

(English version)

**Question for written answer E-000950/25  
to the Commission  
Andi Cristea (S&D)  
(5 March 2025)**

**Subject:** Introduction of a European passport for medical radioisotopes and its incorporation into European e-health records

Sustainable prevention, early diagnosis, equal access to treatment and better quality of life are key priorities of the European Union in the fight against cancer. The use of medical radioisotopes is vital in the diagnosis and treatment of many oncological and non-oncological conditions.

Patients who have recently undergone procedures involving radioisotopes may experience problems at security checks, especially at airports. Radiation sensors can pick up the residual traces of radioisotopes in the body, triggering security alarms. These incidents may result in thorough checks being conducted, and in significant delays, additional costs and considerable psychological stress for patients.

1. In these circumstances, does the Commission not consider that a European medical radioisotope passport should be introduced and incorporated into patients' European e-health records, so as to enable them to quickly show they have recently been administered with radioisotopes and to ease security checks while respecting data privacy?
2. What steps can the Commission take to support the implementation of such a mechanism and hence reduce the adverse impact of such situations on patients?

Submitted: 5.3.2025

**Answer given by Mr Várhelyi on behalf of the European Commission  
(10 June 2025)**

Council Directive 2013/59/Euratom <sup>(1)</sup> lays down provisions at EU level for the protection of the public, workers and patients against the dangers of exposure to ionising radiation.

It requires to give information to patients who have undergone nuclear medicine procedures on the risks of ionising radiation and appropriate instructions aiming to restrict doses to persons in contact with them.

However, this directive does not include provisions on a European passport for medical radioisotopes. In 2011, the Heads of the European Radiological Protection Competent Authorities (HERCA) network <sup>(2)</sup> prepared a 'patient release card' <sup>(3)</sup>, to be used on a voluntary basis, as a standard document in case of transboundary movement of nuclear medicine patients across Member States.

Electronic Health Records (EHRs) may include information on procedures involving radioisotopes in line with their practices and legal requirements.

Article 14 of the European Health Data Space (EHDS) Regulation <sup>(4)</sup> defines the priority categories of personal electronic health data in the scope of the European Electronic Health Record Exchange Format (EEHRxF), the rights of natural persons and the certification of EHR systems.

Information on radioisotopes procedures could be exchanged as part of these priority categories, if relevant for healthcare provision, as they are not meant for non-medical uses.

The EEHRxF technical specifications will be defined under Article 15 of the EHDS Regulation and be based on input from experts and stakeholders.

A European medical radioisotope passport is not in the scope of the EHDS, but, under its Article 24, the Commission may support supplementary cross-border digital health services if Member States provide them through MyHealth@EU.

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<sup>(1)</sup> Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, OJ L 13, 17.1.2014, p. 1.

<sup>(2)</sup> HERCA is a voluntary association of 56 radiation protection authorities from 32 European countries including the 27 EU Member States.. More information at <https://www.herca.org>.

<sup>(3)</sup> <https://www.herca.org/download/4681/?tmstv=1743758182>.

<sup>(4)</sup> Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 OJ L, 2025/327 <http://data.europa.eu/eli/reg/2025/327/oj>.