HAUTE AUTORITÉ DE SANTÉ

GUIDE

# Doctrine of the Commission for Economic and Public Health Evaluation

## CEESP evaluation principles for healthcare products for pricing purposes

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# Contents

# 1. Introduction

As part of the responsibility of the French National Authority for Health (HAS)[1] for assessing the cost-effectiveness and budget impact of healthcare products liable to offer moderate to major therapeutic improvement and have a significant impact on National Health Insurance expenditure, the Commission for Economic and Public Health Evaluation (CEESP) issues an economic opinion which is sent to the Healthcare Products Pricing Committee (CEPS), with a view to guiding price negotiations for these products by the CEPS. The economic opinion is delivered independently from that issued by the HAS Transparency Committee (CT) or Medical Device and Health Technology Evaluation Committee (CNEDIMTS).

Placing the economic analysis[2] in the reimbursable care package regulation and price-setting process determines the scope of the findings issued as to the cost-effectiveness or budget impact of healthcare products and the key messages conveyed by the CEESP to public decision-makers. The Commission's deliberations are aligned with this regulatory context, but not necessarily confined to it, if the Commission is of the view that public decision-makers should be made aware of relevant information.

This doctrine document has been drafted not only for actors responsible for negotiating the prices of healthcare products, but also for any person responsible for implementing health policies, conducting economic analyses of the products concerned, as well as for the general public (patients, healthcare system users, etc.).

It stems from the CEESP's resolve to:

- elucidate the drafting process involved when delivering opinions;
- ensure consistency among delivered opinions and equal treatment of submissions in the light of current knowledge;
- provide information to help interpret opinions.

The CEESP doctrine defines the general framework elucidating:

- the grading of methodological reservations expressed during the technical appraisal of manufacturers' submissions;
- the Commission's statements regarding its findings;
- the key messages that it wishes to convey to public decision-makers, especially with a view to negotiating healthcare product prices.

It is not the CEESP's position on the methodology for economic analysis. On this point, manufacturers should refer to the methodological guidance documents published for economic evaluations and for Budget Impact Analyses (BIAs), respectively.

The doctrine is based on jurisprudence data built from the CEESP's experience in its role in the **economic evaluation** of healthcare products and from all the deliberations made during meetings.

The doctrine is designed to evolve, if the CEESP deems it necessary, in order to account for changes in regulations or context, for example.

[1] Article R. 161-71-3 of the French Social Security Code (in French)

[2] Hereinafter in the document, the term economic analysis is used to refer to economic evaluations, particularly cost-outcome analyses (COAs) based on efficiency, and budget impact analyses (BIAs).

# 2. Methodological compliance

## 2.1. Objective of the economic analysis

The CEESP is mindful of the definition of the objective of the economic analysis and may be required to redefine it if the approach used is not in line with the objective defined by the manufacturer (e.g. analysis conducted on a specific population or on a portion of the marketing authorisation indication or the indication for which inclusion in reimbursement lists is requested, given the data involved). This redefinition may give rise to a methodological reservation, particularly in the case of a substantial proportion of the target population for whom the cost-effectiveness or budget impact are not assessed.

If the manufacturer demonstrates that it is not possible, in the light of the data available, to define the **cost-effectiveness frontier** with all clinical relevant options, the CEESP notes the lack of **cost-effectiveness evaluation** in respect of the product, and analyses, where applicable, the economic outcomes furnished by the manufacturer within the scope of a clearly redefined objective.

> **The CEESP focuses on:**
> - defining a clear and precise objective, in line with the data involved;
> - the consistency of the analysis developed relative to the defined objective;
> - the link between the definition of the objective and the various indications described by the manufacturer, especially that of the marketing authorisation and that of the application for reimbursement.

## 2.2. Methodological reservation principle

The economic analysis must comply with the methodological principles detailed in HAS economic evaluation guidance documents, in order to produce valid information.

On the basis of the technical appraisal of the HAS Economic and Public Health Evaluation Department (SEESP) and its critical analysis of the application submitted by the manufacturer, the CEESP may express reservations on the methodology used to generate the data involved in the economic evaluation (e.g. efficacy, safety, utility score, costs) or on the methodological choices used in the model.

Methodological reservations refer to a specific and clearly identified methodological item. Several reservations may therefore be expressed on the same aspect of the evaluation, for example, the cost or utility evaluation may include reservations on the measurement method and on the valuation method.

The methodological reservations may relate to the base case analysis, namely the primary analysis and the associated sensitivity analyses. Supplemental or exploratory analyses may be the subject of critiques or of limitations within the scope of the technical analysis, but are not subject to formal methodological reservations.

> **The CEESP focuses on:**
> - expressing reservations on strictly methodological arguments;
> - expressing reservations on a specific and clearly identified methodological item.

## 2.3. Grading of reservations

A reservation is expressed when a methodological choice is deemed not to comply with the current recommendations. The grading of the reservation is dependent on the acceptability of the argument put forward by the manufacturer and on the expected impact of this methodological choice on outcomes, particularly in terms of uncertainty.

The grading of the reservation is necessarily dependent on the product assessed and on the analysis context. In this way, the impact of non-compliance of a quality of life evaluation method will increase if health-related quality of life is a significant outcome of the assessed product, or more broadly a key item in respect of the disease.

**Minor reservation**: item deemed to fail to comply with the current recommendations, but which is justified or which has a negligible expected impact on the findings.

**Important reservation**: item deemed to fail to comply with the current recommendations, which can be justified, with a significant expected impact on the findings (particularly in terms of uncertainty). An important reservation does not call into question the validity of the economic evaluation but challenges the robustness of the quantitative outcomes set out or their proposed interpretation.

**Major reservation**: item deemed to fail to comply with the current recommendations which invalidates all or part of the economic evaluation. The arguments associated with this item are not necessarily sufficient: a major shortcoming, even if it is justified, means that the analysis is no longer valid or informative.

### In the case of important or minor reservations

The CEESP is of the view that the method on which the **Cost-Outcome Analysis** (COA) or the BIA of the healthcare product assessed in the indication population is based is acceptable, despite raising some reservations. The CEESP is of the view that a combination of multiple important reservations does not result in a major reservation.

### In the case of at least one major reservation

The CEESP is of the view that the method on which the COA or the BIA of the healthcare product assessed in the indication population is based is not acceptable.

A major methodological reservation implies that the outcomes linked with this major methodological problem cannot be considered valid and are therefore non-interpretable. These outcomes are therefore mentioned in the opinion as a manufacturer claim invalidated by the CEESP.

The CEESP may however take into consideration and present some economic outcomes that it deems relevant for public decision-makers, or more generally, for the population as a whole, concerning items beyond the scope of the major methodological reservation.

> **The CEESP focuses on:**
>
> - grading a methodological reservation accurately in view of the recommendations in force, the impact on the outcome of the economic analysis and the analysis context;
> - the scope of the major reservation, in order to be able to extract any relevant information for public decision-makers not invalidated by the major reservation(s).

# 3. The CEESP's findings

Methodological quality of the economic analysis is a prerequisite for favourable CEESP's findings in respect of cost-effectiveness or budget impact, but is not enough on its own.

The CEESP carries out interpretation work based firstly on the characterisation of the level of uncertainty associated with relevant economic outcomes. More broadly, the CEESP contributes to the elucidation and discussion of the items of interest of the analysis.

## 3.1. Relevant economic outcomes

The relevant outcomes of the economic analysis are presented in summarised format so as to provide a basis for the Commission's findings.

If the CEESP is of the view that the COA or BIA has a major methodological shortcoming, it does not include the incremental cost-effectiveness ratio (ICER) or the budget impact estimated by the manufacturer in the opinion. However, if ideemed relevant it may present other economic outcomes or any other data helping elucidate the decision which would not be compromised by the major methodological reservation.

If there is no major methodological reservation the CEESP analyses the outcomes estimated by the manufacturer in terms of uncertainty or of transferability to routine practice. The main parameters having an impact on the outcome and the main sources of uncertainty are identified. However, the ICER or the budget impact is not systematically presented, and is predicated by the uncertainty qualification as discussed in section 3.2 below.

If relevant and insofar as possible, the CEESP shows the determining factors of a potential imbalance between the expected efficacy gain and the additional cost generated by the product.

Under certain conditions the CEESP is of the view that outcomes of analyses conducted by the SEESP may be presented: these analyses help demonstrate or support a point of interest of the analysis but do not substitute the outcome of the main analysis. These analyses are not intended to be systematic once there is a shortcoming in the analysis provided by the manufacturer.

> **The CEESP focuses on:**
> - identifying the relevant economic outcomes or any data supporting the decision on price negotiation.

## 3.2. Uncertainty qualification

The degree of confidence that can be attributed to the outcomes of the economic analysis of a product is dependent on the uncertainty (e.g. parametric uncertainty) generated by the methodological choices and the underlying data available. After an accurate identification of the key parameters which have the presumed high expected impacts on the outcomes of the analysis, the CEESP qualifies the level of overall uncertainty surrounding the outcomes of the economic analysis provided.

**The uncertainty is studied appropriately and the outcomes are deemed to be robust**

When the parameters impacting outcomes the most are identified and tested in sensitivity analyses, the uncertainty may be studied appropriately and the outcomes discussed.

Where possible, the CEESP seeks to quantify the uncertainty by specifying the lower and upper ICER / net benefit (NB) or budget impact values potentially achieved using the most and least favourable parameters, assumptions or modelling choices in respect of the product. These scenarios, whether they are favourable for the assessed product or conservative, must be based on plausible choices in view of the knowledge available on the product at the time of evaluation.

As the prices of the product and of comparators are frequently a key component of the total cost of care the CEESP endeavours to mention, where relevant, the impact of these prices on the ICER / NB or on the budget impact.

The CEESP may accept that the level of uncertainty is unquantifiable for some parameters but that it can be assessed qualitatively, referring to a likely miscalculation of the outcomes where permitted by the information available.

#### The uncertainty is major

The overall uncertainty generated by all of the methodological choices or by the data entered in the model may, in some cases, be major, including in qualitative terms even if no particular source of uncertainty is associated with a methodological choice stemming from a major reservation. This scenario may be encountered when the evaluation is based on a series of strong assumptions applied to bridge a gap in current knowledge (e.g. immature clinical data, available data not pertaining to the right population, poorly defined positioning in the therapeutic strategy).

In this case the CEESP finds in favour of major overall uncertainty and the outcomes of the COA or BIA are not deemed valid and interpretable.

The overall uncertainty can be described as major when:

- this uncertainty cannot be assessed quantitatively and/or qualitatively
- the estimation of some key parameters is too uncertain and leads to unstable outcomes;
- multiple methodological reservations have been expressed, leading to uninterpretable outcomes.
- the assumptions or methodological choices in respect of the analysis are not plausible with regard to routine practice.

> **The CEESP focuses on:**
> - specifying the level of uncertainty surrounding the outcomes of the economic analysis.

## 3.3. Findings of the economic analysis

Once the methodological compliance and uncertainty have been analysed the CEESP is able to decide whether or not it is possible to include the cost-effectiveness and budget impact of the healthcare product in the indication for which it is liable to be reimbursed.

Where possible, the CEESP may also identify the favourable conditions for product cost-effectiveness.

### 3.3.1. Findings of the cost-outcome analysis

The CEESP's findings stemming from the COA concern the proof of cost-effectiveness and the other economic items documented by the analysis.

As regards the cost-effectiveness criterion, the different types of findings that can be issued by the CEESP are as follows:

- the product is cost-effective; the product is dominant;
- the product's cost-effectiveness is documented with the estimation of an ICER / NB, the uncertainty is studied appropriately and the outcomes are deemed to be robust; in this case the CEESP presents and discusses the outcomes of the probabilistic analyses. For example, when comparing two strategies the CEESP presents the willingness to pay to achieve an 80% probability that the product is cost-effective, or when multiple comparators are included, the CEESP presents the outcomes of multi-option acceptability curves;
- there is no proof of cost-effectiveness due to a major methodological reservation invalidating the outcomes of the economic evaluation;
- there is no proof of cost-effectiveness due to major overall uncertainty;
- The product is not cost-effective; the product is not on the cost-effectiveness frontier, i.e. the product is dominated;
- it is not possible to assess the cost-effectiveness in view of the clinical data available at the time of submission of the application.

In its findings the CEESP also decides on other relevant items such as:

- targeted comparison to a comparator of interest, independently of other possible options (e.g. the option used most in routine practice);
- the outcomes of a COA on another criterion (e.g. cost per event avoided).

### 3.3.2. Findings of the budget impact analysis

The outcomes of the BIA and the main sources of uncertainty are mentioned in the CEESP's findings.

In particular the percentage increase in National Health Insurance expenditure for care in the indication, following introduction of the product, is specified.

### 3.3.3. Findings in respect of conditions for cost-effectiveness

The data demonstrated by the CEESP on economic outcomes and their degree of uncertainty shed light on the conditions of product cost-effectiveness.

The term " conditions for cost-effectiveness" refers to the sources of leverage available to obtain superior product cost-effectiveness which is expressed in different ways perhaps by a reduction in the ICER, or by a reduction in the risk of the product being more expensive and less effective, or by the product being on the cost-effectiveness frontier, or by the probabilities of maximising the NB for lower willingness to pay values, etc.

The sources of leverage to be used to observe these improvements can be in particular price settings, price regulation mechanisms, the reimbursement population optionally defined in subgroups, role in the therapeutic strategy, prescription conditions, or real-life follow-up of benefits of the product in terms of efficacy and quality of life and costs.

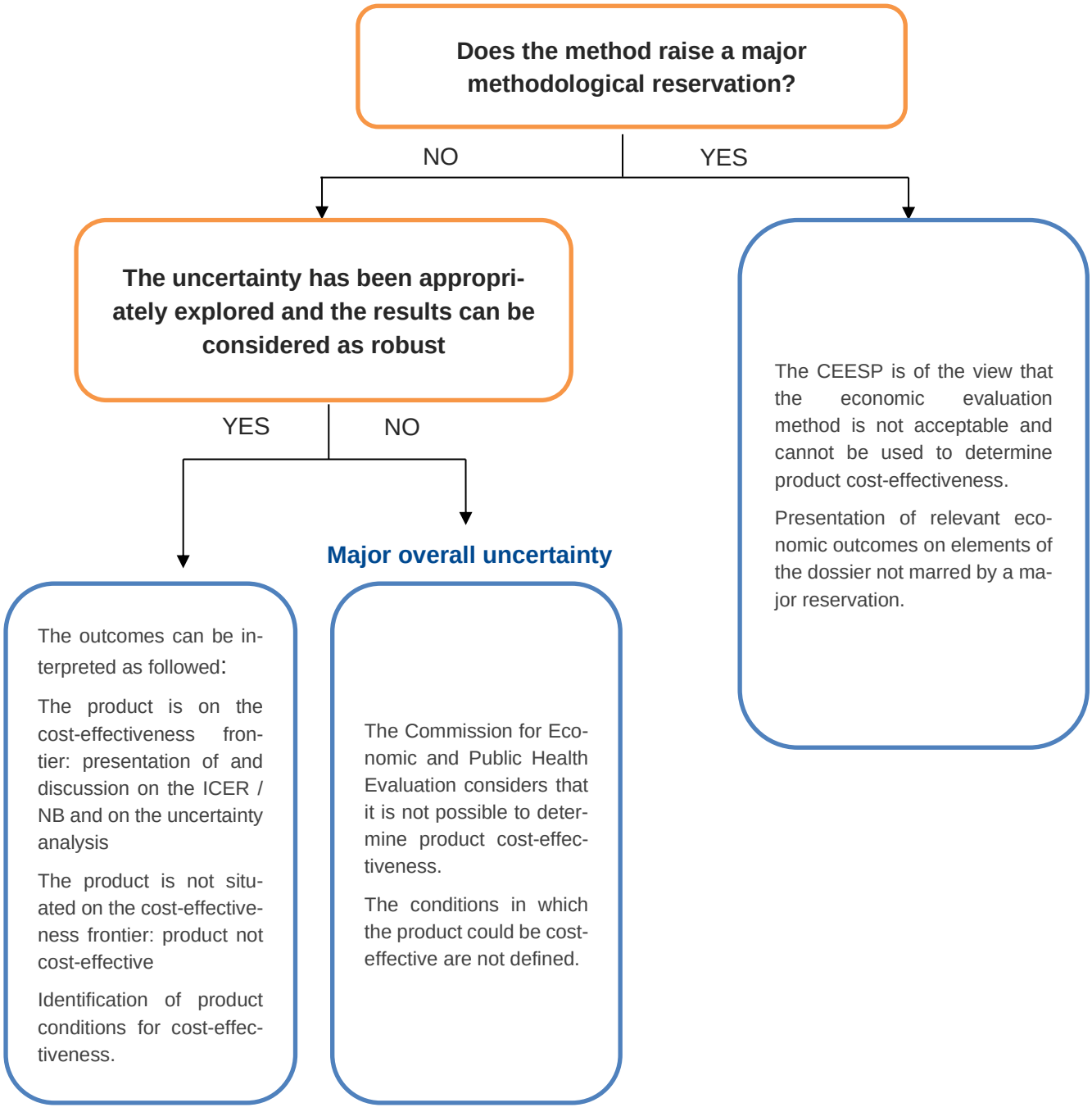
The CEESP sets out the conditions to be met to improve **technical cost-effectiveness**, as well as the budget impact of the healthcare product, e.g.:

- a level of efficacy and safety to be achieved;
- action on the claimed price;
- restriction to one subgroup in particular;
- transferability of simulated patient characteristics to those of patients treated in routine practice.

In particular, the CEESP may have cause to present analyses aimed at identifying the price for which the healthcare product is on the cost-effectiveness frontier or to achieve a predefined ICER/NB level (e.g. equivalent to that obtained on another subgroup, equivalent to the ICER of a comparator deemed similar versus the same comparator).

The CEESP may also be of the view that product conditions for cost-effectiveness have not been met at the claimed price or when the scope of the economic evaluation is very restricted in relation to the indication for which reimbursement has been requested.

The diagram below summarises the main stages of CEESP analyses and findings.



# 4. The CEESP's position to guide public decision-making

## 4.1. Taking a position on the levels of cost-effectiveness and budget impact of healthcare products

At the present time in France public decision-makers do not regulate prices and rates of healthcare products with reference to a particular cost-effectiveness threshold. Nevertheless, in the context of public funding of the product the CEESP may help shed light on the cost-effectiveness ratio and the estimated difference in effectiveness under the price and target population conditions claimed by the manufacturer. The CEESP is also entitled to deliver an opinion on the ICER level that it can rank as high, very high, or extremely high. Qualitative opinions associated with ICERs stem from deliberations on a case-by-case basis and account for the estimated ICER value along with other factors to be taken into consideration with regards to evaluating the context (methodological quality and associated level of uncertainty).

- The acceptability of certain outcomes may also be discussed with regard to willingness to pay thresholds accepted in other countries or outcomes published in the literature for comparable evaluations.
- It is worth noting that good methodological quality, or being situated on the cost-effectiveness frontier, or a specific context (unmet medical need, rare disease, paediatric context, etc) does not prejudge the acceptability of a certain ICER level for the community.

Similarly, the CEESP ranks the amount of the expected budget impact, particularly when it is provided by a product in which the cost-effectiveness result is invalidated due to a major methodological reservation or a major uncertainty which does not compromise the BIA outcomes. The CEESP also decides on the uncertainty associated with the estimated budget impact.

Through this ranking the CEESP seeks to make public decision-makers aware of the risks of disproportionate additional costs of certain products with respect to limited, or even uncertain, health gains, and substantial budget impacts liable to jeopardise the equity and sustainability of the national healthcare system, even if this expenditure concerns a disease of very low prevalence. Hence, the CEESP examines the compatibility of these estimated or expected ICER / NB and budget impact levels with optimal and equitable allocation of collective resources.

## 4.2. Taking a position on claimed price levels to guide the implementation of price regulation mechanisms

Claimed prices in respect of some products may seem excessive in a healthcare expenditure budget context (ONDAM) and in the absence of robust evidence of improvements to patient health and quality of life. The prices negotiated for products introduced onto the market in the absence of a therapeutic alternative or with a new mode of action represent anchored prices that need to be taken into account by the community with a risk of price increases for products arriving at a later stage or in other indications.

In order to provide public decision-makers with the most comprehensive, clear, and useful information in opinions the CEESP may share its ideas on the price regulation mechanisms to be implemented in the price negotiation context with manufacturers. Indeed, it is of the view that the pricing is an action variable for public decision-makers and particularly needs to be set accounting for the uncertainty in

respect of expected health gains in routine practice. These suggestions are discussed in the light of all the data made available within the scope of the application evaluation.

### Significant reduction in claimed price

Claimed prices are very often the source of very high ICER and budget impact amount levels. In this case, the CEESP is of the view that a very significant price reduction is one of the conditions of the product to become cost-effective, and that, at the claimed price, product conditions for cost-effectiveness are not met. This statement is especially true when the outcomes of the economic evaluation are marred by a high level of uncertainty.

### Similar price to those of relevant comparators

Failing comparative data or in the case of insufficient evidence of health gains versus relevant comparators, the CEESP recommends a price negotiation mechanism tailored to this partial knowledge scenario by setting, for example, an equivalent price to that of comparators. This particularly applies to products that have been awarded a conditional marketing authorisation based on inconclusive data or products entering the marketed with early data.

The evaluations conducted on these products should be updated to be able to incorporate the knowledge to be acquired through randomised comparative data collection and use of the product in routine practice.

### Price regulation mechanism on a specific population

On one hand, the scope of the economic evaluation can be extremely restricted relative to the product indication associated with the request for inclusion on reimbursement lists and therefore the negotiation of the price of the product. There is nothing to guarantee that proof of cost-effectiveness of a product on a specific subgroup can be transferred to a wider population.

On the other, the economic evaluation can give rise to better outcomes in terms of cost-effectiveness for a specific subgroup.

In these cases, including the size of the population on which cost-effectiveness is assessed relative to the size of the population approved for reimbursement in price regulation mechanisms is one of the conditions of product cost-effectiveness.

### Regulation mechanism for product combinations

The mass deployment of expensive drug combinations, particularly in cancer treatment, highlights the benefit of regulating prices of treatments based on the combination as a whole. Significant price reductions in all the substances of the combination are frequently a condition for the combination to become cost-effective, given that the price of the combination must take into account the specificities of each substance (mode of administration, adverse effects and associated care costs).

# 5. Data collected in routine practice

Data collected in routine practice refers to any data collected outside clinical trials. They are generated following routine patient care provision and therefore reflect routine practice.

They are based on observational studies and taken from various sources (cohorts, compassionate use programme, registries, medico-administrative database queries, etc.).

## 5.1. Data used in the context of economic analyses

Data collected in routine practice contribute to economic analyses submitted by manufacturers, particularly data compiled in the early access context (e.g. compassionate use programme / temporary recommendations for use), data from existing cohorts / registries or analyses on medico-administrative databases.

They are a valuable tool particularly for:

- analysing the representative nature of simulated population characteristics compared to those of the French population treated or likely to be treated in routine practice;
- estimating the target population retained within the scope of the budget impact analysis;
- defining assumptions and estimating certain modelling parameters, particularly probabilities of transition from one health state to another;
- estimating treatment administration, treatment and disease follow-up, and adverse event management costs;
- providing quality of life data;
- calibrating economic modelling on certain parameters;
- helping validate the outcomes of the economic evaluation if they represent an independent data source from those used in the model.

The CEESP includes them in its uncertainty evaluation. Hence, they are deemed to be supplemental to data collected in the context of randomised clinical studies.

## 5.2. Post-inclusion supplemental data requests

Economic analyses take into account the current scientific and medical context as well as the data available at the time of the request (generally the inclusion of the product in reimbursement lists). Data collected under real conditions of use are therefore of crucial importance in healthcare product reassessments. They can also reduce uncertainty initially deemed to be major.

### 5.2.1. Objectives

Following its findings in respect of the economic analysis the CEESP drafts supplemental data requests. This information helps guide post-inclusion study requests so as to reduce the uncertainty associated with the outcomes or confirm or else assess cost-effectiveness and the budget impact through data from use in routine practice.

This involves setting out expectations in the context of future evaluations in the indication in question.

Some supplemental data requests may be included in the industrial commitments set out in the agreement with the CEPS.

### 5.2.2. Types of requests

Supplemental requests may pertain to:

- data that were not available or insufficiently known at the time of the first evaluation and which could be usefully collected to help support the outcomes in terms of cost-effectiveness or budget impact. These data are identified based on the highlighting, in the critical methodological analysis, of uncertain parameters and assumptions lacking in support which have an important impact on the outcomes of economic analyses;
- the methodological choices for which the CEESP has expressed important or major reservations. In the context of future studies these choices are expected to comply with HAS methodological recommendations;
- analyses not envisaged in the initial evaluation and for which the documentation is expected within the scope of a future evaluation: analysis in a particular population, specific cost study (e.g. micro-costing study in the context of a healthcare product which modifies care), or analysis of the organisational impact for disruptive innovations modifying the organisation of the healthcare system.

In any case, the objective is to enhance the uncertainty analysis and support, or assess, cost-effectiveness and budget impact outcomes by providing knowledge, particularly in respect of:

- the characteristics of the population actually treated in the French context;
- the actual conditions of use of the assessed healthcare product (length of treatment, discontinuation of treatment, compliance, etc.);
- the efficacy of the healthcare product under actual conditions of use in the French context with a longer follow-up period than in trials (overall survival period, progression-free survival period / recurrence / relapse, number of flare-ups, long-term effect of healthcare product (maintenance, decline or lack of effect), etc.);
- the frequency of onset of adverse events and the treatment regimen for these events under actual conditions of use;
- quality of life in the French population, as well as any other relevant measures from the patient's perspective capable of shedding light on the interpretation of outcomes (*patient-reported outcome measures* - PROMs);
- the impacts of the healthcare products on the healthcare system, professional practices and patient care.

Beside the actual conditions of use of the healthcare product the CEESP is mindful of ensuring that proof of cost-effectiveness is based on comparative efficacy data; the production of robust comparative efficacy and safety data is a necessary methodological prerequisite for conducting an cost-effectiveness evaluation.

### 5.2.3. Data source

In order to address these requests it is necessary to produce supplemental outcomes from data sources collected in an ad-hoc fashion (implementation of a pharmacoepidemiological study) or from pre-existing sources (medico-administrative databases, registries or cohorts).

The CEESP specifies, insofar as possible, whether the supplemental data requested require the set-up of a specific collection system or whether this need can be met by existing data.

# Conclusion

As specified above, the doctrine is designed to evolve if the CEESP deems it necessary in order to account for changes in regulations or context, for example.

The CEESP particularly notes the growing need to take better account of the organisational impact of the arrival of new health technologies on the market in its evaluations. This impact is now taken into consideration to define the eligibility of products for economic evaluation. The Commission is now seeking to cultivate more in-depth discussions on the economic evaluation of this impact in order to shed further light for public decision-makers. In parallel, the CEESP is seeking to initiate discussions on improving the economic evaluation of medical devices.

The CEESP would also like to point out its interest in providing contributions from patient and user associations. These contributions help reframe the scientific evaluation of healthcare products in the context of the disease as it is experienced by patients and those close to them (particularly caregivers). Furthermore, they could shed light on the need for care and on qualitative aspects of care and the healthcare system. In its opinions the CEESP systematically mentions patient contributions and summarises the main points of such contributions, where available. The Commission encourages patient and user associations to get more involved in the evaluation of healthcare products with a suitable methodology used to document the experience of the disease and the main points of concern for patients and those close to them (perceived quality of life, adverse effects, expected functional improvement, etc.).

More and more products are arriving on the market in the early phases of development (i.e. phase II), with relatively immature, sometimes non-comparative, data, potentially resulting in conditional MAs. For these products, economic outcomes are very often marred by substantial uncertainty, which makes validation difficult. In this context the CEESP might be required to adapt the description and discussion of this uncertainty in order to facilitate the use of its opinions by public decision-makers who find themselves having to negotiate a price or a rate without precise knowledge of the expected gain in efficacy.

Finally, as the CEESP's work is aimed at guiding resource allocation decisions in the healthcare system in its opinions, the Commission takes care to draw decision-makers' attention to the principle of equal access to care across the country. This issue arises more frequently for innovative therapies which are often associated with organisational and budget-related problems liable to give rise to social and regional inequalities.

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# Abbreviations and acronyms

| | |
|---|---|
| COA | Cost-outcome analysis |
| BIA | Budget impact analysis |
| MA | Marketing authorisation |
| ATU | *Autorisation temporaire d'utilisation* (Temporary authorisation for use) |
| RTU | *Recommandation temporaire d'utilisation* (Temporary recommendation for use) |
| NB | Net benefit |
| CEESP | *Commission d'évaluation économique et de santé publique* (Commission for Economic and Public Health Evaluation) |
| CEPS | *Comité économique des produits de santé* (French Healthcare Products Pricing Committee) |
| CNEDIMTS | *Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé* (Medical Device and Health Technology Evaluation Committee) |
| CT | *Commission de la transparence* (Transparency Committee) |
| HAS | *Haute Autorité de santé* (French National Authority for Health) |
| ICER | Incremental Cost-Effectiveness Ratio |
| SEESP | *Service d'évaluation économique et de santé publique* (Economic and Public Health Evaluation Department) |

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# Glossary

**Supplemental analysis**: analysis not required by the HAS, but which may be conducted to provide additional information (e.g. exploratory analysis of cost-effectiveness in subgroups, quality-of-life study, evaluation of the health of caregivers, PROM, PREM).

**Cost-outcome analysis (COA)**: type of economic evaluation making it possible to measure the incremental cost of a supplementary health unit, expressed in physical units (cost-effectiveness analysis) or utility (cost-utility analysis).

**Economic evaluation**: type of analysis that examines the difference in health outcomes provided by an intervention in relation to the difference in cost it generates.

**Cost-effectiveness evaluation**: type of economic evaluation that makes it possible to identify the cost-effectiveness frontier and estimate the ICER or INB of the interventions studied.

**Technical cost-effectiveness**: a health intervention is technically efficient if it is not dominated (strict or extended dominance). Technically efficient interventions make up the cost-effectiveness frontier.

**Allocative cost-effectiveness**: allocative cost-effectiveness characterises interventions that support the optimal allocation of collective resources, by maximising individual health benefits in a constrained budget.

**Cost-effectiveness frontier**: The interventions on the cost-effectiveness frontier are identified as all non-dominated interventions (strict or extended dominance).

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