

IMPLEMENTATION ROLLING PLAN

2023-2024

REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

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 to provide national authorities and stakeholders with the most updated information.

The HTAR entered into force on January 11, 2022. It will be applicable as of January 12, 2025.

Latest update: February 2024

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) HTAR Article 3				
Eighth meeting of the HTACG	HTAR Article 3		8 March 2024	In preparation
Eighth meeting of the subgroup for methodological and procedural guidance			19 February 2024	In preparation
Eighth meeting of the subgroup for joint Clinical Assessments			20 February 2024	In preparation
Fifth meeting of the subgroup for joint Scientific Consultations			21 February 2024	In preparation
Seventh meeting of the subgroup for the identification of emerging health technologies			22 February 2024	In preparation
Implementing acts				
Adoption	HTAR Articles 15.1(a) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medicinal products	by Q1 2024	In preparation
Adoption	HTAR Article 25.1(a)	Conflict of interest management	by Q2-Q3 2024	In preparation

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Adoption	HTAR Articles 15.1 (a) and (b); 20.1 (c) and (d)	Cooperation by exchange of information with the European Medicines Agency (EMA)	by Q2-Q3 2024	In preparation
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medicinal products	by Q2-Q3 2024	Planned
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medical devices	by Q4 2024	Planned
Adoption	HTAR Articles 15.1 (b) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medical devices	by Q4 2024	Planned
Stakeholder network HTAR Article 29				
Third meeting of the stakeholder network			11 June 2024	Planned
IT Platform HTAR Article 30				
Ninth meeting of the IT users' working group		Working group composed of representatives from Member States, created upon recommendation of the HTACG to ensure the involvement of users in the development of the IT infrastructure	5 March 2024	Planned
First release	HTAR Article 30.1(b)	Beginning of the setup of a secure intranet for the exchange of information between members of the HTACG and its subgroups	2023-2024	Current version went Live on 4.10.2023 and is updated on a monthly basis
Second and Third releases	HTAR Article 30.1(b) HTAR Article 30.1(c) HTAR Article 30.1(d)	Setup of a secure intranet for the exchange of information between members of the Coordination Group and its subgroups, including exchange of information with health technology developers and experts, with the European Medicines Agency and the Medical Device Coordination Group; as well as between members of the	2024	Planned

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
		stakeholder network		
EU support for HTA (capacity building, training, awareness raising, etc.)				
Training of patients contributing to joint health technology activities	EU4Health Work Programme 2022	Capacity building of patients, two projects (HTA4Patients and EUCAPA)	2023-2026	Ongoing More info: HTA4Patients - EUPATIS EUCAPA - home
Fifth HTA information event - Riga	EU4Health Work Programme 2022	Raise awareness of Member States authorities and stakeholders about the HTAR For stakeholders from Latvia, Estonia, Lithuania and Poland	9 April 2024	In preparation More info: From Theory to Practice: Implementing the EU Health Technology Assessment Regulation - European Commission (europa.eu)
Training of national assessors and HTA national authorities	EU4Health Work Programme 2023	Capacity building of HTA national authorities	2024-2025	Call for tenders published on 20.12.2023 and open until 15.03.2024 More info: Funding &

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
				tenders (europa.eu)
SUSTAIN-HTA	Horizon Europe Work Programme (2023-24)	Supporting the uptake of innovative HTA methodology and advancing HTA expertise across EU	2024-2027	Ongoing

ACHIEVEMENTS IN 2022-2023-2024

REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
The Member State Coordination Group on Health Technology Assessment (HTACG) Article 3			
Publication of the up-to-date list of HTACG members	HTAR Article 30.3(a)		Completed Member State Coordination Group on HTA (HTACG) - European Commission (europa.eu)
Meetings of the HTACG			In 2022 held on 21 June and 28 November. In 2023 held on 20 March, 13 June, 25 September and 16 November. In 2024 held on 1 February. More info: Events - European Commission (europa.eu)
Publication of the agenda, flash report and summary minutes of the HTACG meetings	HTAR Article 30.3(c)		Completed
Meetings of the subgroup for methodological and procedural guidance			In 2023 held on 24 April, 22 May, 6 July, 5 October, 9 November and 11 December. In 2024 held on 22 January. More info: Events - European

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
			Commission (europa.eu)
Meetings of the subgroup for joint clinical assessments			In 2023 held on 24 April, 23 May, 7 July, 5 October, 10 November, 12 December. In 2024 held on 23 January. More info: Events - European Commission (europa.eu)
Meetings of the subgroup for joint scientific consultations			In 2023 held on 25 April, 24 May, 6 October, 13 December. More info: Events - European Commission (europa.eu)
Meetings of the subgroup for emerging health technologies			In 2023 held on 25 April, 30 May, 6 October, 24 November, 14 December. In 2024 held on 25 January. More info: Events - European Commission (europa.eu)
IT Platform Article 30			
Setup of the publicly accessible webpage	HTAR Article 30.1(a)	Publicly accessible webpage Regulation on Health Technology Assessment - European Commission (europa.eu)	Completed
Approval of the project for a secure intranet			Completed
Set up of an IT MS users' working group		Working group created upon recommendation of the HTACG to ensure the involvement of Member States users in the	Completed

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
		development of the IT infrastructure	
Meetings of the IT MS users' working group		Working group created on recommendation of the HTACG to ensure the involvement of users in the development of the IT infrastructure	In 2022 held on 22 September, 17 November. In 2023 held on 18 January, 29 March, 25 May, 5 July, 27 September, 29 November.
Stakeholder Network Article 29			
Publication of the list of stakeholder organisations included in the Stakeholder Network	HTAR Article 29.4	Following the call for applications to join the HTA Stakeholder Network on 12 December 2022, the Commission evaluated the applications and published list of selected organisations as set out in Article 30(3)(r).	Completed on 5 May 2023
Meetings of the Stakeholder Network			Held on 14 June and 17 November 2023.
EU support for HTA (capacity building, training, awareness raising, etc.)			
EUnetHTA 21	Third EU Health Programme	Provision of joint HTA work supporting the continuation of EU cooperation on HTA	2021-2023
Raise awareness of Member States authorities and stakeholders about the HTAR		High-level stakeholder conference on the HTAR	Held on 22 June 2022 Conference on the new Regulation on Health Technology Assessment (HTA) - European Commission (europa.eu)
First HTA information event - Stockholm	EU4Health Work Programme 2022	For stakeholders from Sweden, Denmark, Finland, Iceland and Norway.	Held on 11 May 2023 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation (europa.eu)
Second HTA information event -	EU4Health	For stakeholders from Greece, Bulgaria, Cyprus and Romania.	Held on 18 September 2023

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
Athens	Work Programme 2022		From Theory to Practice: Implementing the EU Health Technology Assessment Regulation (europa.eu)
Third HTA information event – Seville	EU4Health Work Programme 2022	For stakeholders from Spain, Italy, Malta and Portugal	Held on 22 November 2023 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation (europa.eu)
Fourth HTA information event – Utrecht	EU4Health Work Programme 2022	For stakeholders from Netherlands, Austria, Belgium, Ireland, Luxembourg	Held on 30 January 2024 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation - European Commission (europa.eu)