

To:

European Commission

President, Ursula Von der Leyen

Executive Vice President and Commissioner for Competition, Margrethe Vestager

Vice President for Promoting our European Way of Life, Margaritis Schinas

Commissioner for Internal Market, Thierry Breton

Member States

Prime Ministers

Ministers of Industry

17 November 2021

Open letter: Urgent call to amend the Temporary State Aid Framework to achieve the Recovery and Resiliency Facility objectives

Medicines for Europe, representing manufacturers of generic, biosimilar and value added medicines, and its national associations call on Governments and the European Commission to align European recovery and resilience policies, including the adjustment of the general criteria for the Temporary State Aid Framework, to serve the purpose of the Next Generation EU: short term recovery and long term prosperity.

After the Covid-19 outbreak, the European Union made unprecedented efforts to support Member States through the abovementioned frameworks, particularly to enhance the diversification and resilience of medicines supply chains based on open strategic autonomy.

Unfortunately, the current rules fail to address the core of the problem for our pharmaceutical manufacturing footprint in Europe. Pharmaceutical production/supply chains require long development time, big upfront initial investments, and a secure supply of machinery and raw materials. Hence, the timelines required to complete a project are much longer than what is foreseen under the temporary State Aid framework. Therefore, to ensure that the State Aid framework works effectively in a pro-competitive way, it is essential that all policies are aligned and coherent with structural fund rules. With these adjustments, pharmaceutical companies would actually have the opportunity to take advantage of the financial support and contribute to increasing growth and security in the EU.

With this objective, we call on Ministers of Industry and the European Commission to adjust the Temporary State Aid Framework to concretely support mature and comprehensive investment plans that can significantly impact the development of the R&D and manufacturing footprint of the pharmaceutical industry in the European Union. In particular, the following amendments should be included in the framework:

- A 5-year temporary relief of State Aid rules for those countries that, within a specific time frame, are able to elaborate a comprehensive program of public/private investment in pharmaceutical production

(including active pharmaceutical ingredients and medicine production), with concrete projects, impact numbers and milestones to be achieved.

- Remove the limitation for Covid-19 related products exclusively. This limitation is unrealistic since even manufacturing plants producing Covid-19 related medicines are never dedicated exclusively to those products.
- Extend significantly the timelines for the completion of the projects. The development of certain pharmaceuticals such as biologicals/biosimilars could take several years. Therefore, a timeline of a few months is impossible to meet for pharmaceutical companies.

Our industry is committed to Europe's security and economic growth. We count on the EU to adjust the rules to give pharmaceutical and active pharmaceutical ingredient manufacturers a fair chance to participate in the EU's Recovery and Resilience policy.

Yours sincerely,



European Generic, Biosimilar and Value Added Medicines Association



Spanish Generic and Biosimilar Medicines Association



Portuguese Generic and Biosimilar Medicines Association



Dutch Generic and Biosimilar Medicines Association



French Generic and Biosimilar Medicines Association



Italian Generic and Biosimilar Medicines Association



Danish Generic and Biosimilar Medicines Association



Irish Generic and Biosimilar Medicines Association



Polish Generic and Biosimilar Medicines Association



Romanian Generic and Biosimilar Medicines Association



Czech Generic and Biosimilar Medicines Association



Finnish Generic and Biosimilar Medicines Association



Belgian Generic and Biosimilar Medicines Association



German Generic and Biosimilar Medicines Association



Spanish Fine Chemicals and Active Pharmaceutical Ingredients (APIs) Association



Bulgarian Generic and Biosimilar Medicines Association



Croatian Generic and Biosimilar Medicines Association



Hungarian Generic and Biosimilar Medicines Association



Slovakian Generic and Biosimilar Medicines Association



Pahellenic Union of Pharmaceutical Industries



Lithuanian National Association of Pharmaceutical Manufacturers



Hungarian National Association of Pharmaceutical Manufacturers



Austrian Generic and Biosimilar Medicines Association