic medicines**. The reform brings clarifications regarding the application of the Bolar exemption, which allows certain activities during the patent protection without prejudice to international agreements.
- **Address medicine shortages.** The reform establishes an EU framework to better monitor medicine shortages, with a stronger coordination role for EMA. Companies will be subject to stronger obligations to prevent shortages, while an EU list of critical medicines will be established and vulnerability assessments carried out, amongst other things.

All these measures will substantially strengthen a sector that is vital for the EU's strategic autonomy. Reform of the pharmaceutical legislation is a key part of the Commission's agenda to ensure EU citizens have access to top-level medicines and treatments, and to support a more competitive and innovative healthcare sector in the EU. It is complemented by the Commission's proposal for a Critical Medicines Act, the recent Life Sciences Strategy and the upcoming Biotech Act, the targeted revision of the rules for medical devices, among other initiatives.

Next Steps

The political agreement is now subject to formal approval by the European Parliament and the Council.

Alain Desbouchages Elected New President of the French Order of Nurses

The National Council of the French Regulatory Body of Nurses (ONI), at its meeting of the 19th of November, elected Alain Desbouchages to succeed Sylvaine Mazière-Tauran as President. He will serve until the end of his three-year term, that is, until April 19, 2027.

Alain Desbouchages is president of the Haute-Garonne departmental council of ONI. He is the OPPAL (Organisation of Patient Pathways and Beds) project manager at the Toulouse University Hospital.

Holding a State Diploma in Nursing obtained from the Toulouse University Hospital (1997), he quickly complemented his clinical training with a Bachelor's degree in Human and Social Sciences, specializing in Health and Social Sciences, from Paul-Valéry University of Montpellier (2007). He progressed into management by obtaining a Health Executive diploma from the Montpellier University Hospital's Health Executive Training Institute (2007), before further developing his commitment to the quality of working life for healthcare professionals through the Inter-University Diploma "Caring for Caregivers" (Paris Descartes – Toulouse III, 2020). In 2024, he passed the competitive examination for senior paramedical health executive at the Toulouse University Hospital, thus confirming his expertise and his progression towards strategic responsibilities in hospital governance.

President Desbouchages declared immediately after his election:
'I am committed to continuing the work of the National Council of the Order of Nurses, in close collaboration with elected officials and local stakeholders to address the challenges facing the profession and public health. I reaffirm my commitment and determination to unite the profession and foster nursing leadership that drives innovative initiatives'

The interim presidency was assumed by Sarah Bonenfant, First Vice-President, who relied on a fully committed national board to ensure the continuity of its missions, serving the profession and patients.

The National Board of the Order remains composed of: Jérôme Follier, Treasurer; Samira Ahayan, General Secretary; Sarah Bonenfant, First Vice-President; Antony Ricci, Second Vice-President; Cyril Moulin and Mabrouk Nekaa, Deputy Treasurers; and Nelly Nollet and Sylvie Vanhelle, Deputy General Secretaries.

ENC warmly congratulates the new President of ONI and looks forward to closely working with him for promoting nursing reputation, public health, patient safety, and excellence in healthcare across the EU.