COMMISSIONE MEDICO SCIENTIFICA INDIPENDENTE

Urgent information note for Members of the European Parliament and the Italian Parliament

Ahead of the vote on 25 November 2026 on the reform package for the Law on Medicines (New Code relating to medicnal products and EMA Regulation)

Dear Honourable Member,

As the Independent Medical-Scientific Commission (CMSi), thanks to the excellent preparatory work carried out by the barrister Holzeisen (available here), we are writing regarding the final vote on the European Union's pharmaceutical law reform package, scheduled for the plenary session on **25 November 2026**.

Although the reform is presented as a measure to simplify and modernise the legislation, an in-depth analysis of the provisions approved by the Council at first reading (28 September 2026) highlights **extremely serious concerns**.
If approved in its current form, this legislative package would introduce mechanisms for permanent deregulation, **undermining the precautionary principle** and **eroding safeguards for the health of European citizens**.

Set out below are the key points and the institutional and health risks which, in our view, require an immediate rethink and the postponement of the vote, which should be preceded by adequate scrutiny and debate:

1. The new legal definition of 'vaccine' and the circumvention of regulations on gene therapies

What the legislation provides for: Article 5 (paragraphs 31 and 32) of the new Code introduces a legal definition of '**vaccine' that is extended to include the treatment** of infectious diseases, explicitly excluding such products from the category of 'gene therapy medicinal products'.

The risk: Substances based on modified or self-amplifying RNA, whilst acting biologically as gene therapies (through the introduction of nucleic acids and prolonged protein synthesis in recipients' cells), are exempt from the strict quality controls and pharmacovigilance required for gene therapy products. This allows for market authorisation in **record time (up to 100 days in the event of a declared 'emergency'**) and facilitates the imposition of compulsory vaccination requirements based on products **with no guarantees of preventive efficacy against infection and transmission** (that is, lacking the primary requirement which, for example under the Italian Constitution, would allow such a measure to be considered a legal obligation for a medical treatment).

2. Lower safety standards and the absence of long-term studies

What the legislation provides for: It perpetuates the absence of in-depth studies on **genotoxicity**, **carcinogenicity**, **mutagenicity** and **pharmacokinetics** (i.e. distribution within the body's organs and

tissues) for products classified as ‘vaccines’, basing safety on mere theoretical assumptions regarding the components rather than on experimental verification (already evident in the current Summary of Product Characteristics).

The risk: A dangerous scientific exemption is being legalised, foregoing the necessary experimental testing of the pharmacodynamics, pharmacokinetics and genotoxicity of experimental pharmaceutical products and shifting the burden of risk directly onto the public, who are effectively treated as subjects in a permanent clinical trial. One need only consider the modified mRNA-based vaccines, which were initially claimed to remain only at the injection site, only for it to be gradually admitted that, thanks to the nanolipid vehicle, they penetrate virtually all the body’s cells, including those of the brain, heart, ovaries and testicles, the placenta, the foetus and breast milk.
Consider also the fact that the products used in the trials were manufactured using laboratory-synthesised mRNA, whilst that subsequently injected into the public was derived from bacterial production, and that incomplete purification left the vials contaminated with plasmid DNA resulting from the production process and possessing genotoxic potential.

3. Institutionalisation of emergency and conditional authorisations

What the regulation provides for: The Regulation establishes temporary authorisations based on incomplete data in the event of **a ‘public health emergency’ declared by the European Commission** (Articles 31–40) and confirms conditional authorisations based on ‘unmet medical needs’ (Article 20).

The risk: Extraordinary powers are being granted to the European Commission to bypass comprehensive clinical data, thereby normalising an emergency practice which, as demonstrated by the experience of 2020–2023, has seen control (placebo) groups discontinued after less than three months of double-blind trials and the approval of products without a proper assessment of their medium- and long-term safety. The European Commission’s powers would take precedence over any differing assessments by individual Member States, regardless of any scientific evidence presented to the contrary.

4. “Regulatory Sandboxes”: free zones for experimentation

What the legislation provides for: Articles 116–118 of the Regulation introduce “Regulatory Sandboxes” delegating to delegated acts of the European Commission the task of defining the details for testing cutting-edge technologies by way of derogation from ordinary regulations.

The risk: This creates a veritable legal ‘black box’, in which human trials of new technologies can take place outside the safeguards provided by international and national laws on clinical trials, in close and opaque collaboration with public-private consortia involving major pharmaceutical companies (e.g. the *BRIDGE* project).

5. ‘Platform technology’ and the bureaucratisation of controls

What the legislation provides for: Article 5 (paragraphs 34–35) and Article 28 introduce the concept of an EMA-certified ‘master file’ for platform technologies (such as mRNA), allowing standardised data packages to be reused for future medicinal products.

The risk: The assessment of new medicines is reduced to a formal check of compliance with the platform, thereby foregoing an examination of the biological specificity and safety (toxicological, etc.) of each new product placed on the market.

What is being asked of the European Parliament?

1) As a first sign of not wishing to force through the approval of such a far-reaching reform without adequate debate, and without even allowing for the necessary time for reflection, we ask that **the decision** scheduled for 25 November **be postponed to the week of 14–17 December**, as indeed provided for in Rule 67 of the Rules of Procedure of the European Parliament. Indeed, scheduling the vote for 25 November would breach the correct timeframes required for inclusion on the agenda: 3 months (extendable to 4 months under Article 67: in this case, at the request of the competent SAN Committee, the deadline for the second reading could be extended to **28 January 2027**)

2) Consider proposing appropriate amendments, allowing sufficient time for discussion and consultation, to the articles that would give rise to the major concerns outlined above (the **texts of the amendments suggested** by mutual agreement between Mr Holzeisen and the CMSI can be viewed here)

3) Failing that, consider voting against the Directive and the Regulation

4) Subject to the proviso that, should the unamended texts nevertheless be approved, an appeal should be lodged by the dissendent MEPs with the European Court of Justice, but for that it is necessary to take the steps we indicate in the attached documents.

On behalf of the Independent Medical-Scientific Commission (CMSI):

• Dr Alberto Donzelli, expert in Public Health, specialist in Hygiene and Preventive Medicine, former member of the CSS

• Dr Eugenio Serravalle, specialist in Preventive Paediatrics, Childcare and Neonatal Pathology

• Dr Maurizio Federico, virologist, former senior official at the Istituto Superiore di Sanità

• Prof. Marco Cosentino, Full Professor of Pharmacology and Toxicology, PhD

• Dr Marco Alessandria, statistician and university researcher, PhD in Medicine and Experimental Therapy

• Dr Loredana Frasca, specialist in Immunology

• Dr Patrizia Gentilini, specialist in Oncology and Haematology

• Prof. Eduardo Missoni, Lecturer in Global Health at the University of Milan-Bicocca

• Dr Panagis Polykretis, PhD in Structural Biology

• Dr Sandro Sanvenero, specialist in Odontostomatology, former member of the FNOMCeO Central Committee

with the support of:

• Dr Paolo Bellavite, specialist in Clinical and Laboratory Haematology and independent researcher

• Prof. Mariano Bizzarri, Department of Experimental Medicine, Director of the Systems Biology Laboratory at Sapienza University, PhD

• Prof. Giovanni Frajese, Professor of Endocrinology and Metabolic Diseases

• Prof. Stefano Petti, PhD. Ranked in the top 2% of scientists worldwide (Stanford University ranking), Department of Public Health and Infectious Diseases, Sapienza University

• Prof. Laura Teodori, former Head of Research, former Adjunct Professor of Biological Risk.