# EUnetHTA

Web-based toolkit to facilitate

European collaboration on evidence

generation on promising health

technologies

WORK PACKAGE 7-STRAND A

DECEMBER 2008

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

**EUnetHTA**

**"Web-based toolkit to facilitate European collaboration on evidence generation on promising health technologies"**

was developed by

**Work Package 7**

**Monitoring development for emerging and new technologies and prioritisation of HTA**

Work Package 7-A Lead Partner: HAS, French National Authority for Health, France

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**Work Package 7:** Monitoring development for emerging/new technologies and prioritization of HTA

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The European network for Health Technology Assessment (EUnetHTA) coordinates the efforts of 64 organisations from 33 countries in the evaluation of health technology in Europe (see appendix A for general description of EunetHTA). The EUnetHTA project is divided into 8 work packages.

# I.    Background

There is often a lack of strong evidence not only on the efficacy and safety, but also on the effectiveness and cost-effectiveness of new promising technologies (innovative technologies)  when a decision has to be taken on their introduction into the healthcare system (e.g. reimbursement or coverage decision). A comprehensive assessment is thus difficult at this time.

Pressure groups (clinicians, manufacturers, and patient groups) however lobby for rapid access to these technologies (marketing approval or coverage) even if the evidence is scarce. They put pressure on regulators and decision makers to take decisions increasingly early in the life-cycle of an innovation, when uncertainty is still high. This increases the risk of inappropriate decisions. If the decision is negative, potential benefits to patients may be unduly delayed whilst waiting for stronger evidence. If it is positive, technologies that may later turn out to be with a low benefit-risk ratio, inefficient, cost-ineffective, or even harmful may be introduced.

To reduce the risk of inappropriate decisions, several countries have developed policy frameworks allowing access to promising technologies on condition that additional evidence is generated (denoted "access with evidence generation" (AEG) in this report). The measures introduced by AEG mechanisms seek an optimal trade-off between stakeholders' needs, flexibility, responsiveness, and rigour. A decision to provide interim, conditional access to the technology is combined with a requirement for prospective data collection (e.g. clinical trials, registries) and often with restricted use of the technology over a defined period. This means that assessment, decisions on access, and additional evidence generation need to be well coordinated.

EUnetHTA work package 7 Strand A (WP7-A) performed an overview of national experiences on AEG mechanisms. On the basis of this overview and discussions among WP7-A members, it drew up a generally applicable 5-step policy framework for AEG mechanisms. Its steps are (see figure 1):

**Step 1.** A first assessment report[1] is produced which pinpoints evidence gaps and data needs with regard to the technology's safety, efficacy, effectiveness, and cost-effectiveness, and proposes a plan for data collection (type of data and study, time period, etc.).

**Step 2**. A decision is made on conditional and temporary access to the technology (marketing approval or coverage). This decision is based on the first assessment report and is accompanied by a request for evidence generation (which type of data needs to be collected and analysed to fill which evidence gaps and to answer any uncertainties formulated by the decision-makers).

**Step 3.** An interim period of conditional access to the technology follows during which the data requested is collected. During this time, conditions of use of the technology are usually

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[1] Regulatory report (in view of marketing approval) and HTA report (in view of coverage)

restricted and well-defined (e.g. within a limited number of centres, performed by highly skilled professionals, etc.), and use must be monitored.

**Step 4.** A second assessment report is produced that includes the additional evidence that has been generated.

**Step 5.** A revised decision on access to the technology based on this second assessment report is taken.

The final outcome may be widespread and appropriate availability of the technology, restricted diffusion, or discontinuation of use.
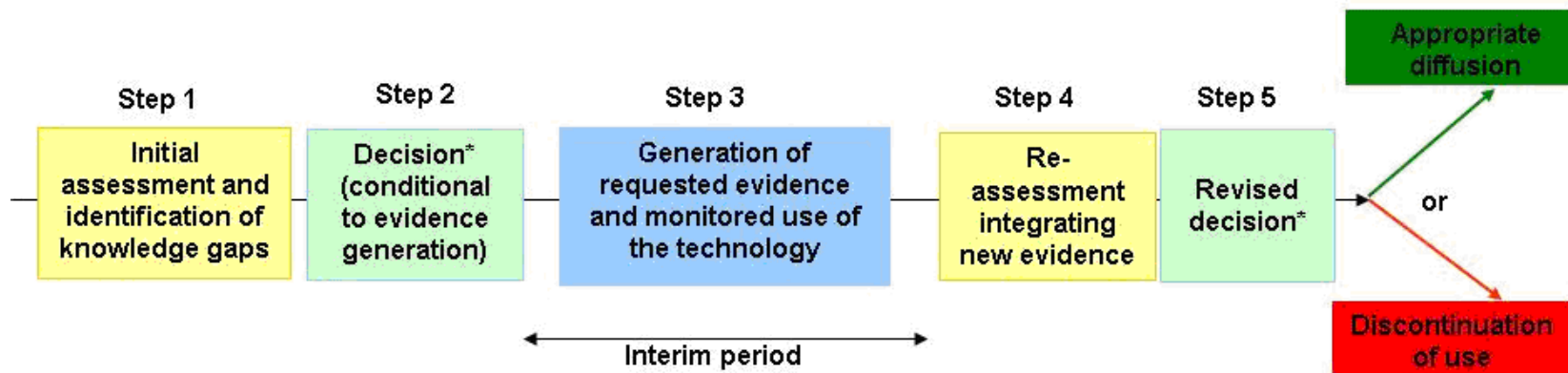
* Either marketing approval or coverage decision

**Figure 1**.    General policy framework for AEG mechanisms for promising health technologies

## II.   Barriers to evidence generation

A number of barriers to evidence generation (Box 1) were identified in the overview performed by WP7-A.

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**Box 1. Barriers to evidence generation**

- Difficulty in agreeing on data requirements and study design
- Evidence generated does not meet quality criteria and cannot therefore inform a decision
- Lack of coordination among the partners and bodies overseeing data collection
- Limited funds to finance the generation of evidence that meets HTA agency and decision-maker requirements
- No well-defined regulatory framework governing coordination and financing

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An important barrier, at the international level, is the lack of structured collaboration among the HTA agencies involved in AEG mechanisms. Information is passed on, mostly by e-mail, from person to person or within informal networks (*e.g.* INAHTA listserv). This is inefficient, time-consuming, a source of misunderstanding, and does not permit easy data storage and sharing. In addition, the information passed on is often incomplete or inadequate. More importantly, there is no way of ensuring that there is no duplication of effort. Valuable time and resources are wasted.

A driving force in the EUnetHTA Project has been the development of communication facilities to support collaborative work among EUnetHTA Members. The project has thus offered an ideal opportunity to set up structured forms of collaboration on evidence generation relating to promising health technologies.

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The objectives of WP7-A were to determine the types of structured collaboration that would facilitate evidence generation and to create a web-based toolkit that would support this collaboration.

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## III. Setting up collaborations to overcome these barriers

The method used to define the types of collaboration is presented in appendix B.

Three levels of collaboration were defined (Box 2).

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**Box 2. Levels of collaboration**

1. Sharing information: low level of commitment, i.e. just sharing relevant information on evidence generation. (e.g. evidence gaps identified; data required; planned, ongoing, or completed clinical studies/registries (with results); decisions taken before and after evidence generation).
2. Coordinated action: Intermediate level of commitment, i.e. getting coordinated by agreeing on a common core protocol. Actions are, however, conducted independently in each interested country.
3. Joint action: High level of commitment, i.e. setting up a joint study (e.g. multicenter, cross-border prospective data collection).

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The EUnetHTA network offers its members an opportunity to set-up all these three levels of collaboration. However, each level requires its own tools and processes. The EUnetHTA project (2006-2008) focused on the development of web-based toolkit for the first level of collaboration only (information sharing). Development of the web-based toolkits for the two other levels is planned to start in 2009.

The web-based toolkit will help:
- identify and share best practices (benchmarking);
- save time and resources, and avoid duplication of work;
- gather a critical mass of data quickly to support decisions based on improved evidence base.

**WP7 strand A has developed a web-based toolkit (a website) to help HTA agencies share information on evidence generation on promising technologies. Each country/region may use results on evidence generation obtained elsewhere whenever these are applicable to their local context.**

## IV. Website to share information on evidence generation on promising health technologies

The method to develop the website comprised four steps (see Appendix B): (i) Definition of the information to be shared, (ii) Development of standard entry forms, (iii) Pilot tests, (iv) IT development[2].

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[2] IT development is presented in appendix C

## IV.1. Definition of the information to be shared

WP7 Partners selected the following key information to be shared (see Box 3).

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**Box 3.  Information on a promising technology**

- HTA status (planned, ongoing, completed, reports available*)*

- Marketing authorization and coverage decision

- Status of interim period of conditional access with evidence generation requirements

- Protocols and available results (clinical studies or registries)

- Use to which the evidence generated has been put (second HTA report and/or revised decision on access, coverage)

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## IV.2.Design and pilot testing of the standard forms

WP7-A was devoted to the development of a toolkit for information sharing among EUnetHTA Members (low level of commitment). Standard forms for requesting and supplying information were designed by the WP7-A Lead Partner. They were tested by 7 of the 31 WP7 Partners in a first test and by 6 in a second test. The participation rate was thus low. Participants tended to be either WP7 partners with substantial experience of AEG mechanisms, or on the contrary partners with little experience. By participating, advanced partners were able to consolidate the quality of their work, and the less advanced partners were able to learn.

The participating partners tested the forms for 21 technologies (Table 1). Information was requested on 13 technologies; only 6/13 requests received a reply. Information was provided "spontaneously" on 8 technologies. More than one request or reply was recorded for 4 technologies (bevacizumab in age-related macular degeneration, transient elastography, implantable cardioverter defibrillator, intensity-modulated radiation therapy (IMRT)).

During quality control of the requests and replies, the WP7-A Lead Partner contacted each participant at least once for details. In general, the participant had not understood one or more items. These were reworded for greater clarity.

**Table 1.** Lists of health technologies used in the pilot tests

| Technology | Request (N) | Reply (N) |
|---|---|---|
| Bevacizumab in age-related macular degeneration [2] | 2 | 0 |
| Biochemical markers of liver fibrosis[1] | 1 | 0 |
| Blood titration of gamma-interferon[1] | 1 | 0 |
| Colorectal cancer screening[2] | 1 | 0 |
| High-intensity focused ultrasound[1] | 1 | 0 |
| Magnetic navigation system[2] | 1 | 0 |
| Transient elastography[1] | 2 | 0 |
| Bevacizumab in colorectal cancer[2] | 0 | 1 |
| Cardiac multislice and coronary computed tomography[2] | 0 | 1 |
| Deferasirox[2] | 0 | 1 |
| Endovascular grafts for abdominal aortic aneurysms[2] | 0 | 1 |
| Human papillomavirus vaccine for cervical cancer prevention[2] | 0 | 1 |
| Lenalidomide[2] | 0 | 1 |
| Natalizumab[2] | 0 | 1 |
| Portable glycosylated haemoglobin measurement systems[2] | 0 | 1 |
| Extra-cranial stereotactic radiotherapy[1] | 1 | 1 |
| Implantable cardioverter defibrillator[1] | 1 | 3 |
| Intensity-modulated radiation therapy[1] | 1 | 2 |
| Percutaneous aortic valve replacement[1] | 1 | 1 |
| Tympanostomy tubes[1] | 1 | 1 |
| Ventricular assistance[1] | 1 | 1 |

[1] First pilot test, [2] second pilot test

## IV.3.Example of the value of sharing information

In the pilot test, the WP7-A Lead Partner completed a request for information on IMRT as HAS was planning a reassessment. It requested information on coverage, effectiveness, and appropriateness of use. Two partners replied to this request. One provided valuable information on the status of IMRT in their country (marketing authorization (CE mark) and coverage), on the AEG mechanisms that had been set up (registry and monitoring of use), the protocol implemented, and the sources of registry funding. On the basis of this reply, HAS decided to postpone the reassessment of IMRT until the additional data collected by this partner became available. The new data will be included in the HAS re-assessment report and will be used to support the decision on coverage.

## IV.4.Creation of the web-based toolkit: a website

The structured standard forms for information entry are available on a website (**E**unethta **I**nterface to **F**acilitate **F**urthering of **E**vidence **L**evel (http://eiffel.eunethta.has-sante.fr/)). This website is for use by EUnetHTA members only and can be accessed through a link from the EUnetHTA website.

- **Website content**

The website provides access to the forms for requesting information ("request form"), posting information in response to a request ("posting form"), and posting information spontaneously ("spontaneous posting form") (see Appendix D). The website also provides an online queryable database containing all the information requested or posted. It will be fed automatically, as and when the forms are filled. The forms completed for 21 technologies during the pilot testing have been entered into the database.

When completing the forms, users must specify if the information provided is confidential (to be sent only to the user requesting the information) or semi-confidential (available to database users, *i.e.* EUnetHTA Members). Each member is responsible for the quality of the information they provide.

- **Website access**

Figure 2 shows how the website is used:

- The user searches the database for information on a promising health technology (action 1).

- If no information is retrieved or if it is insufficient, he/she completes the standard "request form" on the request page (action 2).

- The "request form" undergoes a quality control process to ensure that the information entered corresponds to the items of the form (action 3).

- The "request form" is published on the website (action 4) and all EUnetHTA Members are notified by e-mail.

- Members who can provide the information requested complete the standard "posting form" (action 5).

- The "posting form" undergoes quality control to ensure that the information entered corresponds to the items of the form (action 6).

- The "posting form" is then published on the website (action 7) and the user who requested the information is informed by e-mail that a member has responded to his/her request.

- Any user can provide information spontaneously by completing the "spontaneous posting form" (action 5').

- All the information exchanged is automatically stored in the database. All members are informed of entries by e-mail alert.
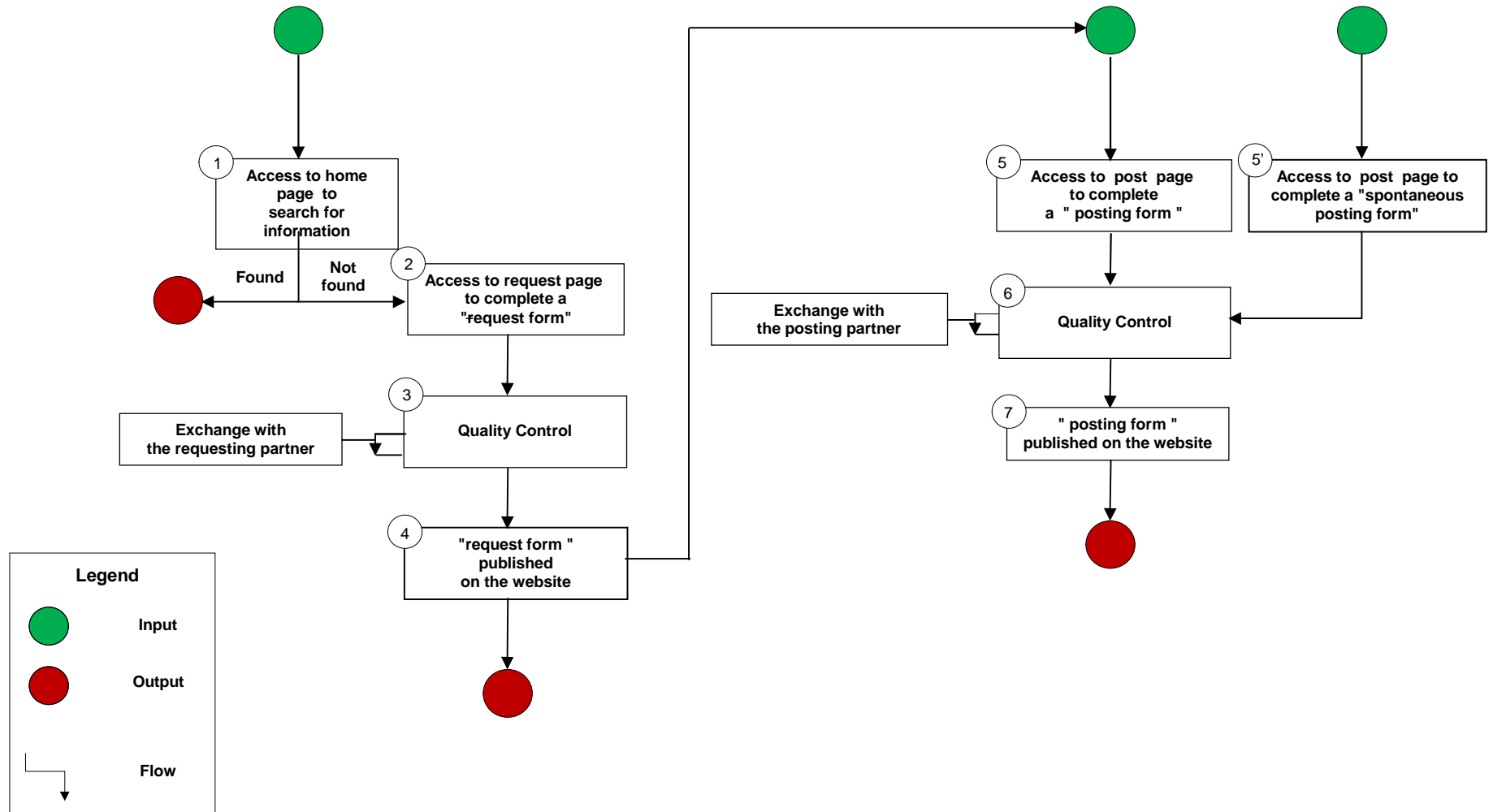
**Figure 2**. How to use the website

- **Intended website users**

The intended website users are EUnetHTA Members, *i.e.* "publicly funded" organisations that produce or contribute to HTA. Three user profiles were identified (Box 4).

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**Box 4. Website user profiles**

1. Someone who seeks information on a promising health technology (e.g. on diffusion in other countries, clinical data) in order to complete an HTA report (assessment or reassessment).

2. Someone who seeks information within the context of AEG. This user would like to know about planned, ongoing, or implemented AEG in other countries (e.g. available clinical data, difficulties encountered, funding…) in order to advise on an interim period of conditional access for a given technology. At any time, this user can update the search to find out what progress has been made and whether the technology has been diffused.

3. Someone who provides information on a promising technology either in response to a request or spontaneously.

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# V.    Conclusions

Providing timely access to promising technologies is a major issue in healthcare. Several European countries have developed "access with evidence generation" (AEG) mechanisms for taking decisions on access but have found that information is scarce, not easy to find, and evidence is difficult to generate.

WP7-A has developed standardized forms for requesting and supplying information on promising health technologies which replace informal e-mails. The forms are available on a dedicated website for sharing information on evidence generation among EUnetHTA Members. It is called **E**unethta **I**nterface to **F**acilitate **F**urthering of **E**vidence **L**evel (http://eiffel.eunethta.has-sante.fr/). The transfer of information thus becomes more efficient and the information garnered is more comprehensive. More importantly, the process permits easy storage of information, saves time, and can ultimately avoid duplication of work.

The overview of AEG mechanisms conducted by WP7-A found that the amount of required evidence generated for access to a promising technology differed according to country. Implementation of the AEG mechanism could be full (all the evidence required was generated), partial (only some of the evidence required was generated), or passive (none of the additional evidence required was generated). In practice, few countries obtain all the evidence they need for a sound and robust decision. The website will thus help them attain a critical mass of evidence faster, for a more evidence-based decision.

We identified three potential obstacles to website use: the "Not Invented Here" syndrome, frustration, and habit.

(i) The "Not Invented Here" syndrome: Users may be reluctant to use information that does not come from their own AEG mechanism as they cannot control its quality. A way of overcoming this obstacle it to issue regular reminders to users that they must ensure the accuracy of the information they supply. The supplier is responsible for the quality of the information given. In addition, before making use of the information, the interested party can directly e-mail the supplier to obtain confirmation that the information is indeed accurate.

(ii) Frustration: Clearly, users will be frustrated if the information they need is not in the database, as its content will not immediately reach a critical mass. To speed up supply, EUnetHTA Members will be regularly solicited for information. Users may also be frustrated, even annoyed, if the information is obsolete. Users will thus be regularly also asked to update information.

(iii) Habit: Users may be reluctant to use the website instead of just sending an informal e-mail. A training session on website use will be set up for EUnetHTA Members.

Three limitations of a more general nature were also identified: transferability of the information, lack of transparency, and wording.

(i) Transferability of information: Can the information really be transferred directly in order to be shared? Differences among countries, such as differences in terminology, technology use, physician training, and population risks, come into play. Users will have to use the domain classification of the HTA Core Model (e.g. description and technical characteristics, current use), the glossary of HTA terms (INAHTA, WP5 EUnetHTA), and the toolkit for adapting an HTA report to their local context.

(ii) Lack of transparency: Only WP7 Partners were involved in the project. Moreover, they were involved in the testing of forms for information requests and supply only, with a rather disappointing participation rate. They were not involved in website testing. Transparency will increase as soon as we have developed tests of the website for all EUnetHTA Members. Website access is currently restricted to EUnetHTA Members because some of the data on promising technologies (e.g. clinical data) is confidential and not intended for the general public. However, plans are being made to provide general access to the non-confidential items in the future (e.g. level of diffusion of the health technology in different healthcare systems, status of HTA report).

(iii) Wording: The wording used in the forms needs to be improved further. During the pilot tests, explanations had to be given to each participating WP7 Partner on how to complete the forms. The terms "new" and "promising" also need to be defined according to the level of diffusion of the technology in the healthcare system. For example, some partners considered technologies such as implantable cardiac defibrillators and tympanostomy tubes "promising" whereas they are in routine use in other countries. We plan to develop an online glossary of key terms used in the website to facilitate a common understanding.

In conclusion, for the website to become fully operational, it will be necessary to include the user reminders identified above concerning information supply, quality, and updating, to provide a glossary of key terms, to perform large-scale tests involving all EUnetHTA Members, and to organise training sessions on the final product.

The development of a website for sharing information meets the needs of the first of the 3 levels of collaboration we defined for facilitating evidence generation on promising health technologies. The three levels are: (i) sharing information, (ii) implementing coordinated

actions, and (iii) setting up joint actions. They correspond to the 3 levels of collaboration of the future EUnetHTA Collaboration (voluntary information sharing, coordination of common activities, and joint actions).

When there is no evidence to share on promising technologies, it will be necessary to get coordinated and even set up joint actions to generate additional evidence. Toolkits will have to be developed for these two higher levels of commitment:

1. The toolkit to facilitate coordinated but independent generation of new evidence on a promising health technology may include a rapid agreement process to define core protocols for collecting a common set of data, and methodological developments on core protocols (*e.g.* type of data needed to fill the evidence gaps, study/register designs for monitoring studies).

2. The toolkit to facilitate joint actions may include a framework for collaborative collection of lacking evidence across EUnetHTA Members and methodological developments on criteria for selecting the technologies to be monitored.

# VI. Appendices

## VI.1. Appendix A – General information on European network for Health Technology Assessment (EUnetHTA)

- **Background**

Health Technology Assessment (HTA) is increasingly used in European countries to inform decision- and policy-making in the health care sector. Several countries have integrated HTA into policy, governance, reimbursement or regulatory processes. Therefore, the EU and Member States in 2004 expressed the need for a sustainable European network for HTA.

(EUnetHTA) was established to respond to this need. The European Commission and Member States co-funded the three year project (2006–2008) with the aim to develop a sustainable network and information resources to inform health policy making. The project, which was based on three prior projects, connected national HTA agencies, research institutions and health ministries and enabled an effective exchange of information and support to policy decisions.

- **What is health technology assessment?**

EUnetHTA used the definition of health technology offered by the International Network of Agencies for Health Technology Assessment (INAHTA): "Any intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care" (5).

EUnetHTA defined health technology assessment (HTA) as "a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform

the formulation of safe effective, health policies that are patient focused and seek to achieve best value".

- **EUnetHTA aims and strategic objectives**

The EUnetHTA project was established to create an effective and sustainable network for HTA across Europe that could develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTAs in Members States.

The strategic objectives of the EUnetHTA project were to:
- reduce duplication of effort in order to promote more effective use of resources
- increase HTA input to decision making in Member States and the EU in order to increase the impact of HTA
- strengthen the link between HTA and health care policy making in the EU and its member states
- support countries with limited experience of HTA.

- **Structure of EUnetHTA**

The EUnetHTA Partnership involved 64 organisations: 1 Main Partner, 33 Associated Partners, and 30 Collaborating Partners. In total, 33 countries (Europe: 25 EU and 2 EEA countries (Norway, Iceland), Switzerland and Serbia; outside Europe: Australia, Canada, Israel, USA) participated in the project. The list of partners is accessible at: www.eunethta.net .

- **Management and leadership**

EUnetHTA governance structure consisted of
- the Steering Committee which comprised the heads of each of the Associated Partners or representatives appointed by the head. The head of the Main Partner chaired the Steering Committee. The Steering committee mandated the the management of the network to:
  - the Executive Committee representing the Main Partner and Work Package Lead Partners,
  - the Secretariat under the leadership of the Main Partner which provided managerial support to the overall project and ensured ongoing contact to the DG SANCO.

Collaborating Partners participated in the work packages and received internal communication on a regular basis.

The modes of operation of the network were described in a standard operating procedures (SOP) manual, a communication strategy, and supported by virtual and face-to-face meetings, website (with the Members Only work area), regular e-newsletter and other types of communication tools. The Associated Partners agreed on 3-year work plan during the first Steering Committee meeting and project results were presented at the EUnetHTA Conference "HTA's Future in Europe", in journal articles and conference presentations.

- **Work Packages and major results**

The scientific work in the EUnetHTA project took place in separately managed Work Packages (WPs), each led by a Lead Partner. The following major results were achieved:
- A well functioning network of partners and colleagues from HTA agencies, research institutions and health ministries (WP1 - DACEHTA/National Board of Health, Denmark)
- A well functioning Information platform and website (www.eunethta.net) (WP2 - SBU, Sweden and Co-Lead Partner – DIMDI, Germany)
- Internal evaluations that helped to adjust work plans (WP3 – NOKC, Norway)
- A comprehensive, evidence-based and validated common framework for HTA information (HTA Core Model) applied to two types of technology to produce generic Core HTAs a) on medical and surgical interventions (Drug Eluting Stents) and b) on diagnostic technology (Multislice CT coronary angiography) (WP4 - FinOHTA, Finland)
- A handbook instructing in the use of the Core HTA Model (WP4 - FinOHTA, Finland)

- An Adaptation Toolkit (and a guidance document) composed of a series of checklists and resources which address the relevance, reliability and transferability of data and information from existing reports (WP5 - NCCHTA, UK)
- A book "Health technology assessment and health policy-making in Europe" (WP6 - DACEHTA/National Board of Health, Denmark)
- A web-based Stakeholder Open Forum, a Draft Stakeholder Policy and Discussion Topic Catalogue; (WP6 - DACEHTA/National Board of Health, Denmark)
- Web-based tools for information sharing on the monitoring of new promising technologies and information service on emerging technologies (WP7 – HAS, France, and Co-Lead Partner- LBI/HTA, Austria)
- A handbook on HTA capacity building (WP8 - CAHTA, Spain)
- A proposal for a permanent EUnetHTA Collaboration after two rounds of public consultation (WP1 - DACEHTA/National Board of Health, Denmark)

Based on best practice each Work Package developed the methods suitable for their purpose, which is described in WP-specific products. The Lead Partners were responsible for coordination within the WP, for bringing work forward, producing and reporting results, for sending management information reports to the Main Partner and for responding to internal evaluation questionnaires.

- **The next phase**

Through a series of internal and public consultation rounds, the network developed a Proposal for the EUnetHTA Collaboration (published June 16, 2008) detailing the approaches for the future development of the network. A group of founding partners was established after this to implement the proposal for EUnetHTA Collaboration.

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## VI.2. Appendix B – Methods

The need for international collaboration to facilitate evidence generation on promising health technologies became immediately apparent during the meetings and discussions among WP7 Partners. The WP7-A Lead Partner drafted a proposal on different modes of collaboration which was discussed and agreed upon at a workshop attended by all WP7 Partners (Dublin, April 2007). The decision was taken to focus first on sharing of information on evidence generation. This meant establishing which information should be shared and developing standard forms for information sharing. It also meant developing a web-based toolkit (a website) for data entry and access to an online database.

- **Definition of information to be shared**

The proposals made by the Lead Partner on the data to be entered were discussed and agreed upon at the Dublin workshop (April 2007).

- **Standard information entry forms**

Three meetings were devoted to the development of standard information entry forms. The two first meetings were between the leaders of WP7-A and WP2 (Communications) (Paris, Mar. & Oct. 2007). They were devoted to technical development planning and to a review of the first draft of the forms, respectively. The third meeting was an internal meeting of the HAS staff involved in the project (Paris, Nov. 2007) in order to make the necessary amendments to the draft forms.

- **Pilot tests**

Two pilot tests of the forms were conducted. In the first pilot test, HAS staff and two WP7 Partners (CVZ and ASRR) completed the forms designed for requesting information, using as examples technologies in which they were particularly interested (Nov – Dec. 2007). WP7 Partners were then asked to complete the forms designed to answer queries (posting information form) (Jan. 2008). Their comments were used to amend the forms. In the second pilot test, WP7 Partners were asked to test both the forms for requesting and posting information on technologies in which they were particularly interested (May 2008). Their comments were again used to amend the forms. Each completed form was checked by the WP7-A Lead Partner to make sure that the information provided was in line with the items of the forms.

- **IT development**

The website was developed by the IT department of HAS. The Lead Partner of WP2 (Communications) acted as IT consultant so that the website would be interoperable with the EUnetHTA HTA Information system. The work schedule was: (a) identification of needs, (b) definition of website content, (c) technical development (electronic forms and online database), and (d) website testing by WP7-A Lead Partner.

# VI.3. Appendix C – IT Work: identification of needs

We identified 13 working processes:

1.  Making a request for information (request form)
2.  Quality check of the request (exchange between the quality controller and the requester-validation workflow)
3.  Identification of any link with existing requests
4.  Requesting publication
5.  Making a response (posting form)
6.  Quality check of the response (exchange between quality controller and the requester-validation workflow)
7.  Identification of any link with existing requests and/or responses
8.  Data indexation
9.  Posting of the response on the website
10. Notification to relevant members
11. Member alerts (e-mails)
12. Searching for information (request form, posting form)
13. General administration (including user access and authorization)

- **Computer security study (EBIOS method)**

*Presentation*

The EBIOS method formalises an approach for assessing and treating risks relating to information systems. It is applicable at the pre-design stage or to existing systems, across the entire system or part of it. It is broken down into five steps (Figure 3).

*Conclusion of the EBIOS study*

During the industrialization phase, 6 different risks will be covered:
- trapping software;
- deterioration of data;
- theft of law;
- bugging distance;
- passive listening;
- information without any guarantee of origin.

Security recommendations:
- Establish a security policy and a user charter (for all users of the EUnetHTA WP7-A system) and confidentiality agreements (for providers with access to confidential data).
- Display the safety instructions on the management of passwords and login.
- Implement authentication means limiting the risk of identity theft (e.g. virtual keyboard).
- Display other safety instructions and use of anti-virus software.
- Implement a communication / awareness plan to educate users about security issues and to define the rights and duties of users.
- Implement logical protections blocking the access to an unauthorized user (secure interconnection, etc.).
- Protect LDAP.
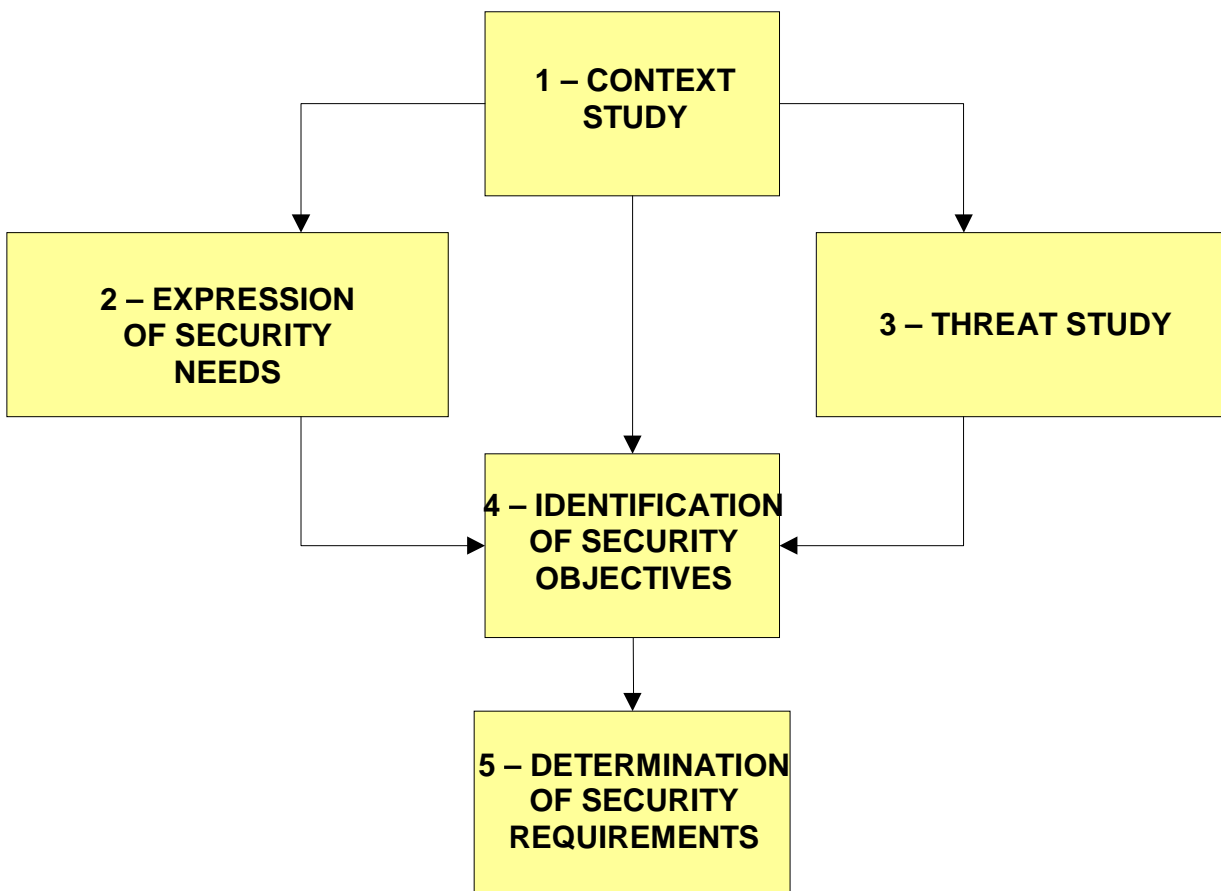
**Figure 3.** A 5-step approach to information systems security

## VI.4. Appendix D - Screenshots of pages of the website

- **Request Page**

- **Post Page**

- **Forms**

*Requesting information*

**INFORMATION REQUESTED**

| 4. | Which information do I want ?* | |
|---|---|---|

| 5. | What kind of information am I interested in ?* | ☐ Description and technical characteristics |
|---|---|---|
| | *Please develop and class the information described in question 4 according to the domains listed in the core model-WP4* | ☐ Current use |
| | | ☐ Clinical effectiveness |
| | | ☐ Safety |
| | | ☐ Economic evaluation |
| | | ☐ Organisational aspects |
| | | ☐ Societal aspects |
| | | ☐ Ethical aspects |
| | | ☐ Legal aspects |
| | | ☐ Other aspects (please specify) |
| | Precisions | |

**CONTEXT OF THE REQUEST**

| 6. | For what purpose am I searching information ?* | |
|---|---|---|

| 7. | Health Technology Assessment report performed in my country/region | |
|---|---|---|
| | Please, precise date of publication, the conclusions | |
| | And/or attach the report | |
| | *Size Max : 10mo* | New file for upload: [ ] Parcourir... |
| | *5 files max* | New file for upload: [ ] Parcourir... |
| | | New file for upload: [ ] Parcourir... |
| | | New file for upload: [ ] Parcourir... |
| | | New file for upload: [ ] Parcourir... |

| 8. | Status of the technology in my country/region | |
|---|---|---|
| 8.1 | **Marketing** | |
| | **Pre-marketing authorization access program** | ☐ |
| | *e.g. Temporary authorizations for Use in France: ATU* | |
| | *Applicable for drugs and devices* | |
| | Please, precise for which reasons it was granted | [                    ] |
| | **Marketing authorization/ CE mark granted***  *Applicable for drugs and devices.*  *For procedures click « Other »* | ○ Yes  ○ Yes : authorization with commitment (1)  ○ No  ○ On going  ○ Other  *(1) e.g. risk-managment plan and other commitments, complementary study on efficacy... please fill question 9* |
| | If yes or on going | ☐ EU authorization via EMEA  ☐ National authorization  ☐ CE mark |
| | Precisions  *If yes : please, precise in which indications.*  *If other : please precise (eg. Marketing authorization not requested by manufacturer)* | [                    ] |
| 8.2 | **Reimbursement / coverage** | |
| | **Decision on reimbursement/coverage*** | ○ Yes  ○ Yes with monitoring actions (2)  ○ No  ○ On going  ○ Other  *(2) complementary data collection requested (e.g. conditional coverage) please fill question 9* |
| | Precisions  *If yes : please, precise in which indications and by which decision-makers (e.g. Health Insurrance, MoH,...).*  *If other : please precise (e.g. life style drugs excluded form reimbursement)* | [                    ] |
| | **This decision was based on the HTA report described in question 7** | ☐ |

| 9. | **Additional data collection (studies/registries) requested following a marketing or coverage decision (question 8)** | |
|---|---|---|
| | **Which additionnal data were requested ?** | ☐ On efficacy/effectiveness (under experimental condition) <br> ☐ On appropriateness of use determination (under real life condition) <br> ☐ Other |
| | If other, please specify | |
| | **In which indications** | |
| | **By which organization** | |
| | **For which reasons** | |
| | **Reimbursement/coverage decision is temporary and conditional to this data collection** | ▢ ▼ |
| | Precisions | |
| | **Expected impact on reassessment and/or revised decision** | |
| | Precisions | |

| 10. | **Status of the additional data collection (studies/registries) requested following a marketing or coverage decision (question 8)** | ▢ ▼ |
|---|---|---|
| | Precisions | |

[ Store draft ]  [ Discard draft ]  [ Send for publishing ]

*Posting information*

| | | |
|---|---|---|
| **4.** | **Status of the technology in my country/region** | |
| **4.1** | **Marketing** | |
| | **Pre-marketing authorization access program** | ☐ |
| | *e.g. Temporary authorizations for Use in France: ATU* | |
| | *Applicable for drugs and devices* | |
| | Please, precise for which reasons it was granted | [                    ] |
| | **Marketing authorization/ CE mark granted***<br>*Applicable for drugs and devices.*<br>*For procedures click « Other »* | ○ Yes<br>○ Yes : authorization with commitment (1)<br>○ No<br>○ On going<br>○ Other<br><br>*(1) e.g. risk-managment plan and other commitments, complementary study on efficacy... please fill question 5* |
| | If yes or on going | ☐ EU authorization via EMEA<br>☐ National authorization<br>☐ CE mark |
| | Precisions<br>*If yes : please, precise in which indications.*<br>*If other : please precise (eg. Marketing authorization not requested by manufacturer)* | [                    ] |
| **4.2** | **Reimbursement / coverage** | |
| | **Decision on reimbursement/coverage*** | ○ Yes<br>○ Yes with monitoring actions (2)<br>○ No<br>○ On going<br>○ Other<br><br>*(2) complementary data collection requested (e.g. conditional coverage) please fill question 5* |
| | Precisions<br>*If yes : please, precise in which indications and by which decision-makers (e.g. Health Insurrance, MoH,...).*<br>*If other : please precise (e.g. life style drugs excluded form reimbursement)* | [                    ] |
| | **This decision was based on the HTA report described in question 3** | ☐ |

**ADDITIONAL DATA COLLECTION (studies/registries) IN MY COUNTRY/REGION**

**5.** **Additional data collection (studies/registries) requested following a marketing or coverage decision (question 4)**

**Which additionnal data were requested**
- ☐ On efficacy/effectiveness (under experimental condition)
- ☐ On appropriateness of use determination (under real life condition)
- ☐ Other

If other, please specify

**In which indications** ☐

**By which organization**

**For which reasons** ☐

**Reimbursement/coverage decision is temporary and conditional to this data collection**

Precisions
*If yes : please, precise in which indications and by which decision-makers (e.g. Health Insurrance, MoH,...).*
*If other : please precise (e.g. life style drugs excluded form reimbursement)*

**Expected impact on reassessment and/or revised decision**

Precisions

**6.** **Status of the additional data collection (studies/registries) requested following a marketing or coverage decision (question 4)***
- ○ Non monitoring
- ○ Planned
- ○ On going
- ○ Finished
- ○ Main analysis available
- ○ Submitted for publication
- ○ Published (journal, website...)

Precisions

**INFORMATION POSTED**

| | | |
|---|---|---|
| **7.** | **The clinical study or registry about which I am sending information** | |
| **7.1** | **This study/registry is linked to marketing or coverage decisions reported in question 4\*** | ○ Yes<br>○ No |
| **7.2** | **Aim of the clinical study/register** | [                    ] |
| **7.3** | **Main outcome** | [                    ] |
| **7.4** | **Planning** | |
| | Planned starting date | Year: [    ]  Month: [    ]  Day: [    ] |
| | Starting date | Year: [    ]  Month: [    ]  Day: [    ] |
| | End date | Year: [    ]  Month: [    ]  Day: [    ] |
| | Duration of follow up | [                    ] |
| **7.5** | **Clinical study/register design**<br>*Multiple entries possible* | |
| | **Data/information collected under** | ☐ Experimental conditions<br>☐ Real-life conditions |
| | **The study is/will be** | ☐ Prospective<br>☐ Retrospective<br>☐ Cross sectional<br>☐ Longitudinal |
| | **Clinical evaluation** | ☐ RCT<br>☐ Non-RCT<br>☐ Cross over<br>☐ Case control<br>☐ Cohort<br>☐ Case series<br>☐ Meta-analysis |
| | **Economic evaluation** | ☐ Cost-effectiveness analysis<br>☐ Cost-utility analysis<br>☐ Other |
| | **Register** | ☐ |
| | **Other study** | ☐ |

| 7.6 | **Protocol of the clinical study/register available** | ☐ |
| | | |
| | If possible, please attach the protocol | |
| | *Size Max : 10mo* | New file for upload: [          ] [ Parcourir... ] |
| | *5 files max* | |
| | | New file for upload: [          ] [ Parcourir... ] |
| | | New file for upload: [          ] [ Parcourir... ] |
| | | New file for upload: [          ] [ Parcourir... ] |
| | | New file for upload: [          ] [ Parcourir... ] |
| 7.7 | **Sources of funding of this clinical study/register** | ☐ Governmental Body<br>☐ Public HTA agency<br>☐ Industry<br>☐ Public Health care service<br>☐ Public Health insurance<br>☐ Private Health insurance<br>☐ Health care professional organisation<br>☐ Independant research organisation<br>☐ Other organisation |
| 7.8 | **Difficulties that were/are encountered when setting up the clinical study/register** | ☐ Funding<br>☐ Ethical aspects<br>☐ Organisational aspects<br>☐ Legal aspects<br>☐ Confidentiality aspects<br>☐ Other aspects |
| | Precisions | [                    ] |

| 8. | **Results of the clinical study/register available** | [ ▼ ] |
| | | |
| | If possible, please attach the study report | |
| | *Size Max : 10mo* | New file for upload: [          ] [ Parcourir... ] |
| | *5 files max* | |
| | | New file for upload: [          ] [ Parcourir... ] |
| | | New file for upload: [          ] [ Parcourir... ] |
| | | New file for upload: [          ] [ Parcourir... ] |
| | | New file for upload: [          ] [ Parcourir... ] |
| | Or describe the main results | [                    ] |
| | Or link the Website | URL:<br>[                    ]<br>Text:<br>[                    ] |

**9. What kind of information I am posting***

*Please develop and class the information described in question 8 according to the domains listed in the core model-WP4*

☐ Description and technical characteristics
☐ Current use
☐ Clinical effectiveness
☐ Safety
☐ Economic evaluation
☐ Organisational aspects
☐ Societal aspects
☐ Ethical aspects
☐ Legal aspects
☐ Other aspects (please specify)

Precisions

**10. Impact of the results of the clinical study/register on reassessment and/or revised decision**

Yes ▾

Please precise

**11. Other comments**

**12. Confidentiality of posted information***

*If you choose yes, only information about the author and the name of the technology will be seen by the other members of the EIFFEL toolkit.*

○ Yes
○ No

Confidentiality precisions

[ Store draft ]  [ Discard draft ]  [ Send for publishing ]

Legal Notice | Sitemap

*Posting information spontaneously*

**Welcome to**

**E**UnetHTA **I**nterface to **F**acilitate **F**urthering of **E**vidence **L**evel

Search >> ?    ok

HOME | REQUEST | POST | CONTACTS

**New Spontaneous post - SP00069**

(*) : These questions are mandatory

**TECHNOLOGY I AM POSTING INFORMATION**

| 1. | Type of technology* | ☐ Drug<br>☐ Device<br>☐ Diagnostic procedure<br>☐ Therapeutic procedure<br>☐ Screening procedure<br>☐ Association of technologies (e.g. drug eluting stents, Theranostics)<br>☐ Other (please specify) |
|---|---|---|
| | Precisions | |

| 2. | Name of the technology*<br>*for drugs and devices: brandname® and generic name* | |
|---|---|---|
| | **Company**<br>*for drugs and devices* | *precise here the name of the compagny holding the makerting autorisation or CE mark* |
| | **Description of the technology*** | |
| | **Coding**<br>*if any* | |
| | Type of code<br>*e.g. ATC/DDD for drugs* | |
| | Code No | |

| 3. | **Therapeutic Group**<br>*i.e cardiovascular* | |
|---|---|---|
| | **Disease(s) and indication(s) concerned by this technology*** | |
| | **Coding number**<br>*according to ICD-10 WHO* | |
| | **Orphan drug** | ☐ |
| | Precisions | |

**STATUS OF THE TECHNOLOGY IN MY COUNTRY/REGION**

| 4. | **Health Technology Assessment report performed in my country/region** | [dropdown] |
|---|---|---|

Precisions
*Please, precise the date of publication and the conclusions*

[text area]

And/or attach the report
*Size Max : 10mo*
*5 files max*

New file for upload: [____] Parcourir...

New file for upload: [____] Parcourir...

New file for upload: [____] Parcourir...

New file for upload: [____] Parcourir...

New file for upload: [____] Parcourir...

| 5. | **Status of the technology in my country/region** |
|---|---|
| 5.1 | **Marketing** |

**Pre-marketing authorization access program**  ☐
*e.g. Temporary authorizations for Use in France: ATU*
*Applicable for drugs and devices*

Please, precise for which reasons it was granted  [____]

**Marketing authorization/ CE mark granted***
*Applicable for drugs and devices.*
*For procedures click « Other »*

○ Yes
○ Yes : authorization with commitment (1)
○ No
○ On going
○ Other

*(1) e.g. risk-managment plan and other commitments, complementary study on efficacy...) please fill question 5*

If yes or on going
☐ EU authorization via EMEA
☐ National authorization
☐ CE mark

Precisions
*If yes : please, precise in which indications.*
*If other : please precise (eg. Marketing authorization not requested by manufacturer)*

[text area]

| 5.2 | **Reimbursement / coverage** | |
|---|---|---|
| | **Decision on reimbursement/coverage***  | ○ Yes<br>○ Yes with monitoring actions (2)<br>○ No<br>○ On going<br>○ Other<br><br>*(2) complementary data collection requested (e.g. conditional coverage) please fill question 6* |
| | Precisions<br>*If yes : please, precise in which indications and by which decision-makers (e.g. Health Insurrance, MoH,...).*<br>*If other : please precise (e.g. life style drugs excluded form reimbursement)* | |
| | **This decision was based on the HTA report described in question 4** | ☐ |

**ADDITIONAL DATA COLLECTION (studies / registries) IN MY COUNTRY/REGION**

| 6. | **Additional data collection (studies/registries) requested following a marketing or coverage decision (question 5)** | |
|---|---|---|
| | **Which additionnal data were requested** | ☐ On efficacy/effectiveness (under experimental condition)<br>☐ On appropriateness of use determination (under real life condition)<br>☐ Other (please specify) |
| | If other, please specify | |
| | **In which indications** | ☐ |
| | **By which organization** | |
| | **For which reasons** | ☐ |
| | **Reimbursement/coverage decision is temporary and conditional to this data collection** | [ ▼ ] |
| | Precisions<br>*If yes : please, precise in which indications and by which decision-makers (e.g. Health Insurrance, MoH,...).*<br>*If other : please precise (e.g. life style drugs excluded form reimbursement)* | |
| | **Expected impact on reassessment and/or revised decision** | |
| | Precisions | |

| 7. | Status of the additional data collection (studies/registries) requested following a marketing or coverage decision (question 5)* | ○ Non monitoring<br>○ Planned<br>○ On going<br>○ Finished<br>○ Main analysis available<br>○ Submitted for publication<br>○ Published (journal, website...) |
|---|---|---|
| | Precisions | |

**INFORMATION POSTED**

| 8. | The clinical study or registry about which I am sending information | |
|---|---|---|
| 8.1 | This study/registry is linked to marketing or coverage decisions reported in question 5* | ○ Yes<br>○ No |
| 8.2 | Aim of the clinical study/register | |
| 8.3 | Main outcome | |
| 8.4 | Planning | |
| | Planned starting date | Year: ___ Month: ___ Day: ___ |
| | Starting date | Year: ___ Month: ___ Day: ___ |
| | End date | Year: ___ Month: ___ Day: ___ |
| | Duration of follow up | |

**8.5 Clinical study/register design**

*Multiple entries possible*

**Data/information collected under**
- ☐ Experimental conditions
- ☐ Real-life conditions

**The study is/will be**
- ☐ Prospective
- ☐ Retrospective
- ☐ Cross sectional
- ☐ Longitudinal

**Clinical evaluation**
- ☐ RCT
- ☐ Non-RCT
- ☐ Cross over
- ☐ Case control
- ☐ Cohort
- ☐ Case series
- ☐ Meta-analysis

**Economic evaluation**
- ☐ Cost-effectiveness analysis
- ☐ Cost-utility analysis
- ☐ Other

**Register** ☐

**Other study** ☐

**8.6 Protocol of the clinical study/register available** ☐

If possible, please attach the protocol
*Size Max : 10mo*
*5 files max*

New file for upload: [            ] [ Parcourir... ]

New file for upload: [            ] [ Parcourir... ]

New file for upload: [            ] [ Parcourir... ]

New file for upload: [            ] [ Parcourir... ]

New file for upload: [            ] [ Parcourir... ]

**8.7 Sources of funding of this clinical study/register**
- ☐ Governmental Body
- ☐ Public HTA agency
- ☐ Industry
- ☐ Public Health care service
- ☐ Public Health insurance
- ☐ Private Health insurance
- ☐ Health care professional organisation
- ☐ Independant research organisation
- ☐ Other organisation

**8.8 Difficulties that were/are encountered when setting up the clinical study/register**

☐ Funding
☐ Ethical aspects
☐ Organisational aspects
☐ Legal aspects
☐ Confidentiality aspects
☐ Other aspects

Precisions

---

**9. Results of the clinical study/register available**  [ ▼ ]

If possible, please attach the study report
*Size Max : 10mo*
*5 files max*

New file for upload: [          ] [ Parcourir... ]

New file for upload: [          ] [ Parcourir... ]

New file for upload: [          ] [ Parcourir... ]

New file for upload: [          ] [ Parcourir... ]

New file for upload: [          ] [ Parcourir... ]

Or describe the main results

Or link the Website

URL:

Text:

---

**10. What kind of information I am posting***

*Please develop and class the information described in question 8 according to the domains listed in the core model-WP4*

☐ Description and technical characteristics
☐ Current use
☐ Clinical effectiveness
☐ Safety
☐ Economic evaluation
☐ Organisational aspects
☐ Societal aspects
☐ Ethical aspects
☐ Legal aspects
☐ Other aspects

Precisions

---

**11. Impact of the results of the clinical study/register on reassessment and/or revised decision**  [ ▼ ]

Please precise

**12.** **Other comments**

**13.** **Confidentiality of posted information**\*

*If you choose yes, only information about the author and the name of the technology will be seen by the other members of the EIFFEL toolkit.*

Confidentiality precisions

○ Yes
○ No

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# VI.5.Appendix E - Partner organisations of Work Package 7

LEAD PARTNER
HAS (French National Authority for Health), France

CO-LEAD PARTNER
LBI-HTA (Ludwig Boltzman Institute of Health Technology Assessment), Austria

ASSOCIATED PARTNERS
- AETS (National Health Technologies Assessment Agency), Spain
- AETSA (Andalusian Health Technologies Assessment Agency), Andalousia, Spain
- ASSR (Regional Agency for Health and Social Care), Emilia-Romagna, Italy
- Avalia-t (Galician Health Technologies Assessment Agency), Galicia, Spain
- CAST (Centre for Applied Health Services Research and Technology Assessment), Denmark
- Cochrane Collaboration
- CVZ (College voor zorgverzekeringen), Netherlands
- DACEHTA (Danish Centre for Health Technology Assessment), Denmark
- DAHTA@DIMDI (Deutsche Institut für Medizinische Dokumentation und Information), Germany
- HIQA (Health Information and Quality Authority), Ireland
- IPHRS (Institute of Public Health of the Republic of Slovenia), Slovenia
- NOKC (Norwegian Knowledge Centre), Norway
- Osteba (Basque Office for Health Technology Assessment), Basque Country, Spain
- Region Veneto, Health and Social Planning Department, Italy
- SBU (Swedish Council on Technology Assessment in Health Care), Sweden
- University of Bremen, Competence Center for Clinical Trials, Germany
- Università Cattolica del Sacro Cuore, Health Technology Assessment Unit, Italy
- University of Lübeck, Institute for Social Medicine, Germany
- University of Tartu, Department of Public Health, Estonia.

COLLABORATIVE PARTNERS
- AHTAPOL (Polish Agency for Health Technology Assessment), Poland
- CEDIT (Committee for Evaluation and Diffusion of Innovative Technologies), France
- CMTP (Center for Medical Technology Policy), United States
- European Observatory on Health Systems and Policies, Belgium
- EuroScan, The International Information Network on new and emerging health technologies
- ICTAHC (Israel Center for Technology Assessment in Health Care), Israel
- NICE (National Institute for Clinical Excellence), United Kingdom
- OECD (Organisation for Economic Co-operation and Development Biotechnology Division), France
- PHGEN (Public Health Genomics European Network), Germany
- SNHTA (Swiss Network for Health Technology Assessment), Switzerland.