

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: **October 2023**

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) HTAR Article 3				
Sixth meeting of the HTACG	HTAR Article 3		16 November 2023	In preparation
Fifth meeting of the subgroup on methodological and procedural guidance			9 November 2023	In preparation
Fifth meeting of the subgroup on Joint Clinical Assessments			10 November 2023	In preparation
Fourth meeting of the subgroup on identification of emerging health technologies			24 November 2023	In preparation
Sixth meeting of the subgroup on methodological and procedural guidance			11 December 2023	In preparation
Sixth meeting of the subgroup on Joint Clinical Assessments			12 December 2023	In preparation
Fourth meeting of the subgroup on Joint Scientific Consultations			13 December 2023	In preparation

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Fifth meeting of the subgroup on identification of emerging health technologies			14 December 2023	In preparation
Implementing acts				
Adoption	HTAR Articles 15.1(a) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medicinal products	by Q4 2023	In preparation
Adoption	HTAR Article 25.1(a)	Conflict of interest management	by Q1 2024	In preparation
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 Q1 2024	In preparation
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medicinal products	by Q2 2024	Planned
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medical devices	by Q3 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				
Second meeting of the stakeholder network			17 November 2023	In preparation
IT Platform HTAR Article 30				
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
Eighth meeting of the IT MS users' working group		Working group created upon recommendation of the HTACG to ensure the involvement of users in the development of the IT infrastructure	19 November 2023	Planned
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,	2024	Planned

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		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 stakeholder network		
EU support for HTA (capacity building, training, awareness raising, etc.)				
Training of patients and clinical experts contributing to joint health technology activities	EU4Health Work Programme 2022	Capacity building of patients and clinical experts, two projects (HTA4Patients and EUCAPA)	2023-2024	In preparation
Training of national assessors and HTA national authorities	EU4Health Work Programme 2023	Capacity building of HTA national authorities	2024	In preparation
Third HTA information event – Seville	EU4Health Work Programme 2022	For stakeholders from Spain, Italy, Malta and Portugal	22 November 2023 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation (europa.eu)	In preparation
Fourth HTA information event – Utrecht	EU4Health Work Programme 2022	For stakeholders from Netherlands, Austria, Belgium, Ireland, Luxembourg	30 January 2024	In preparation
Raise awareness of Member States authorities and stakeholders about the HTAR	EU4Health Work Programme 2022	Dissemination activities in Member States	A further three information events will be planned in 2024.	In preparation

ACHIEVEMENTS IN 2022-2023

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			
<i>Call for nominations - the HTACG</i>	HTAR Article 3.2	Designation of member institutions and their representatives by Member States (as well as observer institutions and their representatives by EEA countries), covering expertise in both medicinal products and medical devices.	Completed in March 2022
Publication of the up-to-date list of HTACG members	HTAR Article 30.3(a)		Completed
First meeting of the HTACG			Held on 21 June 2022
Publication of the agenda, flash report and summary minutes of the HTACG first meeting	HTAR Article 30.3(c)		Completed
Second meeting of the HTACG			Held on 28 November 2022
Publication of the agenda, flash report and summary minutes of the HTACG second meeting	HTAR Article 30.3(c)		Completed
Publication of the rules of procedure of the HTACG	HTAR Article 30.3(c)		Completed
Third meeting of the HTACG			Held on 20 March 2023
Publication of the agenda, flash report and summary minutes of the HTACG third meeting	HTAR Article 30.3(e)		Completed
<i>Call for nominations - subgroup for the development of methodological and procedural guidance; subgroup for Joint Clinical Assessments; subgroup for Joint Scientific Consultations; subgroup for the identification of emerging health</i>	HTAR Articles 3.3; 3.7 (k)	Designation of member institutions and their representatives by Member States (as well as observer institutions and their representatives by EEA countries), covering expertise in both medicinal products and medical devices.	Completed in March 2023

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<i>technologies</i>			
Fourth meeting of the HTACG	HTAR Article 3		Held on 13 June 2023
Publication of the agenda, flash report and summary minutes of the HTACG fourth meeting	HTAR Article 30.3(e)		Completed
Fifth meeting of the HTACG	HTAR Article 3		Held on 25 September 2023
Publication of the agenda and flash report of the HTACG fifth meeting	HTAR Article 30.3(e)		Completed
First meeting of the subgroup on methodological and procedural guidance			Held on 24 April 2023
First meeting of the subgroup on Joint Clinical Assessments			Held on 24 April 2023
First meeting of the subgroup on Joint Scientific Consultations			Held on 25 April 2023
First meeting of the subgroup on identification of emerging health technologies			Held on 25 April 2023
Second meeting of the subgroup on methodological and procedural guidance			Held on 22 May 2023
Second meeting of the subgroup on Joint Clinical Assessments			Held on 23 May 2023
Second meeting of the subgroup on Joint Scientific Consultations			Held on 24 May 2023
Second meeting of the subgroup on identification of emerging health technologies			Held on 30 May 2023
Third meeting of the subgroup on methodological and procedural guidance			Held on 6 July 2023
Third meeting of the subgroup on Joint Clinical Assessments			Held on 7 July 2023
Third meeting of the subgroup on			Held on 6 October 2023

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
Joint Scientific Consultations			
Third meeting of the subgroup on identification of emerging health technologies			Held on 6 October 2023
Fourth meeting of the subgroup on methodological and procedural guidance			Held on 5 October 2023
Fourth meeting of the subgroup on Joint Clinical Assessments			Held on 5 October 2023
IT Platform Article 30			
Setup of the publicly accessible webpage	HTAR Article 30.1(a)	Publicly accessible webpage on ec.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 development of the IT infrastructure	Completed
First meeting 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	Held on 22 September 2022
Second meeting 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	Held on 17 November 2022
Third meeting 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	Held on 18 January 2023
Fourth meeting 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	Held on 29 March 2023
Fifth meeting 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	Held on 25 May 2023
Sixth meeting of the IT MS users' working group		Working group created upon recommendation of the HTACG to ensure the involvement of users in the development of the IT infrastructure	Held on 5 July 2023

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
Seventh meeting of the IT MS users' working group		Working group created upon recommendation of the HTACG to ensure the involvement of users in the development of the IT infrastructure	Held on 27 September 2023
Stakeholder Network Article 29			
Launch of the open call		Launch of open call for applications addressed to all eligible stakeholder organisations	Launched on 12 December 2022 – deadline 17 February 2023
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 the list of successful organisations as set out in Article 30(3)(r).	Completed on 5 May 2023
First meeting of the stakeholder network			Held on 14 June 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
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 - Athens	EU4Health Work Programme 2022	For stakeholders from Greece, Bulgaria, Cyprus and Romania.	Held on 18 September 2023 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation (europa.eu)