IMPLEMENTATION ROLLING PLAN

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: 10 January 2025

All actions - year 2025 (will be updated periodically)

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) and its subgroups HTAR Article 3				
Meetings of the HTACG	HTAR Article 3	Member State Coordination Group on HTA (HTACG) - European Commission	In 2025: 28 February, 30 June, 25 September, 23 October, 28 November	Planned
Meetings of the subgroup for the development of methodological and procedural guidance			In 2025: 20 January, 10 March, 12 May, 7 July, 8 September, 6 November	Planned
Meetings of the subgroup for joint clinical assessments			In 2025: 21 January, 18 February, 11 March, 8 April, 12 May, 10 June, 8 July, 9 September, 7 October, 6 November, 2 December	Planned
Meetings of the subgroup for joint scientific consultations			In 2025: 22 January, 19 February, 12 March, 9 April, 13 May, 11 June, 9 July, 10 September, 8 October, 7 November, 3 December	Planned
Meetings of the subgroup for the identification of emerging health technologies			In 2025: 23 January, 13 March, 13 May, 10 July, 11 September, 7 November,	Planned

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Publication of the up-to-date list of HTACG members and subgroups members	HTAR Article 30.3(a)	Medicinal products Medical devices	Regular updates	Completed
Implementing acts				
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medical devices	by Q1 2025	Opinion of HTA Committee received, adoption in preparation
Adoption	HTAR Articles 15.1 (b) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medical devices	by Q2 2025	In preparation
Guidance documents by HTACG				
Procedural guidance for joint scientific consultation on medical devices and *in vitro* diagnostic medical devices	HTAR Article 3 (7)(f)	Detailed procedural rules for joint scientific consultation.	Q1 2025	In preparation
Format and template of requests from health technology developers for joint scientific consultation – medical devices and *in vitro* diagnostic medical devices	HTAR Article 21(a)	Supporting document to the joint scientific consultation Implementing Act.	Q1 2025	In preparation
Format and template for the dossier submitted by the health technology developer for joint scientific consultation - medical devices and *in vitro* diagnostic medical devices	HTAR Article 21(b)	Supporting document to the joint scientific consultation Implementing Act.	Q1 2025	In preparation
Format and template for the joint scientific consultation outcome document medical devices and *in vitro* diagnostic medical devices	HTAR Article 21(c)	Supporting document to the joint scientific consultation Implementing Act.	Q1 2025	In preparation

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Guidance for the selection of joint scientific consultations for medical devices and *in vitro* diagnostic medical devices	HTAR Article 17(3)	Guidance describing the selection of technologies for joint scientific consultation.	Q2 2025	In preparation
Procedural guidance on joint clinical assessments for medical devices and *in vitro* diagnostic medical devices	HTAR Article 3(7)(e)	Detailed procedural steps and timeframe for the conduct of joint clinical assessments	Q3 2025	In preparation
Guidance for the selection of medical devices and *in vitro* diagnostic medical devices for joint clinical assessment	HTAR Article 7(4)	Supporting document for the drafting of the recommendation of the Coordination Group on Health Technology Assessment referred to in Article 7(4) HTAR	Q3 for 2025	In preparation
Guidance on filling in the joint clinical assessment dossier template – medical devices and *in vitro* diagnostic medical devices	HTAR Article 3(7)(d)	Supporting document to the joint clinical assessment Implementing Act.	Q3 2025	In preparation
Guidance on filling in the joint clinical assessment report template – medical devices and *in vitro* diagnostic medical devices	HTAR Article 3(7)(d)	Supporting document to the joint clinical assessment Implementing Act.	Q3 2025	In preparation
Stakeholder network HTAR Article 29				
Meetings of the HTA Stakeholder Network		Implementation of the Regulation on health technology assessment - European Commission	In 2025: 1 July and 24 October	Planned
Working group focusing on the processes for identifying patients and clinicians for the joint work			Q1 2025	Planned
IT Platform HTAR Article 30				
Release 2	HTAR Article 30.1(b) HTAR Article 30.1(c)	Go-live Secure intranet for the exchange of information between members of the Coordination Group and its	7 January 2025	Completed

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
	HTAR Article 30.1(d)	subgroups, including Joint Clinical Assessment for Medicinal Products and Joint Scientific Consultations for Medicinal Products processes.		
Update Release 2		Functionalities updates as well as Medical Devices processes.	Q2-3 2025	Planned
Release 3		Major updates on all joint work processes.	Q4 2025	Planned
EU support for HTA (capacity building, training, awareness raising, etc.)				
Factsheets on joint clinical assessments and joint scientific consultations for medicinal products		The fact sheets aim to inform specialist audience (health technology developers, patients, and health professional organisations) about the JCA and JSC processes.	Q1 2025	In preparation
Q&A Document		The Q&A document provides answers to questions frequently asked by stakeholders related to Regulation (EU) 2021/2282 on health technology assessment.	Q1 2025 first release	In preparation
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
Training of national assessors and HTA national authorities	EU4Health Work Programme 2023	Capacity building of HTA national authorities	2024-2026	Ongoing More info: Funding & tenders (europa.eu)
Single framework contract for joint clinical assessments and joint scientific consultations	EU4Health Work Programme 2024	To support the conduct of joint clinical assessments and joint scientific consultations	2024-2026	Call for tenders closed. Evaluation of proposals ongoing.

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under Regulation (EU) 2021/2282 on health technology assessment				More info: EU Funding & Tenders Portal
Conference on the application of the Regulation (EU) 2021/2282 on Health Technology Assessment	EU4Health Work Programme 2024	A one-day hybrid conference to mark the start of the application phase of the HTA Regulation.	2 July 2025	Planned
Webinar for health technology developers of medicinal products		Chairs and Co-chairs of the Member State Coordination Group on HTA and its subgroups explain the process for joint clinical assessments and joint scientific consultations.	24 January 2025	In preparation The EU HTA Regulation: Webinar for health technology developers of medicinal products - European Commission
Webinar for health technology developers of medical devices		Chairs and Co-chairs of the Member State Coordination Group on HTA and its subgroups explain the process for joint clinical assessments and joint scientific consultations.	Q3 2025	Planned

ACTIONS COMPLETED - Years 2022-2024

Implementation of 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 list of HTACG members and subgroups members	HTAR Article 30.3(a)		Completed (will be updated periodically) 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, 10 June, 19 September and 28 November. More info (agendas, minutes): Events - European Commission (europa.eu)
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. In 2024 held on 22 January, 19 February, 18 March, 18 April, 27 May, 25 June and 10 September, 7 October, 12 November and 9 December. More info (agendas, minutes) : 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, 26 June and 10 September, 8 October, 13 November and 10 December. More info (agendas, minutes): Events - European Commission (europa.eu)

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
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, 27 June and 9 September, 10 October., 14 November and 11 December. More info (agendas, minutes): 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, 28 June, 9 September, 15 November and 12 December. More info (agendas, minutes): Events - European Commission (europa.eu)
Implementing acts			
Implementing act for joint scientific consultations for medicinal products	HTAR Article 20.1	Commission Implementing Regulation (EU) 2024/3169 of 18 December 2024 laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level	Adopted on 18 December 2024
Implementing act on management of conflict of interest	HTAR Article 25.1(a)	Implementing regulation - EU - 2024/2745 - EN - EUR-Lex of 25 October 2024 laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council as regards the management of conflicts of interest in the joint work of the Member	Adopted on 25 October 2024

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		State Coordination Group on Health Technology Assessment and its subgroups	
Implementing act on collaboration with EMA	HTAR Articles 15.1 (a) and (b); 20.1 (c) and (d)	Implementing regulation - EU - 2024/2699 - EN - EUR-Lex of 18 October 2024 laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council, detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and in vitro diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices	Adopted on 18 October 2024
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 on 23 May 2024
Guidance documents by HTACG			
Methodological guidance on direct and indirect comparisons	HTAR Article 3(7)(d)	Methodological Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons	Adopted by HTA Coordination group on 8 March 2024

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		Practical Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons	
Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments	HTAR Article 3(7)(d)	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	HTAR Article 3(7)(d)	Guidance on outcomes for joint clinical assessments	Adopted by HTA Coordination group on 10 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
Guidance on validity of clinical studies	HTAR Article 3(7)(d)	Guidance on the validity of clinical studies for joint clinical assessments - European Commission (europa.eu)	Adopted by HTA Coordination group on 19 September 2024
Guidance on Scoping process	HTAR Article 3(7)(d)	Guidance on the scoping process - European Commission	Adopted by HTA Coordination group on 28 November 2024
Guidance on procedural steps and timeframe for joint clinical assessments	HTAR Article 3(7)(e)	Procedural guidance for JCA medicinal products - European Commission	Adopted by HTA Coordination group on 28 November 2024
Guidance on filling in the joint clinical assessment dossier template	HTAR Article 3(7)(d)	Guidance on filling in the joint clinical assessment (JCA) dossier template – Medicinal products - European Commission	Adopted by HTA Coordination group on 28 November 2024
Guidance for the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations	HTAR Article 3(7)(g)	Guidance on the appointment of assessors and co-assessors for Joint Clinical Assessment (JCA) and Joint Scientific Consultation (JSC) - European Commission	Adopted by HTA Coordination group on 28 November 2024
Procedural guidance for joint scientific consultation on medicinal products	HTAR Article 3 (7)(f)	Procedural Guidance for Joint Scientific Consultations (JSC) on Medicinal Products (MP) - European Commission	Adopted by HTA Coordination group on 28 November 2024
Format and template of requests from health technology developers	HTAR Article 21(a)	Request template	Adopted by HTA Coordination group on 28 November 2024

SUBJECT	LEGAL BASIS	DESCRIPTION	STATUS
for joint scientific consultation – medicinal products			
Format and template for the dossier submitted by the health technology developer for joint scientific consultation - medicinal products	HTAR Article 21(b)	Briefing document template for Joint Scientific Consultation (JSC) for Medicinal Products (MP) - European Commission	Adopted by HTA Coordination group on 28 November 2024
Format and template for the dossier submitted by the health technology developer for parallel joint scientific consultation - medicinal products	HTAR Article 21(b)	Briefing document template for Parallel HTA Coordination Group (HTACG)/European Medicines Agency (EMA) Joint Scientific Consultation (JSC) for Medicinal Products (MP) - European Commission	Adopted by HTA Coordination group on 28 November 2024
Format and template for the joint scientific consultation outcome document medicinal products	HTAR Article 21(c)	Outcome document for Joint Scientific Consultations (JSC) on Medicinal Products (MP) - European Commission	Adopted by HTA Coordination group on 28 November 2024
Guidance for the selection of joint scientific consultations for medicinal products	HTAR Article 3(7), in combination with Article 17(3)	Guidance for the selection of Medicinal Products (MP) for Joint Scientific Consultations (JSC) - European Commission	Adopted by HTA Coordination group on 28 November 2024
Stakeholder Network Article 29			
Publication of the list of stakeholder organisations included in the Stakeholder Network	HTAR Article 29(4) and Article 30(3)(r)	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 organisations as set out in Article 30(3)(r).	Completed on 5 May 2023
Publication of the list of stakeholder organisations included in the Stakeholder Network after the supplementary Call for applications to join HTA Stakeholder Network	HTAR Article 29(4) and Article 30(3)(r)	Following the supplementary call for applications to join the HTA Stakeholder Network on 9 September 2024, the Commission evaluated the applications and published the list of organisations as set out in Article 30(3)(r).	Completed on 29 November 2024 Current members and observers

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Meetings of the HTA Stakeholder Network			Held on 14 June and 17 November 2023. In 2024 held on 11 June and 29 November. Events - European Commission
IT Platform HTAR Article 30			
Setup of the publicly accessible webpage	HTAR Article 30.1(a)	Publicly accessible webpage Health technology assessment - European Commission	Completed (will be updated periodically)
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, 5 June and 9 October.
Secure exchange of information between the health technology developers and the HTAR Secretariat.		Setup a secure space for the exchange of information between the health technology developers and the HTAR Secretariat.	Completed
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

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			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	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)
Sixth HTA information event - **Budapest**	EU4Health Work Programme 2022	For stakeholders from Hungary, Croatia, Czechia, Slovakia and Slovenia	Held on 6 September 2024 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation - European Commission (europa.eu)
Seventh HTA information event - **Paris**	EU4Health Work Programme 2022	For stakeholders from France and Germany.	Held on 5 November 2024 From Theory to Practice: Implementing the EU Health Technology Assessment Regulation - European Commission
Webinar for health technology developers of medicinal products		Chairs and Co-chairs of the Member State Coordination Group on HTA and its subgroups explained the process for joint	Held on 15 November 2024 The EU HTA Regulation: Webinar for health technology developers of medicinal products - European Commission

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		clinical assessments and joint scientific consultations.	