Economic Evaluation of Medical Devices By the French National Authority (2014-2022): Where Do We Stand?

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Introduction

Since October 2013, the French National Authority for Health (HAS) has been assessing the cost-effectiveness of healthcare products and technologies presumed to be innovative and likely to significantly impact Health Insurance expenditure.

A product is presumed to be innovative if the manufacturer claims an added medical benefit (Levels 1 to 3 on a scale of 1 to 5). Before 2022, a significant impact on Health Insurance expenditure was defined as an impact on the organization of care, professional practices or patient care conditions OR when expected sales are equal to or greater than twenty million euros a year. These eligibility criteria have recently moved.

For drugs, a third criterion has been added. Any advanced therapy medicinal product (ATMP) must submit an economic assessment.

For medical devices, the criterion of organizational impact has been removed, which reduces the eligibility requirements for medical devices (MDs).

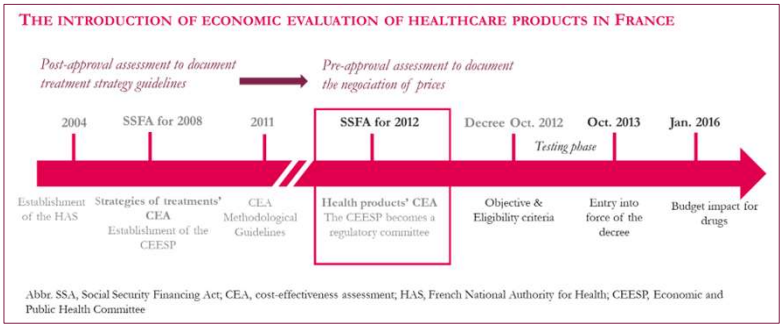
Drummond and al. noted the relative lack of economic evaluations of MDs as compared with pharmaceuticals and questioned whether devices have any special characteristics that inhibit their assessment[1].

The aim of this analysis of the opinions issued by the CEESP on medical devices is to describe the main limitations identified in the assessments carried out by manufacturers.

Methods

The purpose of the survey is to allow for a descriptive analysis of the CEESP opinions published between 2014 and 2022.

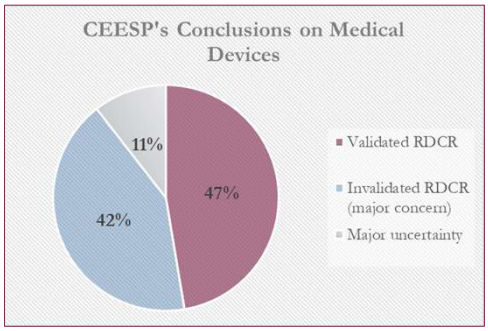
The nature of the methodological limitation and the level of concern (Major, Important, Minor) were extracted from the Vyoo Agency Database which compiles all the opinions issued by the CEESP since its creation.



Results

Description

- 195 opinions were published between 2014 and 2022 (173 drugs, 17 medical devices & 6 vaccines) in 204 indications (179 drugs, 19 medical devices & 6 vaccines).
- 17 opinions on MDs with 16 cost-effectiveness analyses (one dossier included only a budget impact analysis)
- 10 MDs assessed taking into account the incremental versions.
- Cardiology accounts for 79% of indications assessed

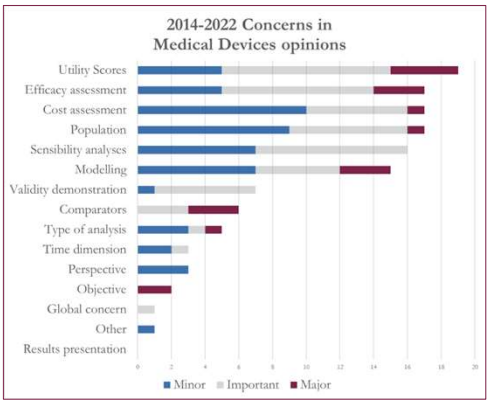


Medical Devices & Pharmaceuticals Comparison

- The result of the assessment has been validated by the CEESP for 47% (8/19) of the indications. The validation rate was 55% (99/179) for pharmaceuticals. This discrepancy can partially be explained by the resubmission of the same model for different versions of the MD keeping the same concerns.
- The invalidation of MDs' results was mainly explained by a major concern (42%, 9/19). The major uncertainty was less frequent (11%, 2/19). These rates in drug opinions were 33% (59/179) and 12% (22/179) respectively.

Main items with a methodological concern

- Utility score assessment is the main source of methodological limitations (20 concerns in 16 ACE), with a major concern in more than 25% of cost-effectiveness analyses (5/16 ACE). In drug appraisals, efficacy is the first source of methodological limitation (323 concerns in 173 ACE), with 25% of the dossiers with at least one major concern (43/173 ACE).
- Efficacy assessment is the 2nd source of methodological limitation (17 concerns in 16 ACE), with a major concern in almost 20% of cost-effectiveness analyses (3/16 ACE). One issue was the absence of data specific to the current version. The updated HAS guidelines included a clarification: "In the absence of specific data on the device for which the request is made, and when the changes are incremental, extrapolation of the data available for prior versions is acceptable, provided that the incremental character of the changes is documented."
- Cost assessment and population definition are the third sources in terms of total methodological limitations (17 concerns each, but with only one major concern).
- Modelling is the third source in terms of major concerns with comparators and objective definition.
  - The Markov model has been used in more than 80% of cost-effectiveness analyses (13/16 ACE). The criticisms focused on the structure, including the clinical plausibility of the states and the criteria for their definition (8/11 concerns).
  - The later ones have been criticized in old submissions (before 2018).



Conclusion

No methodological specificities were identified for the economic evaluation of medical devices compared to drugs, except for the evaluation of incremental versions. The principal hurdle to tackle was the utility score assessment.

References

1. Drummond, M.F., Tarricone, R. and Torbica, A. (2018) Economic Evaluation of Medical Devices. In: Hamilton, J.H., (ed.) Oxford Research Encyclopedia of Economics and Finance. Oxford University Press , Oxford
2. HAS (2020) Choices in methods for economic evaluation. https://www.has-sante.fr/upload/docs/application/pdf/2020-11/methodological_guidance_2020_-choices_in_methods_for_economic_evaluation.pdf