

Feedback on the EU Pharmaceuticals Strategy Roadmap

15 September, 2020 - EULAR, the European League Against Rheumatism, the organisation representing clinicians, health professionals and patients united in the fight against more than 200 diseases in the field of rheumatic and musculoskeletal conditions, welcomes the initiative of the European Commission to modernise and update the existing regulatory framework for pharmaceutical products in the European Union.

After 20 years since key components of EU pharmaceutical law were adopted, new challenges have arisen and are calling for new responses. Among these are:

- Medicines shortages linked for instance to market mechanisms, commercial strategies, crisis demand or dependence on third country production – with almost all of these factors being emphasised in the COVID-19 crisis;
- Persistent, if not increasing, inequalities in access to medicinal products, with a growing number of products not available to patients and hospitals in some European countries;
- New product categories which combine, for instance, elements of a conventional medicinal product with those of medical devices or digital applications;
- The need for innovation in all parts of Europe's health systems (products, services and organisation of care).

EULAR recognises the key importance of medicinal products in responding to the challenge of chronic conditions. Rheumatic and musculoskeletal conditions (RMDs) play a key role in the sustainability of health and social system, as they are one of the most prevalent disease groups. They furthermore elicit high cost to public budgets through disability and work absence caused by many of them. Research into RMDs is of great benefit for other chronic conditions as well, since many research findings in this field directly benefit research on other major diseases.

EULAR calls on the European Commission, the other European institutions and the Member States to improve access to affordable pharmaceuticals by:

- Modernising the legislative and non-legislative frameworks governing pharmaceuticals at EU level to make them fit for the challenges of the 2020s;
- Enhancing collaboration at EU level between national authorities to guarantee full and timely access to quality products in all parts of Europe;
- Opting for common European approaches wherever possible, including for instance market authorisations for products on the borderlines of conventional pharmaceuticals, such as products combining a pharmaceutical and a medtech component or a digital application;
- Strengthening cooperation between public authorities and representations of patients, clinicians and health professionals for sharing best practices.

EULAR would furthermore like to emphasize a number of issues mentioned in the European Commission's roadmap document¹:

1. A pharmaceutical strategy should always put the patient first. It is therefore important to give aspects such as patient safety or needs-orientation priority over economic considerations such as the viability of business models in the pharmaceutical industry.
2. The development of a new policy on pharmaceuticals must take place in a fully inclusive manner, with patients', doctors' and health professionals' systematic involvement in all phases of decision-making.
3. Innovation is key when it comes to offering optimal treatment options to European citizens. European researchers, especially in non-commercial environments, need strong public support and funding to perform their tasks with success. The independence of non-commercial research needs protection beyond the core scope of pharmaceuticals legislation. The conditions for successful innovation to take place in Europe need to be improved in all stages of the innovation cycle, from basic research to translation of research into new products and applications. Incentives for researchers to stay in Europe should be strengthened.
4. Real-world data are necessary as much as clinical trials; therefore, a more flexible and adapted guidance on GDPR application for health research outside trials should be provided by the regulators.
5. Scientific evidence must be at the center of European and national decision-making related to the accessibility of products (e.g. decisions on market authorisations, Health Technology Assessments and other cost-benefit evaluations, reimbursement). Scientific advice should also be central in defining therapeutic offers to patients in the different national health systems (e.g. decisions on the use of generics and biosimilars or decisions on whether pharmaceuticals or alternative treatment options are preferable).
6. Inequalities, especially between European countries and regions, deserve stronger attention from policy-makers. In too many cases, innovative (or even well-established) products are not available to all citizens. The European Commission should analyse systematically the reasons for such imbalances and propose concrete solutions. In this context, incentives for enhanced collaboration between national health authorities involving all groups of payers should be created, for instance in the area of joint cross-border procurement. At the same time, European Member States should facilitate cooperation on this front.
7. Particular attention should go to sectors which have often been neglected by commercial product development, such as children (pediatric medicine) or rare/orphan diseases. In such areas, European Union action can be of particular added value.

EULAR would like to underline that a pharmaceuticals strategy should not be an isolated initiative but should be part of an integrated approach to EU health and research policy. Regulatory frameworks governing medicinal products must be linked to other frameworks shaping health systems in Europe and protecting or improving the health of European citizens. Non-pharmaceutical treatment options should not be neglected in favour of pharmaceutical products. Priorities identified in the pharmaceutical strategy should be followed by concrete funding opportunities, for instance in programmes such as EU4Health and Horizon Europe.

¹ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceuticals-safe-and-affordable-medicines-new-EU-strategy->