PLAN FOR DEMONSTRATING VALUE IN HEALTH CARE

MEDICINAL PRODUCTS: NEW SCIENTIFIC ADVICE PROCEDURE FRANCE

MAY 2020

PREPARED BY

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2020

WHAT DOES 'NEW' LOOK LIKE?

In April 2020 the Haute Autorité de Santé (HAS) has set out new requirements on which medicinal products can seek scientific advice. Make sure you meet them!

Topline

- **Standard and accelerated advice** procedures will be available
- HAS answers medical and medico-economic questions regarding **draft protocols for pivotal studies (generally phase III trials)** in accordance with HTA methods and current clinical guidelines.
- If HAS has participated in an early dialogue in collaboration with other European HTA agencies and/or in parallel with the EMA, the procedure **will not be duplicated on a national level.**
- Confidential and non-binding for HAS and the manufacturer.
- **HAS can consult experts and patients** in preparing its response to questions included in the scientific advice.
- Discussions and documents submitted during these national early dialogues **can be in English,** at the request of the pharmaceutical company seeking the early dialogue

Eligibility

Only scientific advice requests meeting the eligibility criteria defined in the Article L. 161-37 11° of the CSS will be accepted, i.e., requests submitted by a pharmaceutical company concerning:

- **a medicinal product with a new mechanism of action in the disease, and**
- **targeting an indication for which there is an unmet or insufficiently covered need, and**
- **when the early dialogue can be finalised before the start of the pivotal clinical trials**

CSS: CODE DE LA SÉCURITÉ SOCIALE (FRENCH SOCIAL SECURITY CODE)

THE PROCESS

Seven days after submission of the briefing document HAS will inform the manufacturer if the scientific advice procedure is *standard* or *accelerated*. When making the decision HAS will consider the briefing document, the degree of knowledge and complexity of the disease and the clinical development proposed.

The flow of procedure for the standard and accelerated pathway

	D - 37	Manufacturer submits request for scientific advice
HAS feedback on eligibility of the request	D - 37	
	DO	Submission of the briefing document
Choice of procedure by HAS	D +7	

Standard procedure

Accelerated procedure

HAS to request explanations on open issues to manufacturer	D + 45	
	D +60	HAS to send written recommendations to manufacturer
	D +70	Manufacturer to request clarifications
	D +75	Recommendations finalised and closure of procedure
Manufacturer to submit meeting slides for F2F meeting	D + 82	
F2F meeting	D + 90	
Manufacturer will submit meeting minutes	D +100	
HAS will send feedback and recommendations	D +110	

The standard procedure is completed ~ 110 days after submission of the briefing document and the accelerated procedure ~ 75 days.

PREPARE THE BRIEF

If the request for scientific advice is decided by HAS as eligible, the manufacturer has 30 days to submit the required briefing documents using the SESAME platform.

SESAME:HAS ONLINE PLATFORM HTTPS://SESAME.HAS-SANTE.FR/PORTAIL/

E

The briefing document should include:

- description of the disease,
- medical need,
- target indication,
- early development data,
- planned pivotal development,
- planned post-launch evidence generation (if applicable) and whether a French or European registry has already been identified.

The briefing document should also include the questions (maximum of 10 questions) HAS should address during the scientific advice. Each question should be followed by a corresponding, separate Company's position including a comprehensive justification of the chosen approach.

E More explanations - request separate document on briefing book content HAS France

STANDARD PROCEDURE PREPARE THE MEETING

45 days before the meeting

HAS will send the manufacturer a list of issues to be addressed during the face-to-face meeting.

Meeting presentation

Discussions during face-to-face meeting will be structured around a PowerPoint presentation prepared by the manufacturer. This presentation, along with the list of participants, should be sent to HAS via the SESAME platform at least 8 days before the date of the meeting. The presentation should focus on the list of issues send by HAS. The clinical background and the mechanism of action of the medicinal product should not be presented, if no issues are raised by HAS on these topics.

The two hour face to face meeting

The meeting takes place on HAS premises on the date pre-specified in the early dialogue calendar. HAS will inform the manufacturer who from HAS will attend the meeting. The meeting is preferred face to face, but tele/video conference can be considered.

After the meeting

The manufacturer is responsible for the meeting minutes and should send the draft minutes to HAS within 10 days after the meeting. Meeting minutes will not be published. HAS will provide final recommendations in response to the questions raised by the manufacturer 20 days after the face-to-face meeting. If one or several patients were consulted by the HAS, the minutes of this consultation will be appended to the final recommendations (pending prior agreement from patient[s]).

ACCELERATED PROCEDURE

75 days in total

This procedure concludes 75 days following submission of the briefing document and does not include a face-to-face meeting.

2 months after submission of the briefing document

In response to the submitted questions HAS will share with the manufacturer draft written recommendations The manufacturer has 10 days to submit requests for clarifications. HAS will share final recommendations and close the procedure. IF HAS has consulted patients, the minutes of the consultations will be included in the final recommendations (pending prior agreement from the patient[s])

APPOINTMENTS

Appointments will be provided along a prescheduled calendar for the standard and accelerated procedures

The timelines, including the date of the face-to-face meeting, depend on the submission date.

Standard procedure

Timelines for national early dialogues on medicinal products

PROCÉDURE STANDARD
STANDARD PROCEDURE

Demande de RP déposée avant le *ED request submitted by*	Détermination de l'éligibilité *Feedback on eligibility*	Soumission du *briefing document* *Briefing document submission*	Détermination de la procédure *Choice of procedure by HAS*	Envoi de la *list of issues* *List of issues sent*	Envoi de la présentation pour le rendez-vous face-face *Face-to-face meeting slides sent*	Rendez-vous face-face *Face-to-face meeting*	Envoi des minutes *Meeting minutes sent*	Envoi des réponses écrites finales *Final recommendations sent*
13/05/2020	20/05/2020	19/06/2020	26/06/2020	31/07/2020	09/09/2020	17/09/2020	27/09/2020	07/10/2020
17/06/2020	24/06/2020	24/07/2020	31/07/2020	07/09/2020	14/10/2020	22/10/2020	01/11/2020	11/11/2020
03/07/2020	22/07/2020	21/08/2020	01/09/2020	05/10/2020	11/11/2020	19/11/2020	29/11/2020	09/12/2020
29/07/2020	31/07/2020	04/09/2020	11/09/2020	19/10/2020	25/11/2020	03/12/2020	13/12/2020	23/12/2020
09/09/2020	16/09/2020	16/10/2020	23/10/2020	30/11/2020	06/01/2021	14/01/2021	24/01/2021	03/02/2021
07/10/2020	14/10/2020	13/11/2020	20/11/2020	18/12/2020	03/02/2021	11/02/2021	21/02/2021	03/03/2021
12/11/2020	18/11/2020	18/12/2020	18/12/2020	01/02/2021	10/03/2021	18/03/2021	28/03/2021	07/04/2021
09/12/2020	16/12/2020	15/01/2021	22/01/2021	01/03/2021	07/04/2021	15/04/2021	25/04/2021	05/05/2021
13/01/2021	20/01/2021	19/02/2021	26/02/2021	02/04/2021	12/05/2021	20/05/2021	30/05/2021	09/06/2021
10/02/2021	17/02/2021	19/03/2021	26/03/2021	03/05/2021	09/06/2021	17/06/2021	27/06/2021	07/07/2021
03/03/2021	10/03/2021	09/04/2021	16/04/2021	24/05/2021	30/06/2021	08/07/2021	18/07/2021	28/07/2021

Accelerated procedure

Calendrier des rencontres précoces nationales pour les médicaments en cours de développement clinique
Timelines for national early dialogues on medicinal products

PROCÉDURE ACCÉLÉRÉE
ACCELERATED PROCEDURE

Demande de RP déposée avant le *ED request submitted by*	Détermination de l'éligibilité *Feedback on eligibility*	Soumission du *briefing document* *Briefing document submission*	Détermination de la procédure *Choice of procedure by HAS*	Envoi des réponses écrites *Final recommendations sent*	Demandes de clarifications *Requests for clarifications sent*	Envoi des réponses écrites finales *Final recommendations sent*
13/05/2020	20/05/2020	19/06/2020	26/06/2020	01/09/2020	11/09/2020	16/09/2020
17/06/2020	24/06/2020	24/07/2020	31/07/2020	22/09/2020	02/10/2020	07/10/2020
03/07/2020	10/07/2020	25/08/2020	01/09/2020	23/10/2020	02/11/2020	06/11/2020
24/07/2020	31/07/2020	04/09/2020	11/09/2020	03/11/2020	13/11/2020	18/11/2020
09/09/2020	16/09/2020	16/10/2020	23/10/2020	15/12/2020	31/12/2020	05/01/2021
07/10/2020	14/10/2020	13/11/2020	20/11/2020	12/01/2021	22/01/2021	27/01/2021
04/11/2020	11/11/2020	11/12/2020	18/12/2020	09/02/2021	19/02/2021	24/02/2021
09/12/2020	16/12/2020	15/01/2021	22/01/2021	16/03/2021	26/03/2021	31/03/2021
13/01/2021	20/01/2021	19/02/2021	26/02/2021	20/04/2021	30/04/2021	05/05/2021
10/02/2021	17/02/2021	19/03/2021	26/03/2021	18/05/2021	28/05/2021	02/06/2021
03/03/2021	10/03/2021	09/04/2021	16/04/2021	08/06/2021	18/06/2021	23/06/2021

HAS Actions de la HAS *HAS actions*

Actions de l'entreprise du médicament *Applicant actions*

https://www.has-sante.fr/jcms/c_1625763/fr/deposer-une-demande-de-rencontre-precoce

SOURCES

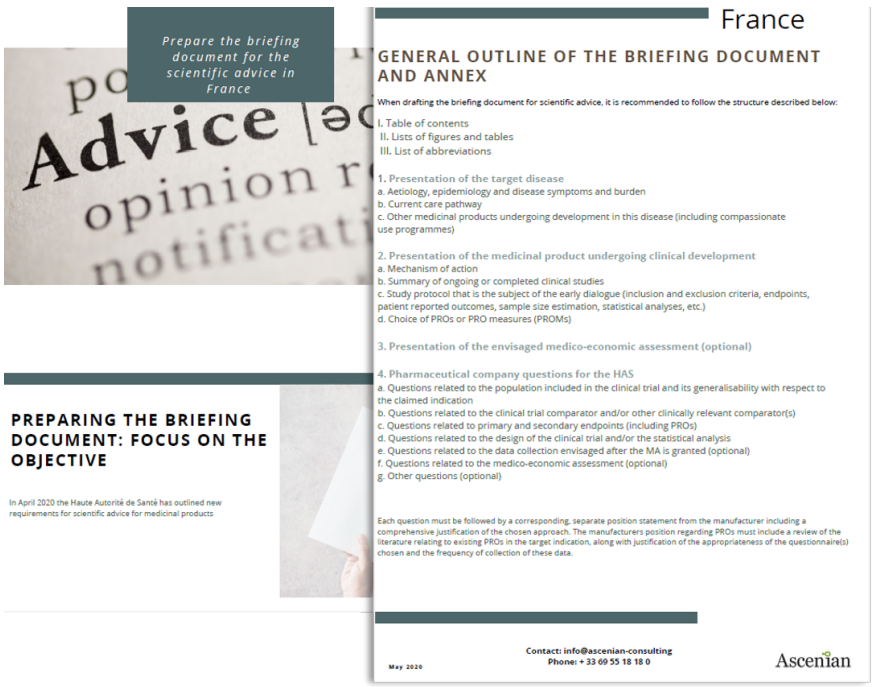
The following sources have been considered

1. New process for early dialogues - medicinal products
https://www.has-sante.fr/jcms/c_1625763/fr/deposer-une-demande-de-rencontre-precoce

GLOSSARY

HAS - Haute Autorité de Santé - High Commission for Health
CT - Commission de la Transparence - Transparency Commission
CEESP - Commission Évaluation Économique et de Santé Publique - Commission for Economic Evaluation and Public Health

YOU MAY ALSO WANT TO CONSIDER……



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