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Medico-economic Evaluation of Healthcare Products. Methodology for Defining a Significant Impact on French Health Insurance Costs and Selection of Benchmarks for Interpreting Results

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Abstract – Decree No. 2012-1116 of 2 October 2012 on medico-economic assignments of the French National Authority for Health (*Haute autorité de santé*, HAS) significantly alters the conditions for accessing the health products market in France. This paper presents a theoretical framework for interpreting the results of the economic evaluation of health technologies and summarises the facts available in France for developing benchmarks that will be used to interpret incremental cost-effectiveness ratios. This literature review shows that it is difficult to determine a threshold value but it is also difficult to interpret then incremental cost effectiveness ratio (ICER) results without a threshold value. In this context, round table participants favour a pragmatic approach based on "benchmarks" as opposed to a threshold value, based on an interpretative and normative perspective, *i.e.* benchmarks that can change over time based on feedback.

Abbreviations. See end of article.

† Articles, analyzes and proposals from the Giens Workshops are those of the authors and do not prejudice the position of their parent organization.

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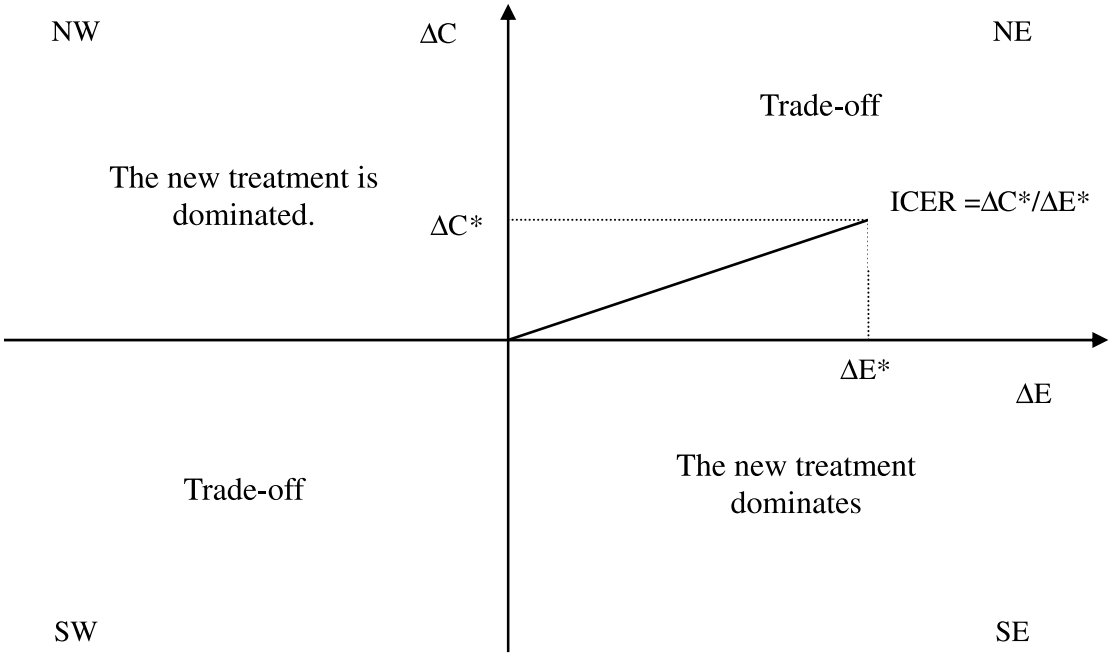

Fig. 1. Diagram outlining the cost/effectiveness plan.
ICER: incremental cost effectiveness ratio ; **NE**: northeast; **NW**: northwest; **SE**: southeast; **SW**: southwest.

1. Introduction

Decree No. 2012-1116 of 2 October 2012[1] on medico-economic assignments of the French National Authority for Health (*Haute autorité de santé*, HAS) significantly alters the conditions for accessing the health products market in France. One year earlier, the 2012 Social Security Finance Act[2] made medico-economic evaluation (alongside clinical added value, price of comparators and sales volumes) the fourth determinant factor in drug pricing.

The economic evaluation of healthcare products is imposed on those products that meet the following two cumulative conditions:

- a claim (or confirmation) of a level I, II or III improvement of the medical benefit provided (*amélioration du service médical rendu*, ASMR)/improvement of the expected benefit (*amélioration du service attendu*, ASA);
- the product or technology has or is likely to have a significant effect on Health Insurance costs given its impact on the organisation of care, professional practices or conditions for patient management and, if applicable, its cost.

Participants in round table No. 4 at the 2013 Giens Workshops (RT4), entitled, "Medico-economic evaluation of healthcare products. Methodology for defining a significant impact on French Health Insurance costs and selection of benchmarks for interpreting results" sought to answer the following questions: How do we define the notion of significant budgetary impact? How do we interpret the results of cost/effectiveness analyses?

The first of these issues has been the subject of a decision taken by the French National Authority for Health (Decision No. 2013.0111/DC/SEESP of 18 September 2013)[3] and a clarification in public correspondence signed by the presidents of the HAS and the Economic Committee for Health Products (Comité économique des produits de santé, CEPS). This paper will therefore focus solely on the elements of discussion between the participants and RT4 recommendations in relation to the second question.

2. The cost/effectiveness analysis: presentation of the framework for analysing and interpreting the incremental cost effectiveness ratio (ICER)

The medico-economic evaluation aim to determine the optimal allocation of resources for the healthcare sector by putting health outcomes and the cost of health technologies into perspective. Healthcare technologies are defined as "*all procedures likely to be used to promote health, prevent, diagnose or treat a disease or for rehabilitation or long-term care. They include medicinal products, devices, procedures and organisation in healthcare systems*" [International Network of Agencies for Health Technology Assessment, INAHTA].

By way of illustration, suppose that a new treatment is to be assessed in comparison to the actual management of a disease. Compared to this benchmark, the new treatment may prove more or less effective (ΔE*) and more or less expensive (ΔC*) [figure 1].