eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21

**Guidance Document**

# TOPIC IDENTIFICATION, SELECTION AND PRIORITISATION (TISP) FOR JOINT CLINICAL ASSESSMENT (JCA) OF HIGH-RISK MEDICAL DEVICES: PROCESS AND TEMPLATES

## D4.7.3 EUDAMED data reporting template & D4.7.4 Guidance for EUDAMED-based TISP process

**Version V2.0, 27/07/2023**

Template version 1.0, September 2021

## DOCUMENT HISTORY AND CONTRIBUTORS

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| V0.4 | 17/08/2022 | Final draft after public consultation |
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| V2.0 | 27/07/2023 | Final deliverable after EC review, validated by CSCQ and CEB |

### Disclaimer



This guidance document was first endorsed by the CEB in September 2022, at the end of the first year of the EUnetHTA 21 service contract. The section on the EUnetHTA 21 TISP process was preparatory work for the two JCA conducted during the second year of the EUnetHTA 21 service contract. Therefore, in the revision of this guidance document (V2.0) in the second year of the service contract, only the section about the TISP process for the period under the HTAR was updated.

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| **CEB** | |

The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group actively write the deliverable, the entire EUnetHTA 21 consortium is involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) reviewed and discussed several drafts of the deliverable before validation. The Consortium Executive Board (CEB) endorsed the final deliverable before publication.

### External Stakeholder Contribution

The draft deliverable was reviewed by associated HTAb and was open for public consultation between 06.06.2022 and 05.07.2022.

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### Copyright

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| | |
|---|---|
| ACE | Agency for Care Effectiveness (Singapore) |
| AGENAS | Agenzia Nazionale per i Servizi Sanitari Regionali |
| AHRQ | Agency for Healthcare Research and Quality |
| AI | Artificial intelligence |
| ASERNIP-S | Australian Safety and Efficacy Register of New Interventional Procedures -Surgical |
| CADTH | Canadian Agency for Drugs and Technologies in Health |
| CE | Conformité européenne/European conformity |
| CEB | Consortium executive board |
| CECP | Clinical evaluation consultation procedure |
| CER | Clinical evaluation report |
| CONITEC | National Commission for the Incorporation of Technologies (Brazil) |
| CS | Common specifications as defined in the MDR |
| CSCQ | Committee for scientific consistency and quality |
| EMA | European Medicines Agency |
| EUDAMED | European database on medical devices |
| EUnetHTA | European Network for Health Technology Assessment |
| FDA | Food and Drug Administration (USA) |
| FSCA | Field safety corrective action |
| FSN | Field safety notice |
| HaDEA | European Health and Digital Executive Agency |
| HOG | Hands-on group |
| HS | Horizon scanning |
| HSS | Horizon scanning system |
| HTA | Health technology assessment |
| HTAb | HTA bodies |
| HTAR | Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment |
| HTD | Health technology developer |
| ICET | Israeli Center for Emerging Technologies |
| IHSI | International Horizon Scanning Initiative |
| IVD | In vitro diagnostic medical device |
| IVDR | In vitro diagnostic medical devices regulation |
| JA3 | Joint Action 3 of EUnetHTA 2016–2021 |
| JCA | Joint clinical assessment |
| MaHTAS | Malaysian Health Technology Assessment Section |
| MD | Medical device |
| MDCG | Medical Device Coordination Group |
| MDR | Medical device regulation |
| MIC | MedTech and In Vitro Diagnostics Cooperative (UK) |
| MS | Member state |
| MUMM | Managed Uptake of Medical Methods (Finland) |

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|---|---|
| NB | Notified body |
| NICE | National Institute for Health and Care Excellence (UK) |
| NIHR IO | National Institute for Health Research Innovation Observatory (UK) |
| NIPH | National Institute of Public Health (Norway) |
| PCORI | Patient-Centered Outcomes Research Institute |
| PECP | Performance evaluation consultation procedure |
| PMA | Pre-market approval |
| RedETS | Spanish Network of Agencies for Health Technology Assessment |
| SALAR | Swedish Association of Local Authorities and Regions |
| SSCP | Summary of safety and clinical performance |
| SRN | Single registration number |
| TISP | Topic identification, selection and prioritisation |
| TLV | The Dental and Pharmaceutical Benefits Agency (Sweden) |
| UDI-DI | Unique device identification device identifier |
| ZIN | Zorginstituut Nederland |

# 1. GENERAL CONSIDERATIONS AND PURPOSE

On 17 September 2021, the European Health and Digital Executive Agency (HaDEA) signed the service contract for the provision of joint health technology assessment (HTA) work supporting the continuation of EU cooperation on HTA with the aim to support EU cooperation on HTA beyond May 2021 when the EU co-funded European Network for Health Technology Assessment (EUnetHTA) Joint Action 3 (JA3) ended.

The EUnetHTA 21 consortium consists of 13 European national HTA agencies and its work will build on the achievements and lessons learned from the EUnetHTA Joint Actions and focus on supporting a future EU HTA system under Regulation (EU) 2021/2282 on health technology assessment (HTAR) and amending Directive 2011/24/EU.

## *1.1. General considerations and uncertainties*

According to the HTAR, only certain high-risk medical devices (MDs) and in vitro diagnostic medical devices (IVDs) are candidates for joint clinical assessments (JCA), i.e., *medical devices classified as class IIb and III* (Article 51 of Regulation (EU) 2017/745 on medical devices (MDR)) *for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure* (Article 54 of MDR) *and in vitro diagnostic medical devices classified as class D* (Article 47 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)) *for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6)* of the IVDR. The HTAR also establishes the basis for JCA of MDs or IVDs after obtaining a Conformité européenne (CE) marking (Recital 37), as the required evidence may only become available after the MD or the IVD has been placed on the market, and to allow for their selection for JCA at an appropriate time.

In the absence of a central database of CE-marked products or products that have entered the regulatory approval pathway, no valid system for topic identification, selection and prioritisation (TISP) could be established in EUnetHTA JA3, which poses a major challenge for the identification of assessment topics that are timely and relevant for the majority of EUnetHTA partners and therefore affects national uptake. The TISP working group in JA3 prepared a set of recommendations for TISP

and it was noted that cooperation with regulatory authorities on MDs and IVDs needs to be further explored[1]. In particular, the planned European database on medical devices (EUDAMED) should provide a means for structured data sharing and hence an opportunity to obtain information about the products that have entered the regulatory pathway or those that already bear a CE marking.

The creation of EUDAMED is one of the key aspects of the MDR and the IVDR. The system is multipurpose. It is a collaborative and interoperable platform, which will function as a registration system, a collaboration platform, and a dissemination system (partially open to the public). EUDAMED aims to enhance overall transparency through better access to information for the public and healthcare professionals, and to enhance coordination between member states (MSs) of the European Union[2]. EUDAMED will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance, and market surveillance. The current version of EUDAMED (release v2.8) is not fully functional; only registration for economic operators[3] and devices, the notified bodies and the certificate modules are operational as of July 2023**.** The final release has been repeatedly delayed. As a consequence of this delay, the registration obligations imposed by the MDR (Articles 123(3) and 122 4th indent) and by the IVDR (Articles 113 (3) and 112 (b)) have been postponed to a later date. Actors (health technology developers (HTDs), distributors, importers, and any other relevant economic operators) will therefore be obliged to register in EUDAMED by the end of 2024. Official announcement of the fully functional EUDAMED is expected once the database is completed with all remaining modules (clinical investigation/performance studies, vigilance and post-market surveillance, and market surveillance). MDs and IVDs (and their clinical data) need to be registered 24 months after EUDAMED is fully functional.

Although this deliverable was termed a EUDAMED-based TISP process in the service contract, it is unclear to what extent the TISP process will rely on information from this database. For the identification

[1] EUnetHTA "Recommendations for Horizon Scanning, Topic Identification, Selection and Prioritisation for European Cooperation on Health Technology Assessment", https://www.eunethta.eu/wp-content/uploads/2020/04/200305-EUnetHTA-WP4-Deliverable-4.10-TISP-recommendations-final-version-1.pdf?x16454

[2] https://health.ec.europa.eu/medical-devices-eudamed/overview_en

[3] Article 2(35) of the MDR defines 'economic operator' as a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) of the MDR.

step under the HTAR, it remains unclear which modules will contain the relevant information and whether and when the Coordination Group subgroup responsible for the identification of emerging health technologies will have access to this information. Hence, a more detailed process description cannot be given yet. Nevertheless, it must be noted that the relevant and requested data will be available in EUDAMED at one point.

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| In light of the delay in registration obligation and absence of a fully functioning database as of July 2023, version V2.0 of this guidance should be reviewed at a later date as some adaptations might be needed. EUnetHTA 21 recommends that the subgroup for the identification of emerging health technologies has early access to EUDAMED before some pieces of information become publicly available and access to certain modules that are not accessible to the public. |

### *1.2. Purpose and scope*

The objectives of this deliverable are twofold and separated along two time horizons:

(a) **For the period of EUnetHTA 21**: to explore sources of topic identification and provide a process description for EUnetHTA 21 (including acquisition activities, i.e., a proactive approach for identifying topics for JCA in EUnetHTA 21). An additional objective is to pilot the topic selection and prioritisation process to be applied under the HTAR.

(b) **For the period** after EUnetHTA 21, **under the HTAR**: to provide a process description for topic identification, selection, and prioritisation, highlighting the uncertain elements and providing recommendations. Based on the pilot and its evaluation, amendments to the process for the period under the HTAR may be proposed. For the reasons explained in Section 1.1, the process description for screening or for other potential uses of EUDAMED to be performed under the HTAR will not be extensively described.

# 2. PROCESS

## *2.1. TISP process in EUnetHTA 21*

### *2.1.1. Topic identification for JCA*

#### *2.1.1.1. Sources for identification*

EUDAMED cannot be used for identification of potential topics for EUnetHTA 21 for the reasons already mentioned. To explore sources of information for identification of potential topics for JCA, the hands-on group (HOG) for this deliverable looked at primary and secondary sources and drew conclusions regarding the usefulness of the information and the feasibility of searching the sources. Primary sources were considered to be trial registries (e.g., clinicaltrials.gov), company websites, various news sites, clinical associations, patient organisations and the approval databases of regulatory bodies (e.g., the US Food and Drug Administration (FDA)). Secondary sources were considered to be horizon scanning (HS) services/initiatives, both in member organisations of the EUnetHTA21 consortium and outside of the EUnetHTA 21 consortium.

The HOG concluded that the primary sources that can be taken into account for EUnetHTA 21 JCA topic identification are the FDA pre-market approval database, the FDA breakthrough devices programme and national scientific advice programs. The secondary sources that can be considered are the National Institute for Health and Care Excellence (NICE) Medtech innovation briefings and the Canadian Agency for Drugs and Technologies in Health (CADTH) HSs. The list of sources and the HOG recommendations on their usefulness and the feasibility of searching them are provided in Appendix 1 Table A 1.

However, in the context of EUnetHTA 21, topic identification will largely depend on the acquisition process, which is a proactive approach developed by EUnetHTA to identify topics for JCA by contacting HTDs and promoting voluntary submission for a JCA (as submission of a dossier by HTDs will only become obligatory under the HTAR). As a first step in the initiation of acquisition activities, a meeting between the EUnetHTA 21 Secretariat, the JCA production HOG and interested HTDs took place at the end of March 2022 to explore potential interest from HTDs, which could result in submission of Letters of Intent. Since then, several other meetings were organised by the EUnetHTA 21 Secretariat: bilateral

meetings with industry representatives and stakeholder events with a broader range of stakeholders including HTDs.

#### *2.1.1.2. Data reporting template*

A structured data reporting template should be used for systematic data collection in the identification step. This template is a separate deliverable in EUnetHTA 21 (D7.4.3) and can be found in Appendix 2 Table A 3. Further information on the template can be found in Section 2.2.1.2 of this guidance.

#### *2.1.1.3. Pilot of the identification step*

The template and the process will be piloted in EUnetHTA 21. For EUnetHTA 21, the scope was limited to high-risk MDs (class IIb and class III). Class D IVD products were excluded from the scope.

A preliminary list for testing the identification sources has already been developed and will be updated and complemented by the topics submitted by the HTDs. The planned time period for the identification pilot is May 2022–August 2022. Identification from other sources should conclude in June 2022. The acquisition process will last until the end of August 2022.

### *2.1.2. Topic selection for JCA*

#### *2.1.2.1. Selection criteria*

In EUnetHTA 21 the topic selection pilot mimics the selection process that is described in the HTAR, and therefore the criteria described in Section 2.2.2.2 of this guidance shall be applied to the selection of topics for JCA. However, as EUnetHTA 21 might need to rely solely on the willingness of HTDs to submit a dossier, it might not be possible to apply the predefined selection criteria of HTAR Article 7(4) if the number and scope of the Letters of Intent submitted are insufficient.

#### *2.1.2.2. Topic selection template*

The template is a separate deliverable in EUnetHTA 21 (D7.4.3) and can be found in Appendix 2 Table A 4. Further information on the template can be found in Section 2.2.2.3 of this guidance.

#### *2.1.2.3. Pilot of the selection step*

If the number and scope of the Letters of Intent submitted are insufficient, the list of products identified via the other sources (listed in Appendix 1 Table A 1) will remain on the list for the pilot selection, even if the HTDs of the products identified do not express a willingness to submit a dossier. Therefore, some of the products selected during this pilot phase might not be assessed in EUnetHTA 21.

The Committee for Scientific Consistency and Quality (CSCQ) JCA, as well as EUnetHTA 21 associated HTA bodies (HTAb; EU/EEA HTAb that will be impacted by the future HTAR but who are not officially part of the EUnetHTA 21 consortium), will be given the data set in the data reporting template and asked to select on the basis of the criteria as described in Section 2.2.2.2. The selection and rationale for selection will be documented in the selection template and shared with the CSCQ JCA and the associated HTAb. The selection should conclude by the end of September 2022. For the detailed selection steps, please refer to Section 2.2.2.4 of this guidance.

### *2.1.3. Topic prioritisation for JCA*

#### *2.1.3.1. Prioritisation criteria*

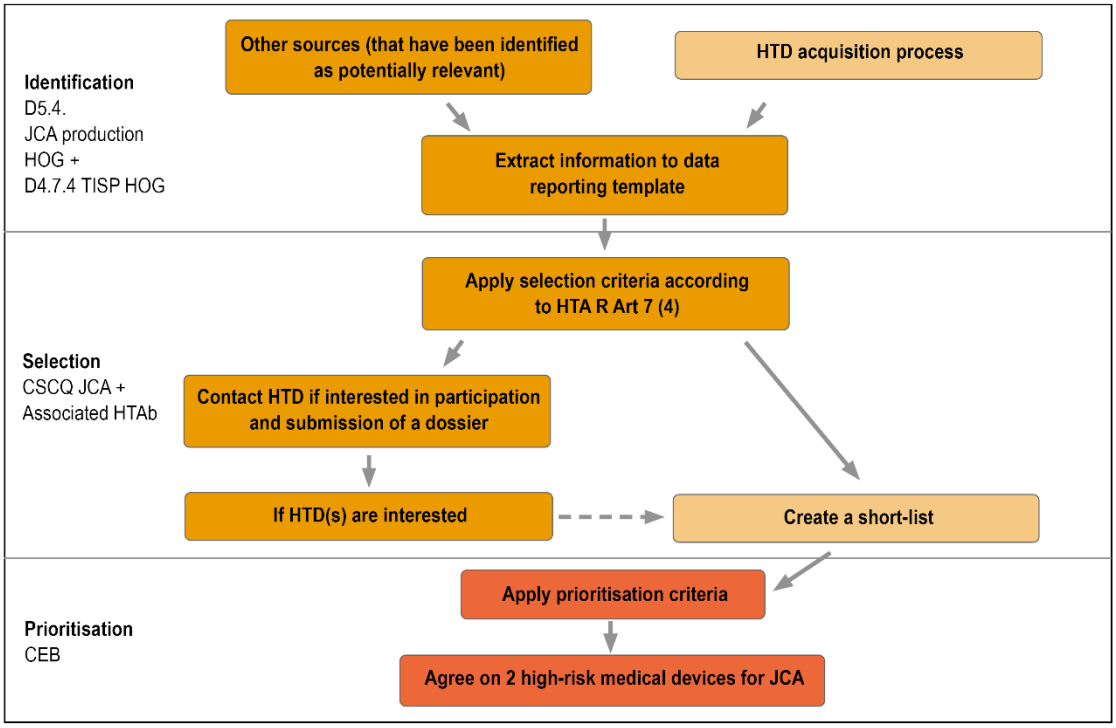
If more than two topics remain after selection in EUnetHTA 21, the prioritisation criteria for potential interest of EUnetHTA consortium members and the resources available will be considered.

#### *2.1.3.2. Pilot of the prioritisation step*

Prioritisation will be carried out, if necessary, at the beginning of October 2022. For a detailed description of the prioritisation step, please refer to Section 2.2.3.2 of this guidance.

Figure 1 shows the proposed process flow for EUnetHTA 21.

*Figure 1 Process flow for EUnetHTA 21*




**Abbreviations**: Art=Article; CEB=consortium executive board; CSCQ=Committee for Scientific Consistency and Quality; EC=European Commission; HOG=hands-on group; HTAb=health technology assessment body; HTAR=regulation on health technology assessment; HTD=health technology developer; JCA=joint clinical assessment; TISP=topic identification, selection and prioritisation.

## *2.2. TISP process for the period under the HTAR*

### *2.2.1. Topic identification for JCA*

Article 22(1) of the HTAR specifies that *the Coordination Group shall ensure the preparation of reports on emerging health technologies expected to have a major impact on patients, public health or healthcare systems. Those reports shall in particular address the estimated clinical impact and the potential organisational and financial consequences of emerging health technologies for national healthcare systems.*

#### *2.2.1.1. Sources for identification*

Two articles of the HTAR indicate the relevant sources for identification. Article 22(2) states that *the preparation of the reports referred to in Article 22(1) shall be based on:*

1. ***existing scientific reports or initiatives*** *on emerging health technologies and*
2. *information from relevant sources including:*

*(a)* ***clinical study registers*** *and* ***scientific reports****;*

(b) [not relevant for MDs and IVDs]

*(c) the* ***Medical Device Coordination Group*** (MDCG);

*(d)* ***health technology developers*** (HTD) *on the health technologies they are developing;*

*(e) members of the* ***stakeholder network*** *referred to in Article 29* of the HTAR.

Article 22(3) adds that *the Coordination Group may consult* ***stakeholder organisations*** *which are not members of the stakeholder network referred to in Article 29 and* ***other relevant experts****, as appropriate*.

The sources mentioned in Article 22(2) and 22(3) are detailed herein:

**1. Existing scientific reports or initiatives**:

If such reports or outputs of such initiatives are available, they could form the basis for the identification. Recital 42 of the HTAR also states that *in order to ensure the efficient use of available resources, it is appropriate to provide for a "horizon scanning" exercise, to allow the early identification of emerging health technologies that are likely to have a major impact on patients, public health and healthcare systems, as well as to inform research. Such horizon scanning could be used to support the Coordination Group in planning its work, in particular in relation to joint clinical assessments and joint scientific consultations, and could also provide information for long term planning purposes at both Union and national levels*.

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| EunetHTA 21 recommends that the HS process makes use of already existing HS initiatives, if they are deemed appropriate by the CG for its topic identification activity, in order to realise efficiency gains. |

Section 2.1 of this document (with a list provided in Appendix 1 Table A 1) and a piece of work by the International Horizon Scanning Initiative (IHSI) Medical Devices Working Group[4] explored the landscape of HS systems. Worldwide, 16 initiatives could be identified, of which 11 HS systems for medical devices are currently ongoing and active, three HS services closed in recent years and two initiatives are currently inactive but have not been closed. The time horizon mentioned most often is 3 years up to a few months before market entry and commercialisation, depending on the stakeholders to be informed. More detailed information can be found in Appendix 1 Table A 2.

**2.** The **additional sources** listed in the HTAR complement the information from the scientific reports or initiatives.

(a) In connection with **clinical study registers**, although not specifically stated in the HTAR, the clinical investigations referred to in MDR Article 62 (clinical investigations conducted to demonstrate conformity of devices) could be considered. As set out in Article 73 of the MDR, an electronic system in EUDAMED for registration of such clinical investigations shall be set up. This will be a single-entry point for the registration, which will allow information sharing among the MSs and between MSs and

[4] IHSI Medical Devices Working Group. *Draft Deliverable.* Unpublished.

the European Commission. Regular screening of clinical investigations for high-risk MDs (class IIb and III MDs that would fall under Article 54 of the MDR) and class D IVDs could allow anticipation of which products will reach the regulatory approval phase and approximately when.

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| EUnetHTA 21 recommends that information about high-risk MDs that would fall under Article 54 of the MDR shall be made available to the subgroup responsible for the identification of emerging health technologies, especially the type of information referred to in Article 73(1) points (c), (d) and (e) of the MDR. |

(c) -(e) Regular or ad hoc exchanges with the **MDCG**[5], **HTDs,** members of the **stakeholder network** and **other relevant experts** shall also be initiated to expand the sources of information for identification.

In addition to Articles 22(2) and 22(3) about the identification sources, Article 15(1) point (b) establishes the basis for cooperation, in particular by exchange of information, with the **notified bodies and the European Medicines Agency (EMA) as Secretariat of the expert panels** on the preparation of JCAs of MDs and IVDs. The candidates for JCA are only those high-risk MDs[6] and IVDs[7] for which the expert panels provide a scientific opinion/view within the framework of the clinical evaluation consultation procedure (CECP)/ the performance evaluation consultation procedure (PECP)[8]. Therefore, the exchange of information would ensure that the MDs and IVDs identified as potential candidates for JCA comply with Article 7(1) points (c)[7] and (d)[8] of the HTAR. If the expert panels decide not to provide an opinion, the MD or IVD cannot be selected for JCA under the HTAR. Expert panel opinions, once they

[5] According to Article 55(3) of the MDR, *the MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device*.

[6] *Medical devices classified as class IIb or III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation, and subject to selection pursuant to* Article 7(4) of the HTAR.

[7] *In vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation, and subject to selection pursuant to* Article 7(4) of the HTAR.

[8] According to Annex IX, Chapter II (5.1) of the MDR, *the expert panel shall decide, under the supervision of the Commission*, whether to provide a scientific opinion on the clinical evaluation assessment report of the notified body based on the clinical evidence provided by the manufacturer, *on the basis of all of the following criteria: (i) the novelty of the device or of the related clinical procedure involved, and the possible major clinical or health impact thereof; (ii) a significantly adverse change in the benefit-risk profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure of the device; (iii) a significantly increased rate of serious incidents reported in accordance with Article 87 in respect of a specific category or group of devices.*

are finalised, are published on the official website of the European Commission, however, in the future, these will be integrated into EUDAMED.

EUnetHTA 21 recommends that the sources listed in Articles 22(2) and 22(3) shall be complemented by cooperation with **notified bodies and the EMA as Secretariat of the expert panels** via the procedural rules referred to in Article 15 (1) to ensure timely access to information.

#### *2.2.1.2. Data reporting template*

In the identification step a structured data reporting template should be used for systematic data collection, as well as a topic selection template, of which certain parts should be completed to prepare for the selection step. The completion of these templates could be based on existing documents from the HTD and/or notified bodies:

(a) Summary of safety and clinical performance (SSCP): MDR Article 32(1) states that for implantable devices and for class III devices[9], other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. The SSCP shall be validated by a notified body and made available to the public via EUDAMED after the CE marking is granted (until the database is up and running, the SSCP can be requested from the HTDs). The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the MD.

(b) Clinical evaluation report (CER): The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report. The notified body assesses the evidence submitted by the HTD in the CER.

[9] The SSCP is only available for implantable devices and for class III devices (see Art. 32 MDR). Thus, not all devices that undergo the CECP will have a SSCP available.

EUnetHTA 21 proposes a data reporting template that is based on the documentation which will be accessible for the subgroup responsible for the identification of emerging health technologies at the time of preparation of the identification list. EUnetHTA 21 recommends that data is extracted into the data reporting template from the SSCP. Additional data required to complete the data reporting template shall be requested from stakeholders (HTD, clinical experts or patient organisations) or found from other sources. In terms of the topic selection template, if the SSCP is not descriptive enough (i.e. the selection template cannot be filled in based on the information therein) or not available, EUnetHTA 21 suggests using the CER as a source.

The data reporting template is a separate deliverable in EUnetHTA 21 (D7.4.3) and can be found in Appendix 2 Table A 3. The topic selection template can be found in Appendix 2 Table A 4.

In terms of the cooperation with notified bodies and expert panels, EUnetHTA 21 recommends that the subgroup responsible for the identification obtain access to the SSCP (or parts of the SSCP) and alternatively to the CER when the expert panel decides whether to provide a scientific opinion.

#### *2.2.1.3. Identification process*

The subgroup responsible for the identification of emerging health technologies identifies potential topics for JCA from scientific reports and initiatives (existing HS initiatives, if appropriate). The subgroup may complement the list by screening the clinical investigations register (in EUDAMED).

To allow for a timely identification, the subgroup responsible for the identification of emerging health technologies would need to be notified at the same time when the expert panel Secretariat informs the European Commission about the expert panel's decision through EUDAMED or when the notified body is informed that the expert panel decides not to provide a scientific opinion.

To prepare for the selection, besides the data reporting template, the white fields in the topic selection template (Appendix 2 Table A 4) shall also be filled in by the subgroup responsible for the identification, together with the JCA subgroup. EUnetHTA 21 recommends that the Secretariat of the expert panel provided by the EMA notifies the subgroup responsible for the identification of emerging health technologies on their decision to provide a scientific opinion at the same time as they inform the European Commission and the notified body.

EUnetHTA 21 recommends continuous data collection with a quarterly cut-off point when the subgroup compiles the list of MDs and IVDs identified.

### *2.2.2. Topic selection for JCA*

According to HTAR Article 7(4), *after 12 January 2025, the European Commission, after seeking a recommendation from the Coordination Group, shall adopt a decision, by means of an implementing act and at least every two years, selecting the medical devices and in vitro diagnostic medical devices* referred to in Article 7(1) points (c)[8] and (d)[9], *for joint clinical assessment based on one or more of the following criteria:*

*(a) unmet medical needs;*

*(b) first in class;*

*(c) potential impact on patients, public health or healthcare systems;*

*(d) incorporation of software using artificial intelligence, machine learning technologies or algorithms;*

*(e) significant cross-border dimension;*

*(f) major Union-wide added value.*

#### *2.2.2.1. Implementing act*

The wording in Article 7(4) of the HTAR in terms of the implementing act leaves some room for different interpretations. Two interpretations were identified by the HOG, which are presented here with their advantages and disadvantages.

1. The implementing act lists the selected MDs and IVDs by name (and relevant HTD).
2. The implementing act lists the MDs and IVDs by the type of device (category or group of devices) and detailed selection criteria that will be applied when selecting the specific MDs and IVDs.

***Interpretation 1*** has the advantage that it ensures predictability for both MSs and HTDs as they will know exactly which products will be assessed and can prepare for a submission. The disadvantage is that it is less flexible because an implementing act is a legal tool, leaving no margin for modification. In addition, as the procedure for an implementing act can take as long as 6–8 months, this means that once the product is identified, selected, and prioritised, starting its assessment would be delayed for this 6–8-month period. This might pose a challenge for patient access in some MSs. There is also a risk of parallel submissions at the national and European levels in order to avoid delaying patient access in some MSs and this could result in duplication of work for both the HTD and HTAb.

***Interpretation 2*** allows for more flexibility as the implementing act would only specify the type of MD, a narrower category under the class IIb and class III devices and class D IVD, without naming any specific products and HTDs. In this way the option is kept open when a product appears that was not identified earlier. The time lag between selection and enforcement of the implementing act (i.e., the 6–8 months) will not pose the difficulties identified for Interpretation 1. This provides flexibility in shaping the annual work programme. An annex document or an independent document from the Coordination Group with a list of the foreseen MDs to assess (specifying their brand names and the relevant HTD) could be attached to the implementing act. Each of the MD listed will be subject to a single-technology JCA.

| |
|---|
| Owing to the pros and cons mentioned and considering the MS needs, ***interpretation 2*** is preferred by EUnetHTA 21. |

#### 2.2.2.2. *Selection criteria*

For uniform and consistent application of the selection criteria of Article 7(4), definition and operationalisation of each criterion are essential. EUnetHTA 21 developed a set of definitions for practical application of the criteria, which is provided below.

**(a) Unmet medical need**

According to Article 4(2) of Commission Regulation (EC) No. 507/2006, an unmet medical need is a condition for which no satisfactory method for diagnosis, prevention or treatment exists in the Union or, if such a method exists, for which the medical technology concerned will be of major therapeutic advantage to those affected. This is especially relevant for rare, life-threatening or chronically debilitating diseases. The diagnostic, prevention or treatment options and the standard of care available, covering all relevant treatment modalities, should be considered.

**(b) First in class**

For a product to be considered first in class, it should be determined novel by the expert panels with a high-level of novelty[10].

**(c) Potential impact on patients, public health or healthcare systems**

For a product to have a potential impact on patients, it should lead to significant improvements in patient morbidity, mortality, quality of life, or a better safety profile. The product may also have an impact on public health or healthcare systems as a whole, depending on the prevalence of the condition or a potential transformation in healthcare delivery that would impose an organisational burden on the healthcare system.

(d) **Incorporation of software using artificial intelligence (AI), machine learning or algorithms**

The device description in the SSCP or the CER should be used to determine the fulfilment of this criterion. When the MD or IVD meets this criterion, at least one of the other criteria, preferably (a), (b) or (c), should be fulfilled as well.

(e) **Cross-border dimension**

For a product to have a significant cross-border dimension, it should fall within the remit of decision-making bodies and the incidence of the disease/condition should be evenly distributed across Europe or at least similar in more than three countries, or the product should address a serious cross-border threat to health.

(f) **Union-wide added value**

For the product to show major Union-wide added value, the clinical studies should either be conducted in Europe or adequately reflect the European patient population and European healthcare

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807(01)&from=EN

standards (the transferability of results should be demonstrated). Addition of another therapeutic option to the portfolio of existing therapeutic options seems less likely to justify major Union-wide added value. The disease to be treated by the product should not be highly geographically or ethnically restricted.

EUnetHTA 21 recommends that the Coordination Group considers a possible prioritisation of the above selection criteria, based on the experiences within the first years after HTAR will come into force. This is particularly important if many MDs undergo CECP and it is not feasible or not necessary to assess them all. EUnetHTA21 recommends that if the selection criteria are prioritised by the Coordination Group, the decision criteria along which the prioritisation is done should be made public.

#### *2.2.2.3. Topic selection template*

Further details and guidance on the interpretation and application of the selection criteria can be found in the proposed topic selection template in Appendix 2 Table A 4.

#### *2.2.2.4. Selection process*

The subgroup for the identification of emerging health technologies, if necessary, with the help of the subgroup for JCA, apply the criteria to the data set to obtain a short-list of products. Members of the stakeholder network can also be asked for input by the subgroup for the identification of emerging health technologies regarding the unmet medical need, the innovative aspect of the products, the potential impact on patients, public health and healthcare systems, and the cross-border aspect, as well as the major added value. The subgroup for the identification of emerging health technologies fills in the white fields in the proposed topic selection template. The Coordination Group shall draw conclusions based on the information found in the white fields, and document it by filling in the grey fields in the proposed topic selection template in Appendix 2 Table A 4.

EUnetHTA 21 recommends that lists are created quarterly and shall be consolidated into one list for prioritisation.

### *2.2.3.Topic prioritisation for JCA*

#### *2.2.3.1. Prioritisation criteria*

According to HTAR Article 6(1), *the Coordination Group shall adopt an annual work programme each year, at the latest by 30 November and subsequently amend it if necessary. The annual work programme shall set out the joint work to be carried out in the calendar year following its adoption, covering the planned number and type of joint clinical assessments, and the planned number of updates of joint clinical assessments according to Article 14.*

According to HTAR Article 6(3), *in the preparation or amendment of the annual work programme, the Coordination Group shall:*

*(a) take into account the reports on emerging health technologies referred to in Article 22;*

(b) [not applicable for MDs and IVDs];

*(c) take into account information provided by the Medical Device Coordination Group established in Article 103* of the MDR *or other sources, and provided by the Commission pursuant to Article 28 of this Regulation on the work of the relevant expert panels referred to in Article 106(1)* of the MDR*;*

*(d) consult the stakeholder network referred to in Article 29, and take into account its comments;*

*(e) take into account the resources available to the Coordination Group for the joint work;*

*(f) consult the Commission on the draft annual work programme and take its opinion into account.*

#### *2.2.3.2. Prioritisation process*

| |
|---|
| EUnetHTA 21 recommends that the subgroup responsible for the identification of emerging health technologies present the short-list (including the rationale for selection) at a Coordination Group meeting. Minutes of the Coordination Group meeting should be published after the meeting. |

The Coordination Group makes the final decision according to the interest of MSs in the topic and the resources available for conducting the JCAs that have been prioritised. If an MS has already assessed the selected device, the Coordination Group might consider de-selecting or not prioritising this device. The timing of JCA for each selected MD should be defined according to the chronology of CE marking granting (among the selected MDs, MDs awarded a CE marking earlier should be assessed first).

Furthermore, in certain occasions it might be reasonable to wait for the results from ongoing (almost finished) studies.

Depending on the interpretation of the HTAR in relation to the implementing act, the prioritisation results shall be published in the implementing act as names of single-technology MDs and IVDs, or the device and IVD types and the detailed selection criteria. Examples could be heart valves that are first in class and incorporate AI, or heart valves that fill an unmet need for patients with cardiac disease and have a major impact on health systems because of costs. The place of prioritisation in the process also depends on the interpretation related to the implementing act. Prioritisation shall occur before preparation of the implementing act if the single-technology MDs and IVDs are specified and included in the implementing act. If the device types and category and the detailed selection criteria are specified in the implementing act, then prioritisation shall occur only after the implementing act is adopted.

Under the HTAR, the annual work programme shall be developed until 30th November each year at the latest.

Table 1 gives an overview on the process flow for TISP under the HTAR when ***Interpretation 2*** of the implementing act is applied.

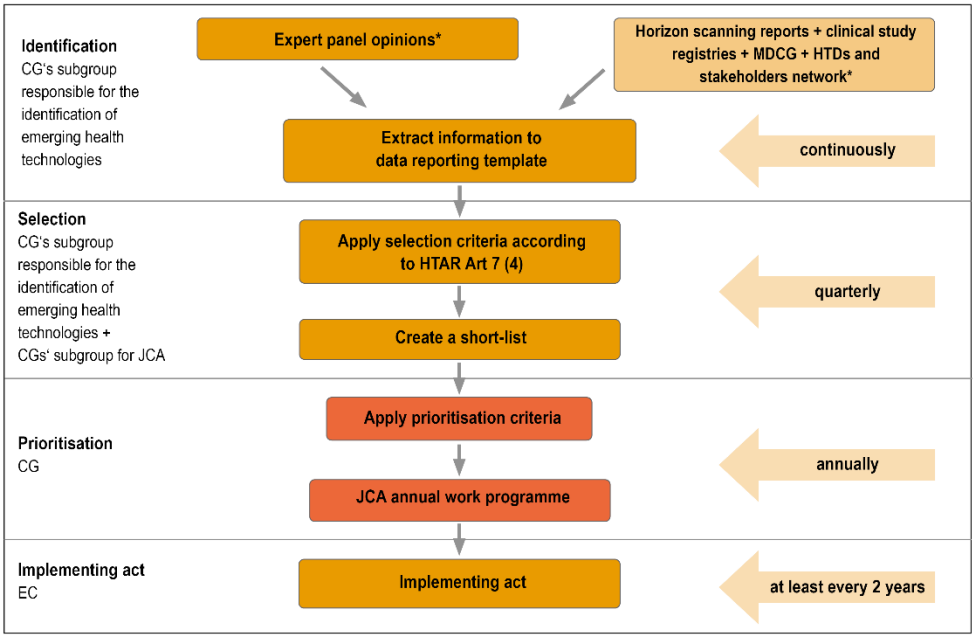
*Table 1 TISP process*

| What | Who | Output | Source | Timeframe | Criteria to be applied |
|---|---|---|---|---|---|
| **Identification** | The Coordination Group subgroup for the identification of emerging health technologies | Report on emerging technologies (HTAR Article 22) expected to have a major impact on patients, public health or healthcare systems | a) Existing scientific reports or initiatives on emerging health technologies;<br>b) Clinical study registers and scientific reports;<br>c) MDCG;<br>d) HTDs on the health technologies they are developing;<br>e) Members of the stakeholder network referred to in HTAR Article 29;<br>f) Stakeholder organisations that are not members of the network referred to in Article 29 and other relevant experts, as appropriate.<br>g) EMA as Secretariat of the expert panels and notified bodies | Continuously with quarterly cut-off point for compilation of data | HTAR Article 7(1) (c) and (d) (class IIb and class III MDs and class D IVDs, that have to undergo a scrutiny process by the relevant expert panel). |
| **Selection** | The Coordination Group subgroup for the identification of emerging health technologies + the Coordination Group subgroup for JCA | Short-list (including the choices made and the rationale for the selection) | a) Report on emerging health technologies;<br>b) MDCG;<br>c) EMA as Secretariat of the expert panels;<br>d) Stakeholder network's comments. | Quarterly | HTAR Article 7 (4)<br>a) unmet medical need;<br>b) first in class;<br>c) potential impact on patients, public health or healthcare systems;<br>d) incorporation of software using AI, machine learning technologies or algorithms;<br>e) significant cross-border dimension;<br>f) major Union-wide added value. |
| **Implementing act** | European Commission | Implementing act | Coordination Group's recommendation | At least every 2 years (preferably annually) | |
| **Prioritisation** | Coordination Group | Annual work programme (planned number and type of assessments) (HTAR Article 6) | a) Short-list (including the choices made and the rationale for the selection)<br>b) European Commission's opinion | Annually (each year by 30th November) | MS interest in the topic and resource availability (depending on the maximum number of JCAs feasible to perform). |

**Abbreviations**: AI=artificial intelligence; HTAR=regulation on health technology assessment; HTD=health technology developer; IVD=in vitro diagnostic medical device; JCA=joint clinical assessment; MD=medical device; MDCG=Medical Device Coordination Group; MS=member state.

Figure 2 and Figure 3 show the proposed process flow under the HTAR.

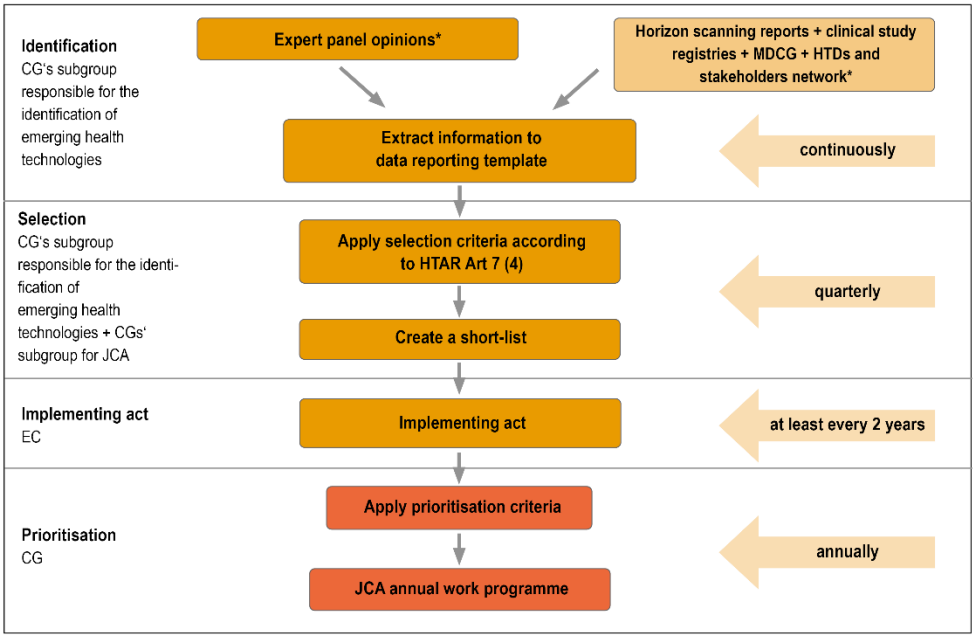
*Figure 2: Flow chart for the period under the HTAR when Interpretation 1 of the implementing act is applied*




**Abbreviations**: Art.=Article; CG=Coordination Group; EC=European Commission; HTAR=Regulation on health technology assessment; HTD=health technology developer; JCA=joint clinical assessment; MDCG=Medical Device Coordination Group

* These two steps do not necessarily occur in parallel in the process, but both are necessary for the identification.

*Figure 3: Flow chart for the period under the HTAR when Interpretation 2 of the implementing act is applied*




**Abbreviations**: Art.=Article; CG=Coordination Group; EC=European Commission; HTAR=regulation on health technology assessment; HTD=health technology developer; JCA=joint clinical assessment; MDCG=Medical Device Coordination Group.

* These two steps do not necessarily occur in parallel in the process, but both are necessary for the identification.

# 3. ACTORS AND THEIR SCOPE IN THIS DELIVERABLE

## *3.1. EUnetHTA 21 actors and associated HTAb*

**CSCQ**

All CSCQ JCA members with a national remit for MD assessment are expected to provide an input to the selection and prioritisation of high-risk MDs for JCA. In the HTAR, the JCA subgroup is expected to have similar functions to the CSCQ JCA.

**CEB**

The Consortium Executive Board (CEB) is the principal decision-making body of the EUnetHTA 21 consortium responsible for endorsement of the list of topics for JCA. In the future, the role of the CEB will be carried out by the Coordination Group.

**Associated HTAb**

The associated HTAb are HTAb from EU/EEA countries that are not members of the EUnetHTA 21 consortium, but they will be subject to the rules of the HTAR as part of the JCA subgroup. They are also invited to participate in the selection of MDs to be assessed in EUnetHTA 21.

**EUnetHTA 21 project manager**

The EUnetHTA 21 project manager is the primary point of contact and is responsible for all communications with external actors (e.g., HTDs, regulators). The main task related to this deliverable is in the acquisition process.

## *3.2. Actors of the MDR/IVDR regulatory process*

Under the HTAR, regular exchanges between the EMA as Secretariat of the expert panels and HTAb are expected, specifically regarding the selection of products for JCA but also during the scoping of the assessment to ensure consistency with the final CE marking indication. In the HTAR, only MDs or IVDs for which the relevant expert panels have provided a scientific opinion within the framework of the CECP or the PECP will be selected for a JCA. However, in the context of EUnetHTA 21 it may be possible to assess class IIb and III MDs that had not gone through this procedure.

## *3.3. Other stakeholders*

**Health technology developers**

In EUnetHTA 21, HTDs are invited to submit a Letter of Intent to express their willingness to have their MDs assessed. If the device is eligible, the HTD is responsible for submitting a dossier and documentation of the evidence according to the requirements and published deadlines.

Under the HTAR, the European Commission informs the HTD when their MD has been selected by the coordination group. The HTD shall then send a Letter of Information specifying the claimed intended use for the MD. The Letter of Information is a recommendation from EUnetHTA 21 and not a HTAR requirement. The HTD is obliged to submit a Submission Dossier according to the requirements specified in Article 9(2), (3) and (4).

**Patients, healthcare professionals and other external experts**

In EUnetHTA 21, HTD submissions will form the basis for topic identification. Nevertheless, consultation with patients, healthcare professionals and other external experts in the form of an open call is foreseen in the identification step. These stakeholders are also invited to give an input during the public consultation on the recommendations made for the process under the HTAR.

Under the HTAR, the Coordination Group shall consult the stakeholder network on selection of JCA topics and take into account its comments (Article 6(3) point d). The Coordination Group may also consult stakeholder organisations that are not members of the stakeholder network referred to in Article 29 and other relevant experts, as appropriate.

# 4. RULES OF THE COLLABORATION

## *4.1. Confidentiality*

Confidentiality applies to the collaboration between regulators, the MDCG, the EMA as Secretariat of the expert panels and EUnetHTA 21. Contacts were initiated by EUnetHTA 21 with the mentioned MD regulatory stakeholders to explore ways for establishing cooperation under the HTAR. However, no formal cooperation has been established yet. In the future, confidentiality agreements and implementing

acts might be needed to ensure that confidential data can be shared. Some (or possibly all) of the information received might then be made publicly available at a later date (e.g., in EUDAMED).

In the selection process in EUnetHTA 21, Letters of Intent can be received from HTDs and are kept confidential by EUnetHTA 21 consortium members.

## *4.2. Conflict of interest*

In EUnetHTA 21, the CSCQ, CEB (and involved HTAb) and involved experts will have signed a EUnetHTA 21 Declaration of Interest form.

HTAR Article 5(3) states that *the representatives appointed to the Coordination Group and its subgroups shall make a declaration of their financial and other interests and update it annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.*

## *4.3. Status of outputs*

The current guidance outlines the process performed in EUnetHTA 21 as well as the process foreseen in the HTAR. However, since formal collaboration has yet to be established with regulators, the MDCG and expert panels, some adaptations might still be needed.

In EUnetHTA 21, a list of topics that encompasses the products identified via HTD acquisition activities and other sources (Table A 1) will be created and shared with the CSCQ JCA and associated HTAb.

Under the HTAR, the annual work programmes, information on planned, ongoing and completed JCAs, and studies on the identification of emerging health technologies will be published on a publicly accessible web page (according to Article 30 (3)).

# 5. PRACTICAL ISSUES

## *5.1. Contact points*

The JCA Secretariat (JCA_Secretariat@zinl.nl) is the primary contact point and is responsible for the communication with external actors (regulatory bodies, HTDs and external experts), if applicable. In this role, they oversee the receipt and sharing of all documents between all actors (internal and external). In addition, the JCA Secretariat is responsible for ensuring the acceptability of the Letter of Intent.

A secure system will be used for all interactions with HTDs. This system would consist of either a secure email system or via Sharepoint. The mode of interaction will be compliant with the General Data Protection Regulation.

# 6. RELATED DOCUMENTS

- Regulations

| Document | Title |
|---|---|
| HTAR | Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2282&from=FR |
| MDR | Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=FR |
| IVDR | Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=FR |

- Other guidance documents of EUnetHTA 21

| Document | Title |
|---|---|
| D4.7.1 & D4.7.2 | D4.7.1 Synthesis of national requirements<br>D4.7.2 Framework for the assessment of high-risk medical devices and in vitro diagnostics<br>https://www.eunethta.eu/wp-content/uploads/2022/07/EUnetHTA-21-Deliverable-D4.7.1-D4.7.2-General-Guidance-Framework-for-high-risk-MDs_V1.0.pdf?x69613 |

# 7. APPENDIX 1 – LISTS OF SOURCES FOR TOPIC IDENTIFICATION

*Table A 1 List of sources for identification of JCA in EUnetHTA 21*

| Possible source for MD identification for JCA | Description (usefulness of information, feasibility of searching ) | Recommendation on its use (Yes/No/Yes with conditions) |
|---|---|---|
| Primary sources | | |
| Trial registries (clinicaltrials.gov) | Early information. There is no built-in filter to search for MDs within the scope of EUnetHTA 21 (high-risk MDs). High volume of ongoing phase II and III trials with high uncertainty about trial end dates. Professional horizon scanning services (e.g. ECRI[11]) deal with scanning trial registries and this requires huge amount of resources and specific knowledge, therefore we omit this information source. | No |
| Company websites | The news sections on company websites usually announce if a certain product has received the CE mark or FDA approval. Announcements are rarely made when a company has submitted a request for approval. Besides, it is not feasible to search all the manufacturer websites. | No |

[11] https://www.ecri.org/

| | | |
|---|---|---|
| News sites (e.g. massdevice.com, prnewswire.com) | Resource-intensive approach. There are many similar websites, none of which is comprehensive. | No |
| Medical journals | Resource-intensive approach. | No |
| Clinical experts, associations and patient organisations | Open call to be published on the EUnetHTA website. | Yes, if the HTD complements the missing information and confirms the CE marking status. |
| FDA PMA database[12] | The FDA PMA database lists devices that have received PMA in the USA and stores very detailed information about the device published in the summary of safety and effectiveness. FDA-approved devices usually already have a CE mark, but this is not necessarily the case. The documentation stored in the database is very comprehensive and the marketing status of the device outside the USA is normally described in Section VII (marketing history). If we include devices from this source, we already have a very detailed set of information about the device that can be extracted to the data reporting form. | Yes, if the HTD complements the missing information and confirms the CE marking status. |
| FDA breakthrough devices programme | This is a voluntary programme for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the programme is to provide patients and healthcare providers with timely access by speeding up development, assessment and review. The criteria for inclusion in the programme are similar to the criteria defined in the HTAR for selection of products for JCA (unmet need, first in class, major added value). However, requests for breakthrough device designation and subsequent decisions are confidential information and hence a list of designated breakthrough devices is not published, but this information can be found sporadically via various news websites and manufacturer websites. Even if the names of single devices are found, information about the product itself is scarce, causing challenges for inclusion in our list. These products typically do not bear a CE marking. | Yes, if HTD share that their device is in the programme (to be asked from HTDs). |
| National scientific consultations | Two examples from the HOG are the scientific consultations conducted by G-BA (Germany) and HAS (France). However, there are some differences in the timing of the consultations. The G-BA Bewertungsverfahren process (evaluation of new treatment methods with high-risk medical devices) is conducted after CE marking, while HAS typically conducts a consultation in earlier phases, before the CE marking procedure (the HTD submits usually a dossier 4–5 years after the consultation). | Yes, if the timing fits EUnetHTA 21 and if the HTAb that conducted the national scientific consultation contacts the HTD and the HTD |

[12] https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals

| | | |
|---|---|---|
| | | agrees to participate under the confidentiality agreement. |
| Joint Scientific Consultations | In EUnetHTA 21, Joint Scientific Consultations are limited to medicinal products and are therefore not applicable for selection of MDs. | No |
| Secondary sources | | |
| NICE Medtech innovation briefings[13] | Medtech innovation briefings are NICE advice. They are designed to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies. The information provided includes: a description of the technology, how the technology is used, the potential role in the treatment pathway, a review of relevant published evidence and the likely costs of using the technology. The list typically comprises products with CE marking approval already. | Yes, if CE marking recently received |
| CADTH horizon scans[14] | The CADTH horizon scanning service identifies and monitors new and emerging health technologies with the potential to have a significant impact on healthcare in Canada. The focus is on those categories of medical devices, clinical interventions, or other health technologies that are, or may become, important or disruptive to Canadian healthcare in the next few years. It summaries information about the use, effectiveness, cost, and implementation. It is published annually. The list contains products before CE marking. The challenge lies in the fact that the products are typically still in an early phase of development and therefore, the information is scarce. | Yes, if HTD complements the missing information and confirms the CE marking status. |
| NIPH HS | Results are published in Norwegian on www.mednytt.no. | No |
| AGENAS HS | This HS is inactive currently. | No |
| RedETS HS | To be explored. | To be decided |
| HS of EUnetHTA 21 partners | ZIN: There is currently one HS document available on diabetes care. https://www.zorginstituutnederland.nl/publicaties/rapport/2022/01/21/pilot-horizonscan-medtech-diabeteszorg<br>TLV: No results have been published to date. https://www.tlv.se/in-english/medical-devices/horizon-scanning.html). | No |
| IHSI | An IHSI Medical Devices Working Group was set up in 2021 to explore the potential and eventual inclusion of medical devices in the IHSI HS activities. Work is in progress and discussions are ongoing. | No |

**Abbreviations**: AGENAS=Agenzia Nazionale per i Servizi Sanitari Regionali; CADTH=Canadian Agency for Drugs and Technologies in Health; CE=Conformité européenne/European conformity; EUDAMED=European database on medical devices; FDA=US Food and Drug Administration; G-BA=Gemeinsamer Bundesausschuss; HAS=Haute Autorité de Santé; HTAR=Health Technology Assessment Regulation; HS=horizon scanning; HTD health technology develop;, IHSI=International Horizon Scanning Initiative; JCA=joint clinical assessment; MD=medical device; NICE=National Institute for Health and Care Excellence; NIPH=National Institute of Public Health (Norway); PMA=pre-market approval; RedETS= Spanish Network of Agencies for Assessing National Health System Technologies and Performance; TLV= The Dental and Pharmaceutical Benefits Agency (Sweden); ZIN=Zorginstituut Nederland.

[13] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/medtech-innovation-briefings

[14] https://www.cadth.ca/sites/default/files/pdf/ER0011%20Horizon%20Scanning%202021%20Tech%20Trends%20v8.0.pdf

*Table A 2 List of HSS identified by IHSI*

| Name of the organization and/or the HSS | Country | Planned, ongoing or closed HSS |
|---|---|---|
| Agency for Care Effectiveness (ACE) | Singapore | Ongoing |
| Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS) | Italy | No proper and standing HSS, but a series of activities and a brief project in the past were undertaken related to horizon scanning for medical devices |
| Agency for Healthcare Research and Quality (AHRQ) | United States | Closed (2011-2015) |
| Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) | Australia | Closed |
| Canadian Agency for Drugs and Technologies in Health (CADTH) | Canada | Ongoing |
| National Commission for the Incorporation of Technologies (CONITEC) | Brazil | Ongoing |
| Israeli Center for Emerging Technologies (ICET) | Israel | Ongoing |
| Malaysian Health Technology Assessment Section (MaHTAS) | Malaysia | Ongoing |
| Managed Uptake of Medical Methods (MUMM) | Finland | Closed (2005–2017) |
| National Institute for Health Research Community Healthcare MedTech and In-vitro Diagnostics Co-operative (NIHR MIC) | UK | Continues ad-hoc |
| National Institute for Health Research Innovation Observatory (NIHR IO) | UK | Ongoing |
| National Institute of Public Health (NIPH) | Norway | Ongoing |
| Patient-Centered Outcomes Research Institute (PCORI) | United States | Ongoing (started 2018) |
| Spanish Network of Agencies for Health Technology Assessment (RedETS) | Spain | Ongoing |
| The Dental and Pharmaceutical Benefits Agency (TLV) and the Swedish Association of Local Authorities and Regions (SALAR) | Sweden | Ongoing |
| Zorginstituut Nederland (ZIN) | Netherlands | Ongoing |

**Abbreviations**: HSS=horizon scanning system; IHSI=International Horizon Scanning Initiative.

# 8. APPENDIX 2 - TEMPLATES

*Table A 3 Data reporting template*

The data reporting template follows the same structure as the summary of safety and clinical performance (SSCP).

It shall be filled in by the subgroup responsible for the identification of emerging health technologies using the SSCP. Additional data shall be requested from stakeholders (HTD, clinical experts or patient organisations) or found from other sources.

It is recommended that the crossed-out text be omitted from the template, given that the topics identified shall be MDs or IVDs that have not been previously CE-marked for the concerned intended use.

| |
|---|
| 1. Device identification and general information |
| 1.1. Device trade name(s) |
| 1.2. Manufacturer's name and address |
| 1.3. Manufacturer's SRN |
| 1.4. Basic UDI-DI |
| 1.5. Medical device nomenclature description/text |
| 1.6. Class of device |
| 1.7. ~~Year when the first certificate (CE) was issued covering the device~~ |
| 1.8. Authorised representative if applicable; name and SRN |
| 1.9. NB's name (the NB that will validate the SSCP) and the NB's single identification number |
| 2. Intended use of the device |
| 2.1. Intended purpose |
| 2.2. Indication(s) and target population(s) |
| 2.3. Contraindications and/or limitations |
| 3. Device description |
| 3.1. Description of the device (including the organisational aspects in relation to the use of the device: e.g., sterile storage, storage temperatures) |
| 3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences |
| 3.3. Description of any accessories that are intended to be used in combination with the device (including the equipment needed for its administration/use) |
| 3.4. Description of any other devices and products that are intended to be used in combination with the device |
| 4. Risks and warnings |
| 4.1. Residual risks and undesirable effects |

| |
|---|
| 4.2. Warnings and precautions |
| 4.3. Other relevant aspects of safety, including a summary of any FSCA (including FSN) if applicable |
| 5. Summary of clinical evaluation and post-market clinical follow-up |
| 5.1. Summary of clinical data related to equivalent device, if applicable |
| 5.2. Summary of clinical data from investigations of the device conducted before CE marking, if applicable |
| 5.3. Summary of clinical data from other sources, if applicable |
| 5.4. An overall summary of the clinical performance and safety |
| 5.5. Ongoing or planned post-market clinical follow-up |
| 6. Possible diagnostic or therapeutic alternatives |
| 7. Suggested profile and training for users |
| 8. Reference to any harmonised standards and CS applied |
| 9. Revision history |

**Abbreviations**: CS=common specifications as defined in the MDR; FSCA=field safety corrective action; FSN=field safety notice; NB=notified body; SRN=single registration number; UDI-DI=unique device identification device identifier.

*Table A 4 Topic selection template*

The subgroup responsible for the identification of emerging health technologies together with the JCA subgroup shall fill in the white fields using the SSCP or the clinical evaluation report (CER). Based on this information, the Coordination Group shall draw conclusions on the criteria and fill in the grey fields.

| | |
|---|---|
| **1. Unmet medical need** | |
| Alternative/existing therapies/treatments for the condition[15] | ☐ yes<br>☐ no |
| Conclusion on unmet medical need | ☐ yes<br>☐ no<br>Reasoning: |
| **2. First in class** | |
| Novelty of device[16] | ☐ device is novel<br>☐ procedure is novel<br>☐ both are novel<br>☐ none are novel |
| Conclusion on first in class | ☐ yes<br>☐ no<br>Reasoning: |
| **3. Potential impact on patients, public health or healthcare systems** | |

[15] As described in the SSCP (possible diagnostic or therapeutic alternatives) or in the CER.

[16] As indicated in the CECP/PECP by the thematic expert panel.

| | |
|---|---|
| Target population size (prevalence, incidence)[17] | |
| Disease characteristics: age of onset, severity, duration (acute or chronic), mortality, morbidity and service use[18] | |
| Potential impact on morbidity, mortality, quality of life, safety, and compliance vs. current treatment(s)[19] | |
| Service reorganisation requirements (staff training, purchase of equipment)[20] | |
| Conclusion on potential impact on patients, public health or healthcare systems | <table><tr><td></td><td>Minor impact</td><td>Moderate</td><td>Major</td></tr><tr><td>Impact on patients</td><td></td><td></td><td></td></tr><tr><td>Impact on public health</td><td></td><td></td><td></td></tr><tr><td>Impact on healthcare systems</td><td></td><td></td><td></td></tr></table><br>Reasoning: |
| **4. Incorporation of software using AI, machine learning technologies or algorithms** | |
| Device description mentioning software using AI, machine learning technologies or algorithms[21] | ☐ yes<br>☐ no<br>Additional information/comments (if applicable): |
| Conclusion on incorporation of software using AI, machine learning technologies or algorithms | ☐ yes<br>☐ no |
| **5. Significant cross-border dimension** | |
| Legal, environmental or social issues with regard to use of the technology (e.g., controversial method, highly invasive, ethical issues)[22] | |
| Conclusion on significant cross-border dimension | ☐ yes<br>☐ no<br>Reasoning: |
| **6. Major Union-wide added value** | |
| Clinical studies conducted in Europe[23] | |
| Clinical studies reflecting the European patient population[24] | |
| Conclusion on major Union-wide added value | ☐ yes<br>☐ no<br>Reasoning: |

**Abbreviations**: AI=artificial intelligence.

[17] As described in the SSCP or CER and verification from other sources.

[18] As described in the SSCP or CER and information from clinical experts and patients.

[19] Information from clinical experts, patients and other stakeholders and as indicated in the CECP/PECP by the thematic expert panel.

[20] Information from clinical experts and the SSCP (suggested training for users) or CER.

[21] As described in the SSCP (description of the device) or CER.

[22] Information from clinical experts, patients and other stakeholders.

[23] Clinical trial identification number e.g. *NCT*