IMPLEMENTATION ROLLING PLAN

REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

This rolling plan contains a list of key activities that the Commission has carried out or intends to carry out in preparation for the implementation of Regulation 2021/2282 on Health Technology Assessment (the "HTAR"). The plan is subject to regular review in order to provide national authorities and stakeholders with the most updated information.

NOTE: the HTAR entered into force on January 11, 2022 and will be applicable as of January 12, 2025.

Latest update: May 2022

	SUBJECT	LEGAL BASIS HTAR	DESCRIPTION	EXPECTED TIMELINE	STATUS/ NEXT STEPS
1.	Setup of the publicly accessible webpage IT Platform supporting the HTAR	Article 30	Publicly accessible webpage on ec.europa.eu Publication by the Commission of the list of the members of the Coordination Group and their appointed representatives, together with their qualifications and areas of expertise and their declarations of conflict of interest after the finalisation of the joint work	Q2 2022	Ongoing
2.	Step-wise development of a secure intranet for the exchange of information between members of the Coordination Group and its subgroups	Article 30	First release of the IT Platform made available to Coordination Group members	Q3 2022	Ongoing
3.	Setup of the Coordination Group		Designation of member institutions and their representatives by Member States and observer institutions and their representatives by EEA countries	Q2 2022 (by 25 March and 31 March respectively)	**Finalised** (last designation letter received from MS on 16 May)
			First meeting of the Coordination Group	21 June 2022	Planned
4.	Raise awareness of Member States authorities and stakeholders about the HTAR		Conference on the HTAR Dissemination activities	22 June 2022	Planned
5.	Setup of the Stakeholder Network	Article 29	Open call for applications addressed to all eligible stakeholder organisations, in particular patient associations,	Q4 2022	Planned

	SUBJECT	LEGAL BASIS HTAR	DESCRIPTION	EXPECTED TIMELINE	STATUS/ NEXT STEPS
			consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals		
			Evaluation by the Commission of applications and publication of the list of stakeholder organisations included in the Stakeholder Network (including the declarations of those organisations on their membership and sources of funding, and the declarations of interest of representatives of stakeholder organisations)	Q4 2022/ Q1 2023	Planned
6.	Setup of the sub-group for the development of joint methodological and procedural guidance	Articles 3.3; 3.7 (k)	The members of the Coordination Group shall designate their national or regional authorities and bodies as members of subgroups of the Coordination Group. The members of the subgroup shall appoint their representatives, who shall have the appropriate HTA expertise, in the subgroups on an ad hoc or permanent basis and inform the Commission of their appointment and any subsequent changes.	Q4 2022	Planned*
7.	Setup of the sub-group for Joint Scientific Consultations	Articles 3.3; 3.7 (k)	The members of the Coordination Group shall designate their national or regional authorities and bodies as members of subgroups of the Coordination Group. The members of the subgroup shall appoint their representatives, who shall have the appropriate HTA expertise, in the subgroups on an ad hoc or permanent basis and inform the Commission of their appointment and any subsequent changes.	Q1 2024	Planned*
8.	Setup of the sub-group for Joint Clinical assessments	Articles 3.3; 3.7 (k)	The members of the Coordination Group shall designate their national or regional authorities and bodies as members of subgroups of the Coordination Group. The members of the subgroup shall appoint their representatives, who shall have the appropriate HTA expertise, in the subgroups on an ad hoc or permanent basis and inform the Commission of their appointment and any subsequent changes.	Q1 2024	Planned*
9.	Setup of the sub-group on identification of emerging health technologies;	Articles 3.3; 3.7 (k)	The members of the Coordination Group shall designate their national or regional authorities and bodies as members of subgroups of the Coordination Group. The members of the subgroup shall appoint their representatives, who shall	Q1 2024	Planned*

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			have the appropriate HTA expertise, in the subgroups on an ad hoc or permanent basis and inform the Commission of their appointment and any subsequent changes.		
10.	Preparation and adoption of implementing acts**	Articles 15.1 (a), (b), and (c); 20.1 (a), (b) (c) and (d); 25.1(a) and (b); 26.1(a), (b) and (c)	Preparatory work (e.g. analysis of deliverables from EUnetHTA 21 and other relevant sources of information) Drafting and adoption of the implementing acts	Q4 2024	Ongoing
		Article 7.4		Q4 2026	Planned

**Timeline to be reviewed together with the Coordination Group*

*** More information will be provided at a later stage*