



**PATIENT INVOLVEMENT
IN HTA:**
EXPERIENCES FROM
THE FRONT LINE OF
HTA PRODUCTION

Panel session
HTAi Annual Meeting
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HAUTE AUTORITÉ DE SANTÉ

PATIENT INVOLVEMENT IN HAS HTA

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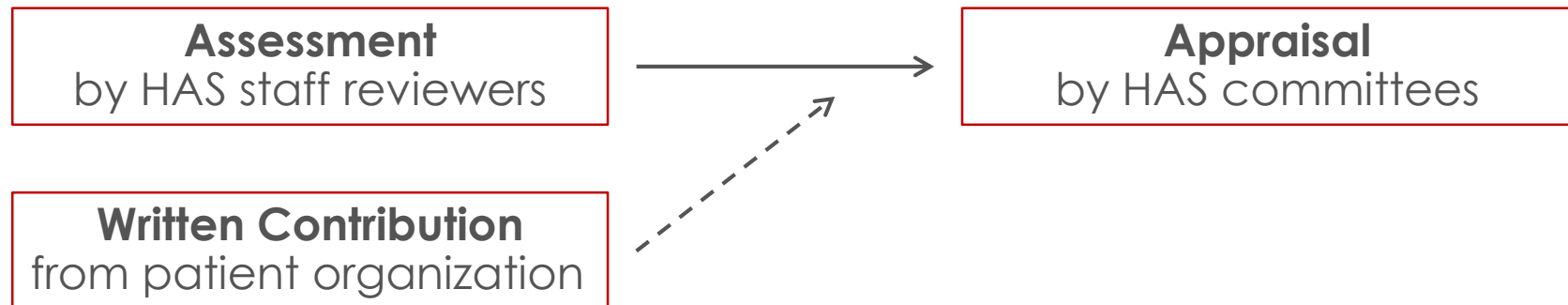
OVERVIEW OF PATIENT INVOLVEMENT IN HAS HTA

- **Public members in our three HTA committees**
 - Drug Clinical Appraisal Committee (two public members)
 - Medical Device Clinical Appraisal Committee (two public members)
 - Economic and Public Health Appraisal Committee (three public members)
- **Assessment of interventional procedures, diagnostics, public health interventions**
- Patient involvement is usual
 - At the different steps of procedure: Scoping phase, Drafting phase, Consultation, Approval of the assessment report
 - Hearings, participations as members of working group or written contribution



OVERVIEW OF PATIENT INVOLVEMENT IN HAS HTA

- **Rapid HTA**
 - What we look at in rapid HTA:
 - Drugs, Medical devices
 - Patient involvement in rapid HTA:
 - Since November 2016, a new procedure to foster the patient perspective in drug and medical device assessment



NB : in addition to this new procedure, there is traditionally also a possibility of hearing with the Medical Device Clinical Appraisal Committee



A KEY SUCCESS

- A strong participation from Patient Organizations in our new procedure on Patient Contribution to Rapid HTA
- From November 2016 to May 2017 :
 - We received 24 written contributions , about 22 drugs (out of 75 drugs opened to contribution), elaborated by 18 patient organizations
 - Concerning different diseases/ health situations : lymphoma, myopathy, pain, melanoma, alpha 1 antitrypsin deficiency...

Commission de la transparence - Commission de l'évaluation économique et de santé publique

Evaluation de : <ALFALASTIN>

Indication(s) du médicament concernées : <Alfalastin est indiqué dans le traitement substitutif des formes graves de déficit primitif en alpha-1 antitrypsine chez les sujets de phénotype PiZZ ou PiSZ avec emphysème pulmonaire>

Merci de lire le Guide pour les associations de patients et d'usagers avant de remplir le questionnaire. Une fois le questionnaire complété, nous vous conseillons de supprimer les encadrés d'aide (zones grisées) pour gagner de la place et améliorer la lisibilité.

1. Information sur l'association de patients

1.1 Informations générales sur l'association

Nom de l'association : ADAAT Alpha1-France

A KEY SUCCESS

- **Monitoring this initiative on Patient Contribution (*poster ID 523*)**
- Our monitoring protocol :
 - 15 questions and indicators that inform the 3 categories of the Donabedian model: structure, process, and outcomes
- Examples of questions :
 - To what extent do POs participate in this new activity? (Q5)
 - Are specific aspects of patient submissions explicitly considered in the HTA appraisal committee deliberations? (Q11)
 - Have POs gained a greater understanding of the decision-making process? (Q12)



Questions about structure (HAS organization)

- Q1. Does the **internal information flow** function well? (Handling of files from firms, posting necessary information once a week about coming assessments, information to interested POs).
- Q2. Are the **dedicated ways of contacting HAS** (email, phone number) used and what for?
- Q3. What are **the resources (time, personnel)** required to accomplish this new process?

Questions about process

- Q4. **Do firms accept** that HAS publishes information about future assessments online? (name of the product+ therapeutic indication) (this information reveals their request for coverage, an aspect of commercial secrecy).
- Q5. To what extent **do POs participate** in this new activity?
- Q6. Does the **submission template** meet HAS' and POs' needs?
- Q7. Are the **explanations and documents** dedicated to POs (on HAS website) sufficient?
- Q8. Do **POs have sufficient time** to contribute?
- Q9. Are **the mechanisms for staff and committee members for accessing the content submitted by patients satisfactory?** (time to read, clarity of the submission, interest of a short presentation at the beginning of the committee discussion? Interest and possibility of asking PO for complementary information?)
- Q10. Is there a need to supplement the **standard submission template** with additional specific questions or hearings?

Questions about outcomes

- Q11. Are specific aspects of patient submissions **explicitly considered** in the appraisal committee deliberations?
- Q12. Have POs gained a **greater understanding** of the decision-making process?
- Q13. Do POs consider that their contribution to this procedure **will be of benefit to them** in other areas of their work?
- Q14. Are POs **satisfied** with this procedure?
- Q15. Does this new procedure provoke **reflections** about our current methods?



CHALLENGES

- **Cultural issues**
 - According to the types of technology/ assessment, enough clarity on what we can obtain from the perspective of patients? Involving patients seen as everyone's responsibility?
- **Methodological/ technical issues**
 - Literature research on patient perspective?
- **Organizational issues**
 - How and to what extent to standardise the involvement of patients across our guidance/guidelines programmes?
 - What involvement at the phase of topic selection?



WAYS TO OVERCOME CHALLENGES

- **Learning from our rapid HTA initiative**
- Trying to be clear on how we take account of patient perspective in our discussions/ reports, generalizing a formal feedback process, putting in place some indicators ...
- **A transversal HAS working group about patient involvement methods**
- One individual from each HAS department. Common lexicon, pooling of tools, ...
- **A patient representative on the new HAS Board (2017)**
- **A new strategic project for HAS HTA at the beginning of 2018**
- An important axis will be dedicated to Patient involvement



AGENCY CONTACT DETAILS

- HAS website www.has-sante.fr
 - English version https://www.has-sante.fr/portail/jcms/r_1455081/Home-page
- Patient contribution to rapid HTA https://www.has-sante.fr/portail/jcms/c_2666630/fr/contribution-des-associations-de-patients-et-d-usagers-aux-evaluations-de-medicaments-et-dispositifs-medicaux
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