

Annex

EU4Health Programme – COM (2020) 405 - ENVI Committee vote 13102020

Amendments supported by EURORDIS-Rare Diseases Europe

	Recital (27)
European Commission proposal	European Parliament (ENVI vote 13102020)
<p>(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council¹⁶ are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.</p>	<p>(27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council¹⁶ are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. <i>ERNs are a ground-breaking platform that represents a unique opportunity and which, based on the innovative use and sharing of knowledge and health data across borders, aims to improve diagnosis and care for people living with a rare or complex disease. Therefore, the Programme should provide adequate funding to support the coordination and collaborative activities of both existing and future ERNs through grants or other instruments that are fit for purpose. It should upscale current funding to ensure that ERNs fulfil the objectives set out in their mission.</i> As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should <i>also</i> contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider <i>reinforcing ERNs, supporting the creation of new ERNs to cover infectious diseases, complex pregnancies and rare and complex mental health diseases. The reinforcement of ERNs can play a key role in supporting the adoption of a common newly developed screening framework at Union level, starting from disease selection criteria and mechanisms, with the aim of overcoming existing inequalities in terms of screening coverage across Member States. The Programme should also consider the development of excellence networks in the field of communicable and non-communicable diseases, including cancer and paediatric cancer, cardiovascular disease, chronic respiratory disease, diabetes, mental health conditions, neurodegenerative diseases and other major chronic diseases, and in the field of health crises management.</i></p>

	Article 4 – paragraph 1 – point 9
European Commission proposal	European Parliament (ENVI vote 13102020)
(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks;	(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, <i>the identification of health technologies meant to benefit from a Union assessment, and strengthening</i> and scaling up networking through the <i>ERNs, [...], including the Orphanet network, in full synergy with Horizon Europe and its Missions and Partnerships, and aiming to increase the coverage of patients and the response to more diseases and health problems;</i>
	Article 14 – paragraph 6
European Commission proposal	European Parliament (ENVI vote 13102020)
6. Under the Programme, direct grants may be awarded without a call for proposals to European Reference Networks.	6. Under the Programme, direct grants <i>shall</i> be awarded without a call for proposals to <i>European Reference Networks with a simplified financial and technical reporting system.</i> <i>6a (new). Adequate funding shall be ensured to consolidate and expand the ERN model of cross-border healthcare by securing the provision of a range of clinical services through different channels, including online second opinion and specialist advice for patients on treatment and management and virtual “online out-patient” clinics.</i>
	Annex I – point g – point xi
European Commission proposal	European Parliament (ENVI vote 13102020)

(xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and support Member States' actions to coordinate the activities of these networks with the operation of national health systems;

Annex I – point g – point xi

(xi a) Support Member States in the revision of their rare disease national plans to enact the necessary financial and organisational arrangements to integrate effectively the European Reference Networks system into the national health systems by supporting as well as the development and implementation of the set of policies, rules and procedures required to anchor the ERN system to the national level;

(xi b) Support the implementation of the ERNs continuous assessment, monitoring, evaluation and quality improvement system;

(xi c) Earmark funding to create effective and permanent mechanisms to build cross-ERNs collaboration to address the multi-systemic needs of low prevalence and rare diseases and to facilitate diagonal networking between different specialities and disciplines;

(xi d) Support Member States in strengthening their Centres of Expertise for rare diseases to build the national health systems competencies to diagnose, treat and manage these diseases, transnational cooperation on codification, information and knowledge in the field of rare diseases, in particular the Orphanet database;