

GIRP response to the European Commission call for feedbacks on the Proposal for a directive of the European Parliament and of the Council on the resilience of critical entities

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GIRP welcomes the Proposal for a directive of the European Parliament and of the Council on the resilience of critical entities and the harmonisation purpose it serves to apply a uniform approach in identifying critical entities, while also accounting for specificities at national level, including varying levels of risk exposure and interdependencies between sectors and over borders.

The COVID-19 crisis has demonstrated the need for a strong and coordinated critical infrastructure at national level to ensure rapid and efficient intervention in the event of cross-border health threats.

Full-service healthcare distributors (wholesale distribution authorisation holders, permanently stocking the full range of medicines) are a critical part of the pharmaceutical supply chain and indispensable to ensure safe and reliable access to medicines for citizens, in and out of emergency situations.

Based on lessons learned from early days in the crisis, during emergency periods, it is essential that full-service healthcare distributors can maintain staffing levels and services, including the ability to carry out deliveries to and within restricted areas. The critical infrastructure status confers full-service healthcare distributors the means to ensure the stability needed to maintain the necessary activity levels for continued medicines distribution.

GIRP members are recognised in most EU Member States as part of the critical infrastructure. That said, this is not systemic, and a number of countries have yet to do so, namely Estonia, France, Lithuania, while our members in Latvia and Slovenia are only partly recognised as critical entity.

The proposed legislation will provide for a stable and consistent regulatory framework across EU Member States for the ultimate benefit of citizens. GIRP supports the measures included in the proposal as proportionate and in line with preparedness needs and would like to point out that in many instances, full-service healthcare distributors have already taken security measures to protect their infrastructures and ensure business continuity.

GIRP also welcomes the inclusion of requirements for EU Member States to “ensuring the provision in the internal market of services essential for the maintenance of vital societal functions or economic activities, in particular to identify critical entities and to enable them to meet specific obligations aimed at enhancing their resilience and improving their ability to provide those services in the internal market.”

GIRP for example recognise as essential the below rights for critical entities (full-line wholesale distributors in the performance of their professional duties) to well function in the context of emergency situations:

- Special permits for drivers to access to restricted areas and to travel without limitations
- Staff permitted to travel to their work sites (e.g., distribution centres)
- Special status for premises to have “rapid decontamination” or deep cleans
- Special access to fuel
- Staff access to on-duty schools and creches, where possible
- Staff access to special funding measures, where possible
- Prioritised access to PPE for staff and drivers
- Support from army or police, if necessary, for protection of stocks of medicines and medical supplies.

Lastly, GIRP fully supports article 5 as an adequate and appropriate measure in the context of cross-border health threats **‘Where an entity has been identified as critical by two or more Member States, the Member States shall engage in consultation with each other with a view to reduce the burden on the critical entity’.**

GIRP strongly believes that the combination of this proposal with the proposal for a directive of the European Parliament and of the Council on measures for a high common level of cybersecurity across the union constitutes a strong element to the European preparedness plan needed to respond to the current pandemic and to any potential future cross-border health threat.