SPARC-Europe response to the roadmap on

Pharmaceuticals strategy – timely patient access to affordable medicines

This consultation is submitted on behalf of – Stakeholder Political Alliance on Radioligand Cancer Therapies (SPARC) - a newly formed multi-stakeholder group comprising healthcare professionals and patients, under the patronage of Members of the European Parliament Tanja Fajon (S&D, Slovenia), and Brando Benifei (S&D, Italy).

We praise the Commission for its intentions to modernise the way EU ensures access to medicines and review healthcare legislation. Such exemplary efforts aim to reconcile innovation with the need to ensure wide access to innovative therapies and medical technologies for unmet needs and this is especially highlighted for rare forms of cancer.

In the area of neuroendocrine cancers, it is difficult to run clinical trials due to the rarity of the condition. The impact of this may be mitigated through international collaborative research efforts such as those led by societies – e.g. the European Neuroendocrine Tumor Society (ENETS) and healthcare networks – e.g. the ERNs, which offer opportunities for collection of real-world data across multiple countries.

Adequate healthcare systems ready to deliver new treatments

Unmet needs are not only linked with the financial implications of treatments but also with the wider challenge of sufficient structural capacity to find and welcome new treatment approaches.

The Commission recognises *"…medical technologies… are transforming the landscape and becoming increasingly integrated as part of overarching therapies. However, the regulatory framework may not be keeping pace with these changes… Health systems may need to be better equipped to ensure deployment and uptake of innovative solutions*." This is particularly accurate for radioligand cancer therapies which deliver radiation targeted to selected types of tumour cells and rely on strong multi-disciplinary cooperation. Robust infrastructure and highly trained specialists are required to ensure the appropriate and safe delivery of these treatments. It would be opportune **to consider legislative and non-legislative initiatives on improving hospital infrastructure (including providing nuclear medicines waste facilities) and training standards across Europe** to bridge the gap between innovation and patients. Hospitals should be able to carry out novel types of treatments. The lack of these considerations could lead to unintended barriers to innovation and an increased national and regional discrepancy in healthcare deployment.

Education

There are a general shortage and training discrepancies in the healthcare workforce which is evident in many Member States and must be addressed. The Commission should **consider particular activities to harmonise education and training standards across Europe for increasingly emerging healthcare sectors such as nuclear medicine specialists and all members of the multidisciplinary cancer team**. We welcome the Commission approach in "*supporting inter-disciplinary cooperation to facilitate need-driven development… particularly in areas of unmet needs"*.

Synergies between the pharmaceutical strategy and other political initiatives

We welcome the Commission's approach in aligning the pharmaceutical strategy with Europe's Beating Cancer Plan. The Commission **should also consider alignment with the Action Plan requested by the Council in its conclusions on non-power nuclear and radiological technologies and applications**. Synergies in the area of cancer treatments (such as radioligand therapies, which use radioisotopes) would be needed to avoid duplication of work.

In conclusion, we welcome the Commission's intentions in improving healthcare for Europeans. We hope the future legislative and non-legislative initiatives would be able to reduce regional inequalities in patient outcomes and improve the readiness of healthcare systems for major healthcare advances.

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