Early dialogue with HAS for a medical device in clinical development

Request for inclusion on the list of products and services qualifying for reimbursement or for an exceptional reimbursement under Article L.165-1-1 of the Social Security Code (national innovation funding)

Methods for submission and proceedings

November 2017
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Objective

The article L.161-37 of the Social Security Code tasks HAS with “organising early consultations with its departments upon request from the companies developing medicinal products, products or services that are innovative given their new mechanism of action and an insufficiently covered medical need, prior to implementation of the clinical trials necessary for assessment [...]”. Such meetings are called early dialogues (EDs).

The objective is to provide the requesting companies with recommendations and answers to questions they have on their clinical development of a product. These recommendations and answers should allow companies to better anticipate the type of clinical data they will need to provide to meet the requirements of the health technologies assessment (HTA). At the end of the process, the aim of the HTA will be conducted for inclusion of the medical device on the list of products qualifying for reimbursement or to obtain an exceptional reimbursement under Article L.165-1-1 of the Social Security Code (national innovation funding)¹.

The challenge is to encourage the collection of relevant data (to assess the clinical benefit of a new medical device or its impact in terms of quality of life), so that the CNEDiMTS² has the data necessary to comment on the regulatory criteria, not only the Expected Clinical Value, but also the Expected Added Clinical Value, to allow a comparison of care strategies. These early dialogues are also focused on preparing an application for national innovation funding; the relevance of the clinical or medico-economic study proposed by the applicant in this context is one of the criteria to be eligible for national innovation funding. During an early dialogue, questions about conducting a medico-economic assessment can also be asked, if a study assessing the efficiency is planned.

General principles

The EDs organised by the HAS departments are optional, non-binding and free. The data provided in the EDs as well as the discussions are confidential.

In no way do the answers provided by HAS departments to questions raised by the company or the developer during these EDs constitute an assessment. The EDs do not prejudice conclusions that may result from the assessment by the CNEDiMTS and, where applicable, by the Committee for Economic and Public Health Assessment (CEESP) when the reimbursement application dossier is submitted. These answers are based on the experience of the HAS departments, the opinions of clinical or methodological experts and existing international guidelines on the subject.

¹See also https://www.has-sante.fr/portail/jcms/c_2035788/fr/forfait-innovation
² These dialogues may concern any medical device as well as any other product or service within the scope of the list of products and services qualifying for reimbursement under Article L. 165-1 of the Social Security Code.
Practical methods

The entire process includes the following steps:

- Request
- Admissibility
- Meeting
- Report of the meeting

1. Request

The ED request should be sent to the Medical Devices Assessment Department by email (contact.sed@has-sante.fr).

The ED request dossier is comprised of:

- The request form (according to Appendix 1), including the description of the product and the questions raised by the company that led to the request;
- the protocol(s) that is(are) the subject of the request and, if available, an investigator's brochure;
- a dossier including all of the publications or study reports already available about the product.

When relevant, an overview of the method planned for the medico-economic assessment is included in this dossier (see also Preparatory dossier for an early dialogue with the Department for Economic and Public Health Assessment).

2. Admissibility

The meeting will be planned after the applicant sends all of the items of the dossier (see above), in compliance with the following conditions:

- These dialogues are organised on the request of the manufacturer or the party carrying out the project. A consultant may participate in the meeting, but no meeting can be accepted with the consultant as sole representative of the applicant.
- The applicant cannot request a second meeting for the same technology.
- HAS assesses the benefit of a scientific consultation according to the items sent; it can refuse a request.
- These meetings can only be held prior to the clinical assessment of the reimbursement application dossier and are only beneficial if the clinical study has not yet started.
- They can take place before CE marking is obtained.
- In addition to the clinical development program, regulatory questions or questions about methods of applying for reimbursement or for exceptional reimbursement may be considered; however, these questions cannot be the main subject of the meeting (see also, if applicable, other proposed methods of dialogue).

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3 In the absence of a protocol, a detailed summary can be accepted
4 https://www.has-sante.fr/portail/jcms/c_1625770/fr/dossier-economique-des-rp
5 https://www.has-sante.fr/portail/jcms/c_2640066/fr/modalites-de-demande-d-un-rendez-vous-pre-depot-et-deroulement-ncedimts
3. Meeting

A one-hour meeting is proposed with the HAS Medical Devices Assessment Department. One or more experts may participate in this meeting, as well as other HAS departments, in view of the questions sent in advance by the applicant.

- The dialogues focus on the clinical development programme of the technology.
- No document can be discussed that was not submitted in advance of the meeting.
- The dialogues take into account the data available on the date of the meeting; the advice and opinions formulated are valid only on the date on which these dialogues take place. Thus, the applicant is not required to implement the advice and opinions; conversely, they do not oblige HAS and cannot be opposed during the assessment by the Committees.

EDs can be conducted in English.

4. Report

Following the ED, the applicant drafts the report according to Appendix 2 and sends it to HAS in a modifiable Word document within 10 days of the meeting. HAS makes any changes it deems necessary and returns the report to the applicant within 10 days. The report is kept by the applicant and by HAS. It is not published.

Management of confidentiality and ethics

In accordance with Article R.161-64 of the Social Security Code, HAS agents are bound by professional secrecy and discretion. This obligation guarantees confidentiality of information brought to their knowledge. No additional confidentiality agreement submitted by a manufacturer will be signed by HAS.

Experts, requested by HAS (if applicable), are also bound by professional secrecy and discretion under Article L. 1451-1 of the Public Health Code. These experts are chosen after analysis of their public declaration of interest (PDI) to avoid any positive or negative conflicts of interest.

Experts participating in these EDs cannot participate in the assessment of the product in question. Moreover, no member of the CNEDiMTS can participate in these EDs.
Appendices

Appendix 1. ED request form for a medical device

This file is intended to collect all of the information necessary to prepare for your ED with HAS about the study you are planning. The protocol of the proposed study should be attached; in the absence of a protocol, a detailed summary can be accepted.

Description / Commercial name of the MD

1. Applicant

<table>
<thead>
<tr>
<th>Identification of the applicant</th>
<th>Company name: Address: Tel./Fax/email:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name, position and contact details of the contact person</td>
<td></td>
</tr>
<tr>
<td>Identification of the manufacturer (if different from the applicant)</td>
<td>Company name: Address: Tel./Fax/email:</td>
</tr>
</tbody>
</table>

2. Device

General description of the device

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of action</td>
<td>What conditions are likely to be treated (depending on the context, what disability)?</td>
</tr>
<tr>
<td>Description of uses and modes of use</td>
<td>In what indication(s)? What is its role in the medical strategy? What are the alternatives? How is the device used?</td>
</tr>
</tbody>
</table>

Methods of use:

<table>
<thead>
<tr>
<th>Associated procedure(s)</th>
<th>Specify whether use of the device requires a diagnostic or therapeutic procedure to be performed by medical personnel or by paramedics. If applicable, specify whether this procedure is included in the NGAP (General Nomenclature of Medical Procedures) or in the CCAM (Joint Classification of Medical Procedures). Specify whether there are ongoing clinical studies about the associated procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other information</td>
<td>Describe, if applicable, the methods of use, team, technical facilities, training necessary, etc.</td>
</tr>
</tbody>
</table>

In case of an innovation

<table>
<thead>
<tr>
<th>Nature of the innovation(s) of the device</th>
<th>Tick the corresponding box(es)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ A new mode of action transforming the management of a condition or disability</td>
<td></td>
</tr>
<tr>
<td>□ A radical transformation of a medical procedure for the use of the device</td>
<td></td>
</tr>
<tr>
<td>□ A radical transformation of a medical procedure through use of the device</td>
<td></td>
</tr>
<tr>
<td>□ Original modes of action in an existing medical procedure</td>
<td></td>
</tr>
<tr>
<td>□ A radical transformation of the organisation of care system associated with a condition or a disability</td>
<td></td>
</tr>
<tr>
<td>□ Introduction of a technology known but not yet used in a class of existing devices</td>
<td></td>
</tr>
<tr>
<td>□ Introduction of a new technology in a class of existing devices</td>
<td></td>
</tr>
<tr>
<td>□ Another innovative nature</td>
<td></td>
</tr>
<tr>
<td>Analytical description of the characteristics of the innovation(s)</td>
<td>Precisely describe the specific characteristics of the innovation(s) and justify the declared innovative nature of these characteristics.</td>
</tr>
</tbody>
</table>
| Medical need | Existence of alternatives:  
Role of the MD compared to alternatives: |

### 3. Marketing status of the device

| CE marking | Date obtained or anticipated schedule:  
If applicable, notified body (specify the identification number and country):  
Indication(s) of the CE marking: |
| Current and/or planned marketing | Schedule and countries involved |

### 4. Benefit

| Severity of the condition(s) involved | In terms of morbidity and mortality (life-threatening, acute/chronic, etc.), severity of the disability (seriousness, duration, temporary or permanent nature), severity of the degradation of quality of life and state of health perceived by the patient, and medical and social consequences. |
| Epidemiological data | Summary of data enabling an estimation of the number of patients affected by the condition(s) concerned |
| Estimated number of patients affected | Estimated number of patients affected by the MD based on the epidemiological data available in view of the care strategy. |
| Clinical benefits and risks | Describe what benefit the proposed device would have compared to the risks associated with its use  
- the nature and level of benefits (regardless of the mode of action – therapeutic, diagnostic or compensation of disability)  
- risks to which the device exposes patients or users. The risks include undesirable effects, risks for the patient and risks for the operators. |
| Impact on organisation and structure of care |  |
| Economic impact | direct costs, organisational costs, care avoided, etc. |
| Other | E.g.: ethical impact, etc. |

### 5. Development programme:

| Maturity of the technology | A brief description to allow assessment of the level of development of the device will be supplemented by the submission of a tabulated summary (history of technical trials, pre-clinical and/or clinical studies, published or unpublished) |
| Ongoing or planned studies in the development programme | The brief description will be accompanied by the study protocol (as a minimum, a detailed summary should be provided) |
| Difficulties encountered Questions to discuss during the dialogue |  |

**List the attached documents:**
In addition to the protocol(s)/summary(ies) submitted for discussion, publications and tabulated summaries of available studies should be provided. If available, the investigator’s brochure will be attached.
Appendix 2. Model of the ED report for a medical device

Early dialogue report

Date of ED:

Subject: COMMERCIAL NAME of the DEVICE / study title / protocol version subject to ED

Participants:
For the Haute Autorité de Santé:

- 

For the applicant

- 

Preamble:
As a reminder, this meeting aims to discuss the study protocol submitted to HAS. In no case may the discussions be taken as a recommendation of any sort obliging HAS; conversely, the company is not required to follow the paths discussed. The discussions are confidential.

Supporting documents:

Points discussed:
Medical devices for treatment of respiratory failure and associated services

All HAS publications can be downloaded from

www.has-sante.fr

HAS / Medical Devices Assessment Department / March 2011