

Dear Member of the European Parliament,

We contact you on behalf of the **Forum on Inequality and Diversity**, an alliance of active citizens' organizations and researchers that counts more than 110 members and project partners.

We are aware that the ENVI committee of the European Parliament is going to vote on reports that will establish a position on the new European Pharmaceutical Legislation.

The Forum is supporting the creation of a European not-for-profit R&D infrastructure on medicines, with its own public mission and delivery capacity. In 2022 the ForumDD launched a **<u>petition</u>** in support of such a proposal, signed by over three thousand and five hundred people. Among them many scientists, physicians and public health experts, including inter alia former Ministries of Health, three Nobel Prizes like Barry Barish, Amartya Sen and Giorgio Parisi.

Hence we have been happy to see that the Parliament, in its plenary session on July 12 voted on the following recommendation in the Report COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI):

"605. Calls on the Commission and the Member States to create a large-scale, missionoriented, public European health R&D infrastructure which operates in the public interest to manufacture medicinal products of health and strategic importance for healthcare, in the absence of existing industrial production, in order to support the EU to overcome market failure, guarantee security of supply and prevent possible shortages of medicines, while contributing to greater preparedness for facing new health threats and emergencies".

We urge ENVI to include in the new pharmaceutical legislation this proposal, that would offer Europe an autonomous capacity, building on the US experience of the National Institutes of Health and beyond it, in order to create a European world leadership in such a crucial domain for public health.

We support the proposal of a European Medicines Facility, as included in Rapporteur's draft concerning the new Regulation on medicinal products as follows:

"Article 40a

Establishment and role of the European Medicines Facility

- 1. The European Medicines Facility ('EMF') is hereby established.
- 2. The main missions and responsibilities of the EMF shall be:

(a) setting out a long-term vision of health priorities in the public interest at a Union level in the form of a strategic roadmap with a number of specific purpose-led R&D projects; in the elaboration of the strategic roadmap, the EMF shall engage in transparent consultation with relevant stakeholders, including scientific communities, Union public health authorities, patient and consumer organisations as well as the relevant agencies established at Union level;

(b) establishing, as a priority, a portfolio of priority pharmaceutical R&D projects addressing at least the following therapeutic areas:

(i) the development of priority antimicrobials provided for in the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high), or PE753.550v02-00 52/109 PR\1288702EN.docx EN taking into account as a priority any equivalent list of priority pathogens adopted at Union level;

(ii) the development of medicinal products for high unmet medical needs as referred to in Article 70(1) of this Regulation and unmet medical needs as referred to in Article 83 of [revised Directive 2001/83/EC], in particular for conditions not sufficiently addressed by the private sector and where the private R&D pipeline is unlikely to deliver on medicinal products and therapies;

(iii) the development of medicinal products for which the private sector charges excessive prices and for which alternatives or generic alternatives are non-existent or unaffordable".

The proposed facility is not alternative to the industry in all fields, but needed to complement private initiative in the public interest. We do hope that the European Parliament will not miss the opportunity of a new approach to face the challenge of unmet medical needs.

We are available for further contacts to deepen how the ENVI Committee would make the history of public health for European citizens by supporting this innovative legislation.

We thank you in advance for your attention and send you our best regards,

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