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: June 2024

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) and its subgroups HTAR Article 3				
Tenth meeting of the HTACG	HTAR Article 3		19 September 2024	In preparation
Meetings of the subgroup for the development of methodological and procedural guidance			25 June 2024 10 September	In preparation
Meetings of the subgroup for joint clinical assessments			26 June 2024 10 September	In preparation
Meetings of the subgroup for joint scientific consultations			27 June 2024 9 September	In preparation
Meetings of the subgroup for the identification of emerging health technologies			28 June 2024 9 September 2024	In preparation
Implementing acts				
Adoption	HTAR Article 25.1(a)	Conflict of interest management	by 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 Q3 2024	In preparation
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medicinal products	by Q3 2024	In preparation
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
Guidance documents by HTACG				
Guidance on Scoping process	HTAR Article 3(7)(d)	Guidance describing the scientific methodology for the scoping process.	Q4 2024	In preparation
Guidance on validity of clinical studies	HTAR Article 3(7)(d)	Guidance on scientific methodology for assessing the validity of clinical studies.	Q3 2024	In preparation
Guidance on procedural steps and timeframe for joint clinical assessments	HTAR Article 3(7)(e)	Supporting document to the JCA Implementing Act.	Q4 2024	Planned
Guidance on filling in the joint clinical assessment dossier template	HTAR Article 3(7)(d)	Supporting document to the JCA Implementing Act.	Q4 2024	In preparation
Guidance for the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations	HTAR Article 3(7)(g)	Guidance detailing how assessors should be selected and formally appointed for joint work.	Q3/Q4 2024	In preparation
Procedural guidance for joint scientific consultation on medicinal products	HTAR Article 3 (7)(f)	Detailed procedural rules for joint scientific consultation.	Q4 2024	In preparation
Procedural guidance for joint scientific consultation on medical devices	HTAR Article 3 (7)(f)	Detailed procedural rules for joint scientific consultation.	Q4 2024	In preparation
Format and template of requests from health technology developers for	HTAR Article 21(a)	Supporting document to the joint scientific consultation Implementing Act.	Q4 2024	In preparation

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
joint scientific consultation – medicinal products				
Format and template of requests from health technology developers for joint scientific consultation – medical devices	HTAR Article 21(a)	Supporting document to the joint scientific consultation Implementing Act.	Q4 2024	In preparation
Format and template for the dossier submitted by the health technology developer for joint scientific consultation - medicinal products	HTAR Article 21(b)	Supporting document to the joint scientific consultation Implementing Act.	Q4 2024	In preparation
Format and template for the dossier submitted by the health technology developer for joint scientific consultation - medical devices	HTAR Article 21(b)	Supporting document to the joint scientific consultation Implementing Act.	Q4 2024	In preparation
Format and template for the joint scientific consultation outcome document medicinal products and medical devices	HTAR Article 21(c)	Supporting document to the joint scientific consultation Implementing Act.	Q4 2024	In preparation
Guidance for the selection of joint scientific consultations for medicinal products	HTAR Article 3(7), in combination with Article 17(3)	Guidance describing the selection of technologies for joint scientific consultation.	Q4 2024	In preparation
Guidance for the selection of joint scientific consultations for medical devices	HTAR Article 3(7), in combination with Article 17(3)	Guidance describing the selection of technologies for joint scientific consultation.	Q4 2024	In preparation
Stakeholder network HTAR Article 29				
Fourth meeting of the stakeholder network			29 November 2024	Planned
IT Platform HTAR Article 30				

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Second 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 stakeholder network	2024	In preparation
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 - EUPATI EUCAPA - home
Sixth HTA information event - **Budapest**	EU4Health Work Programme 2022	Raise awareness of Member States authorities and stakeholders about the HTAR For stakeholders from Hungary, Croatia, Czechia, Slovakia and Slovenia.	6 September 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 closed. Evaluation of proposals ongoing.

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
				More info: Funding & 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 Project kick-off meeting on 12-13 Feb 2024	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) and its subgroups 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, 8 March, and 10 June. 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 the development of methodological and procedural guidance			In 2023 held on 24 April, 22 May, 6 July, 5 October, 9 November and 11 December.

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			In 2024 held on 22 January, 19 February, 18 March, 18 April, 27 May. More info: Events - European 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, 20 February, 19 March, 18 April, 28 May. 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. In 2024 held on 21 February, 20 March, 19 April, 29 May. More info: Events - European Commission (europa.eu)
Meetings of the subgroup for the identification of emerging health technologies			In 2023 held on 25 April, 30 May, 6 October, 24 November, 14 December. In 2024 held on 25 January, 22 February, 21 March, 19 April, 30 May.

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
			More info: Events - European Commission (europa.eu)
Implementing acts			
Implementing act for joint clinical assessments	HTAR Articles 15.1(a) and (c); 25.1(b); 26.1	Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments	Adopted 23 May 2024
Guidance documents by HTACG			
Methodological guidance on direct and indirect comparisons		Methodological Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons Practical Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons	Adopted by HTA Coordination group on 8 March 2024
Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments		Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments	Adopted by HTA Coordination group on 10 June 2024
Guidance on outcomes for joint clinical assessments		Guidance on outcomes for joint clinical assessments	Adopted by HTA Coordination group on10 June 2024
Scientific specifications of medicinal products subject to joint clinical assessments		Scientific specifications of medicinal products subject to joint clinical assessments	Adopted by HTA Coordination group on 10 June 2024
Stakeholder Network Article 29			

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
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. In 2024 held on 11 June.
IT Platform HTAR 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 development of the IT infrastructure	Completed
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	Current version went Live on 4.10.2023
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. In 2024 meetings held on 7 February, and 5 June.
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

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
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 - **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)
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)
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	Held on 9 April 2024 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation - European Commission (europa.eu)