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ANNEXES 1 to 3

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN CENTRAL BANK, THE EUROPEAN INVESTMENT BANK AND THE EUROGROUP

Coordinated economic response to the COVID-19 Outbreak

ANNEX 2- NATIONAL MEASURES RELATING TO MEDICAL PRODUCTS AND DEVICES AND OF PERSONAL PROTECTIVE EQUIPMENT

1. CONTEXT AND NEED FOR A COMMON APPROACH

The COVID-19 virus crisis is an unprecedented health emergency. It represents a serious threat at global level, with a strong impact on Europe.

It is the primary responsibility of EU Member States to take the appropriate health measures in the context of the current crisis. It is crucial that the primary objective of protection of health and human life is pursued by all national measures in compliance with EU rules. The internal market rules support Member States in this respect by ensuring efficiency, synergies and European solidarity.

The single market for medical and personal protective equipment is deeply integrated and so are its value chains and distribution networks. Essential products include protective glasses, facemasks, gloves, surgical overalls and gowns[1]. A good organisation of the overall market in the supply of critical products is the only way to prevent scarcity for the people who need them most – public health systems and, in particular, healthcare professionals, field intervention teams and patients.

This requires a European response. All European Heads of State and Government committed to this and in the conclusions of the President of the European Council after the video conference of 10 March 2020, they tasked the European Commission to centralise the analysis of the needs and to come up with initiatives to prevent shortages. It must be ensured that the internal market functions properly and that any unjustified obstacles are avoided, in particular as regards masks and ventilators.

In this spirit, the Commission has already organised a procurement procedure for personal protective equipment for 20 Member States under the Joint Procurement Agreement launched on 28 February 2020 and, subject to availabilities on the market and reports by Member States, may launch further joint procurements.

Second, together with Member States and the European Medicines Agency, the Commission has set up an executive steering group to monitor potential shortages of medicines due to COVID-19. The Commission is also monitoring the situation in the context of the Medical Devices Coordination Group (MDCG) and its subgroups, for example availability and performance of different diagnostic devices and cooperation regarding different national approaches regarding diagnostic tests. Finally, contacts are being maintained also with the main professional organisations of manufacturers and other economic operators, patients, users etc.

Third, the Commission is analysing the needs and the production capacities required in Europe, with the goal to make sure that protective equipment and medicines are available where they are most needed. The Commission is supporting the industry in its efforts to react to this exceptional situation.

[1] All this equipment is relevant not only for protection against COVID-19 but also in several other fields for healthcare professionals in medical treatments (urgencies, chronic diseases, infective, oncological, surgical operations, personal care etc.) as well as for professionals and users of other industrial and handcraft activities (e.g. environmental protection and waste treatment, chemical and biological processes, etc.).

Fourth, measures may be necessary to ensure that, in case of scarcity, medical and personal protective equipment is reserved on the market and channelled to those who need them most. National measures may be necessary to this effect. Any planned national measure restricting access to medical and protective equipment must be communicated to the Commission, which is to inform the other Member States, to permit comments. To enable a coordinated response, the Commission will establish a joint Task Force. The Commission will also continue to provide all needed coordination in order to facilitate the exchange of information, to identify all needed synergies and to contribute to the effective and consistent implementation of national measures. Any national restrictive measure shall not prevent or discourage the participation of companies established on the national territory to the participation of joint procurement procedures at EU level.

Some Member States have already adopted or are preparing national measures which affect the availability of essential products. If not well designed, such measures risk exacerbating rather than alleviating problems, in particular if they focus on limiting cross-border supplies of the products in question rather than directing them to those who most need them both in the national territory and throughout Europe, while avoiding stockpiling, panic purchases and wastage through non-priority or even counter-productive uses within the Member State in question. Such negative effects are likely to be even more acute when restrictions are imposed by Member States having a leading or central market position in the production, import and distribution of personal protective equipment and of medical devices. The recent decisions by Member States to ban or severely restrict exports – in one case extending to of 1324 products, including paracetamols and medical devices - contribute to the risk of shortages in other Member States, thereby putting at risk the health of people living in Europe and should be corrected as a matter of urgency.

The Commission recalls below the relevant legal provisions and the common objectives which all national measures have to pursue, in order not only to be lawful but above all to support all Member States in their efforts to mitigate the risks and impact of the COVID-19 virus crisis.

2. LEGAL FRAMEWORK FOR RESTRICTIVE NATIONAL MEASURES

Article 35 of the TFEU prohibits national restrictions on exports. Member States may take measures justified by “the protection of health and life of humans”, under Article 36. These individual measures need to comply with the principle of proportionality, i.e. they need to be appropriate, necessary and proportionate to achieve such objective, by ensuring an adequate supply to the persons who need the most while preventing any occurrence or aggravation of shortages of goods, considered as essential – such as individual protective equipment, medical devices or medicinal products – throughout the EU. This means in particular that:

1. A simple export ban alone cannot meet the legal requirement of proportionality. Such a measure does not, in itself, ensure that the products will reach the persons who need them most. They would therefore prove unsuitable to reach the objective of protecting the health of people living in Europe. For example, an export ban would not avoid stockpiling or purchasing of goods by persons who have no or limited objective need and would not ensure channelling the essential goods where they are most needed, i.e. infected persons or health institutions and staff.
2. Measures without a clearly identified scope restricted to actual needs, a solid rationale and/or a limited duration may increase the risk of scarcity and therefore are very likely to be disproportionate.

3. Measures regulating the concerned markets with adequate mechanisms to channel essential goods where they are needed the most both within the Member States and to qualified buyers in other Member States, can be a positive contribution to the overall coordinated European approach to help saving lives.
4. Price regulations may be helpful to avoid soaring and abusive prices, provided these rules apply equally to all relevant traders without discrimination on the basis of nationality or establishment, and provided they are accompanied by other suitable measures to channel supplies to those most in need.