Question for written answer E-004159/2021 to the Commission Rule 138 Joanna Kopcińska (ECR)

Subject: European Electronic Health Record exchange format

The European Electronic Health Record exchange format is characterised by the fragmentation of digital standards and limited digital interoperability between Member States' healthcare systems. An impact assessment shows that the electronic exchange format is not sufficiently used, which reduces interoperability between systems and creates barriers in the single market, given that few Member States follow the voluntary guidelines of the e-Health Network. However, this use of the format seems to stem not so much from ill will or reluctance on the part of the Member States, but rather from the existing legislation in force, such as the GDPR.

- 1. How can the European Electronic Health Record exchange format become a tool for exchanging information and providing real assistance to patients, while remaining in line with existing legislation, where the legal interaction of the format with the GDPR, in particular with Articles 9 and 89 on the regulation of data concerning health, still needs to be thoroughly analysed from a legal perspective?
- 2. Besides the public consultation exercises which ended on 26 July, how and with which actors is the Commission in contact with regard to the establishment of an appropriate legal framework covering access to and exchange of data concerning health for the requirements of healthcare provision, policymaking and regulatory activities?