

Albania and North Macedonia are preparing themselves to transpose the EU legislative framework on digital health

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Albania and North Macedonia are eager to transpose the acquis in e-health area, while Albania set up a digital agency and started the digitisation of electronic health records. According to the roadmap set out by the Council, both countries are supposed to open the accession negotiations in June 2019. In this context, a meeting was organized in Brussels on the 29th March, concerning the transposition of the acquis communautaire in the field of digital health, as part of a broader exercise on the European consumer and health protection set of rules.

On this occasion, the Commission presented the current EU legislative framework on digital health, with a particular focus on Directive 2011/24/EU on the application of patients' rights in cross border healthcare and Commission Implementing Decision 2011/890/EU on the eHealth Network, as well as on the Commission Communication on digital transformation of health and care published in April 2018 and the Commission Recommendation on a European Electronic Health Record exchange format published in February 2019.

Albania and North Macedonia cannot be members of the eHealth Network, and consequently are not able to take part in the EU cross-border exchange of health data through the eHealth Digital Service Infrastructure. However, in preparation for becoming EU members, they have the interest to start building electronic health records and make them interoperable through the adoption of the standards, interoperability specifications and profiles suggested by the Commission Recommendation on a European Electronic Health Record exchange format. This would allow their citizens and health systems to take advantage of the cross-border exchange of health data at EU level once the countries will become EU members in the future, be it for accessing patient's data in case of emergency, or enabling citizens to retrieve their medicines abroad, ensuring thus continuity of care across borders. The countries are already developing some reforms in the field of digital health: Albania set up a specialized agency dealing with digital health issues at national level and the digitisation of citizens' medical records is already on-going.

North Macedonia was granted candidate status by the EU in 2005, and Albania in 2014; they joined the other EU candidate countries Montenegro, Serbia and Turkey. In June 2018, the Council set out the path towards opening accession negotiations in June 2019 for both countries. The formal membership negotiations imply a process that involves the adoption of established EU law, preparations to properly apply and enforce it and implementation of judicial, administrative, economic and other reforms necessary for the country to meet the conditions for joining the EU, known as accession criteria. The present explanatory meeting with Albania and North Macedonia was supposed to prepare both countries to the future adoption of the acquis communautaire, specifically on consumer and health protection (Chapter 28 of negotiations).