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# New French Coverage with Evidence Development for Innovative Medical Devices: Improvements and Unresolved Issues

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ABSTRACT

We describe here recent modifications to the French Coverage with Evidence Development (CED) scheme for innovative medical devices. CED can be defined as temporary coverage for a novel health product during collection of the additional evidence required to determine whether definitive coverage is possible. The principle refinements to the scheme include a more precise definition of what may be considered an innovative product, the possibility for device manufacturers to request CED either independently or in partnership with hospitals, and the establishment of processing deadlines for health authorities. In the long term, these modifications may increase the number of applications to the CED scheme, which could lead to unsustainable funding for future projects. It will also be necessary to ensure that the study conditions required by national health authorities are suitable for medical devices and that processing deadlines are met for the scheme to be fully operational. Overall, the modifications recently applied to the French CED scheme for innovative medical devices should increase the transparency of the process, and therefore be more appealing to medical device manufacturers.

***Keywords:*** coverage with evidence development, innovation, medical device, reimbursement.



## Introduction

In all health care systems, coverage decisions tend to be based on the best available evidence, with the aim of ensuring that resources are judiciously allocated [1]. This may result, however, in a binary "yes" or "no" approach that is biased against innovative and promising technologies for which few clinical data are available. This situation has applied to many innovative medical devices released to market in the European Union. European Union regulations concerning premarket evidence are currently inadequate, and there is often a lack of appropriate data to support the ability of new devices to respond to the expectations of policymakers in the context of a reimbursement process [2,3].

In France, device manufacturers can request the health authorities to reimburse medical devices via two routes [4]. First, reimbursement can be obtained if the characteristics of the device match an existing generic definition on the list of devices qualifying for reimbursement. In such cases, the manufacturer can automatically register the device without the need for any additional evaluation by the national health authorities. The second route available, particularly if the manufacturer is producing an innovative product and wishes to charge a relatively high price, is to apply for reimbursement to the National Committee of Medical Devices and Health Technologies (CNEDIMTS) [5]. This committee initially assesses the expected clinical benefit of the device to determine whether it is sufficient to merit reimbursement. It then evaluates the added clinical value of the device in comparison with existing technologies or alternative treatments [4,5]. In most cases, too few data are available to accurately assess the expected clinical benefit. Consequently, more than half the applications submitted to the CNEDIMTS each year are finally rejected or withdrawn because of a lack of data [6].

Several countries including France have acted to prevent the exclusion of promising technologies due to a lack of clinical evidence, by introducing the Coverage with Evidence Development (CED) scheme. This provides patients with provisional access to a new device while the necessary evidence is acquired to determine whether definitive coverage is warranted [1,7]. Five years after the introduction of the CED scheme in France, however, only two medical devices have benefited: a high-intensity focused ultrasound technique for treating prostate cancer and a retinal prosthesis system to treat patients with severe retinitis pigmentosa. In view of this relative failure, it was generally agreed that there was a need to reform the CED

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scheme. We describe here the history of the CED scheme for medical devices in France. We then present the modifications recently applied to this scheme by the French government. Finally, we discuss the potential improvements following these changes and the issues that remain unresolved.

## History of the French CED Scheme for Medical Devices

Conditional coverage for a new drug was first tested in France in 2003 [8]. It was agreed that risperidone would be reimbursed provided that the company performed studies to determine whether it improved patient compliance. In 2007, the CNEDIMTS proposed the creation of a CED scheme for innovative devices for which the committee was unable to determine the expected clinical benefit. As part of the initial project, the manufacturer was required to conduct a clinical trial on the basis of conditions defined by the CNEDIMTS itself. This early version of the scheme was never implemented. Two years later, a new project was launched, in Article L. 165-1-1 of the French Social Security Code [9]. This article, in application since March 2010, laid down the rules for a new evidence generation scheme for promising health products or procedures. On the basis of technological intelligence or applications for reimbursement, the CNEDIMTS could select eligible innovative devices; however, device manufacturers were not allowed to directly request the inclusion of their products in the CED scheme. The committee would issue an expert opinion that was then transmitted to the French Ministry of Health for a final decision. If the decision was positive, the Ministry of Health subsequently defined the conditions of the clinical trial. The requirements covered the number of patients, indications for use, funding period, and hospitals conducting the study. To our knowledge, over the past 5 years, several medical devices have been designated as eligible by the CNEDIMTS, in addition to the two cited above, yet the Ministry of Health has neglected to make any clear decisions. Consequently, a lack of innovative products is not the result of the CED scheme failure, but perhaps a lack of political will, possibly due to economic reasons.

## Recent Modifications to the French CED Scheme

In February 2015, a new decree came into force, modifying Article L. 165-1-1 [10]. This decree defines four criteria that must be met for a new device to be considered innovative: 1) the medical device must be novel and not simply an updated version of an existing product used for the same indications; 2) the medical device must only recently have become available on the market and not have been previously reimbursed by the French national health insurance agency for the indications concerned; 3) the available clinical data for the product must have clearly established the potential risks for patients and users; 4) the available clinical and/or economic data must have shown that the product is likely to a) provide significant clinical benefit for an unmet or insufficiently covered medical need or b) decrease health care expenditure due to its cost-effectiveness, although only if the device is at least as effective as the standard treatment.

Device manufacturers can now apply directly for the inclusion of their products in the CED program, either independently or in partnership with a hospital. For eligibility, applicants must submit a clinical or economic study project plan that meets three essential conditions (see Table 1). The application is still submitted to the CNEDIMTS for assessment, as well as simultaneously being submitted to the Ministry of Health. In addition to the study project, the applicant is asked to estimate the budget required to carry out the study and must make a formal commitment to provide the national health authorities with full access to the data collected. The decree specifies that the study data can be used by the Economic Committee for Health Products & Services (*Comité Economique des Produits de Santé* [CEPS]) during future price negotiations.

**Table 1 – Conditions required for clinical or economic studies submitted to obtain coverage with evidence development in France.**

| Conditions required for the clinical/economic study |
|---|
| 1. The study must be able to collect additional data required for assessment of the expected clinical benefit of the device. Studies should be comparative unless there is either no relevant comparator or for ethical reasons. |
| 2. Ongoing studies with the device must be presented to assess the relevance of the new study. |
| 3. The feasibility of the study must be considered reasonable in terms of both the protocol and the estimated budget. |

Finally, the decree introduces processing deadlines. The CNEDIMTS now has a maximum of 45 days to check the completeness of the submission and deliver an opinion on the admissibility of the application. The commission subsequently has a maximum of 30 days to confirm the suitability of the proposed study for the collection of additional data required to determine the expected clinical benefit of the product. The duration of the study and the number of patients to be included must also be validated. At the same time, the Ministry of Health determines whether the estimated budget is reasonable. Once both assessments have been completed, the Ministry of Health must confirm its final decision within 30 days. Finally, the funding required for the study is provided entirely by the French national health insurance agency.

## Improvements and Unresolved Issues

In a previous study, we concluded that improvements to the French CED scheme were required to ensure that the process is fully operational [11]. The recent modifications have partly resolved the issues we raised. First, the transparency of the process has increased, by setting criteria that clearly define an innovative device. Before the new decree, it was left entirely to the CNEDIMTS to determine whether a new product could be considered innovative. In addition, device manufacturers can now directly request the inclusion of their products in the CED scheme, as is already the case in other countries, such as Germany [12]. These modifications will probably have a major impact on the market access strategies of medical device companies, who will now consider this coverage option for their products. The French CED scheme is also potentially appealing to device manufacturers because full funding is offered and the reimbursement of study expenses is not requested even if results do not provide conclusive evidence. This is a major strength of the scheme because the collection of supplementary evidence can often result in the manufacturer making a loss in other countries [13,14]. We believe that the French CED scheme offers a great opportunity for small- and medium-sized enterprises (SMEs) with insufficient resources to manage large-scale clinical trials. In France, where 94% of medical device companies are SMEs, the new CED scheme can be regarded as a major support to innovation in this sector, in addition to the research and innovation tax credit recently implemented. In addition, the data collected can be reused in other countries for future reimbursement applications or finding new markets. From the point of view of health care providers, the scheme is likely to improve access to

innovative treatments for unmet medical needs and avoid excessive financial risk for devices with little available evidence. The funding of CED projects, however, may become a critical issue in the long term if the number of applications significantly increases. Therefore, substantial and sustainable funding for future studies will be required, particularly if high-quality evidence is to be obtained [15]. To date, the Ministry of Health has not indicated how many CED projects will be annually funded or whether a maximum budget will be set. Furthermore, the CNEDIMTS and the Ministry of Health will need to devote additional resources to ensure an adequate follow-up of all CED projects.

The possible involvement of hospitals in the scheme is a positive aspect. The early involvement of clinical investigators is likely to favor the successful establishment of future projects. Indeed, French hospitals have experience in hospital-based research programs funded by the Ministry of Health for non-reimbursed innovative devices, which are successful largely due to the involvement of the end users [11]. Partnerships with hospitals are also desirable for SMEs as they frequently require guidance in the design of clinical trials, which is increasingly offered by French university hospitals [16]. However, although randomised controlled trials are considered to be the gold standard for decision-making, the use of a randomised design is not always feasible for medical devices [14,17]. This standard is difficult to achieve with medical devices, for many reasons, including "learning curve" issues, frequent product modifications, and difficulties enrolling patients [18,19]. The French national health authorities should therefore consider alternative methods better suited to medical devices, such as Bayesian methods or tracker studies [20,21].

Finally, the new processing deadlines for the CNEDIMTS and the Ministry of Health should reduce bureaucratic delays, which were perceived as too long by device manufacturers. This will ensure that the process is completed in a more timely and transparent manner. Other countries have recently reformed their CED schemes, with the introduction of faster processing times, such as in the United Kingdom [22]. Nevertheless, the decree does not state whether the time frame will be also limited for pricing negotiations with the CEPS at the end of the study. In addition, the decree does not declare whether the manufacturer can expect a "premium" price on the basis of additional evidence generated and how these data can affect the CEPS price decisions. The primary intent of the scheme, however, is to provide as much evidence as possible to the CNEDIMTS to establish the added clinical value of the device. The CEPS decisions are then largely based on the conclusions made by the CNEDIMTS, which is potentially very positive provided that most uncertainties have been removed.

In conclusion, we feel that the recent modifications to the French CED scheme for innovative medical devices represent a step in the right direction, particularly with respect to greater transparency. The scheme now shares many features with other CED schemes worldwide. As recently stated by Olberg et al. [12], there may be an emerging international standard for CED [12]. It remains to be seen, however, how CED projects will be funded in the long term, how hospital partnerships will be set up, whether national health authorities will consider alternative study methods, and whether the new processing deadlines will be met.

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