CORRESPONDENCE

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

I read with particular interest the article describing the recent modifications of the French Coverage with Evidence Development (CED) scheme for innovative medical devices [1]. Overall, this article provided an accurate description of the history of the French CED scheme for medical devices (also called “Forfait Innovation”) and its recent required improvements. It also interrogated several unresolved issues regarding funding and methodological aspects. Some elements, however, need to be completed or clarified.

First of all, Forfait Innovation is not restricted to only medical devices. This CED scheme also allows the coverage of innovative diagnostic or therapeutic procedures [2]. Thus, Forfait Innovation can be requested by the industry (for medical devices and in vitro diagnostics) as well as by medical professional societies (for procedures). Medicines are not eligible for Forfait Innovation; a dedicated CED scheme is already available in France for medicines—the Temporary Authorization for Use.

In describing the history of Forfait Innovation, Martelli et al. [1] have indicated that the French Ministry of Health defined the conditions of the clinical trial. Actually, such conditions were jointly defined by the French Haute Autorité de santé (HAS) and the French Ministry of Health. Indeed, because it was the HAS, through its Commission Nationale d’Evaluation des Dispositifs Médicaux et Technologies de Santé (CNEDIMTS), that pinpointed critical evidence gaps during the assessment, only it could state whether the proposed study protocol would be relevant to fill the critical evidence gaps.

Between 2009 and 2015, only two innovative health technologies (high-intensity focused ultrasound treatment for prostate cancer and the Argus II epiretinal prosthesis) were finally selected by the French Ministry of Health for Forfait Innovation (Second Sight, Sylmar USA) [1]. Nevertheless, five other health technologies were proposed by the HAS for Forfait Innovation between 2009 and 2015: two medical devices (Paradigm Veo, Medtronic, Minneapolis, MN, USA, and SIR-Sphere, SIRTEx, Sydney, Australia), two procedures (thoracoscopically assisted esophagectomy and laparoscopic right hepatectomy), and one multitechnologic solution (ChondroCelect-related medical device and procedure, Tigenix, Leuven, Belgium). For both proposed medical devices, the French Ministry of Health agreed with the HAS position leading to the assessment of the proposed clinical trials. In both cases, however, the process was stopped after requests from the industry (for economic reasons and for difficulties in agreeing on methodology). For both proposed procedures, the French Ministry of Health did not follow the HAS position because it believed that the procedures were too mature to be considered innovative and that uncertainty was more related to conditions of use rather than clinical benefit (safety, efficacy, or effectiveness). Therefore, both procedures were considered to be more relevant for other schemes (e.g., postlisting studies [3]) than for a conditional coverage through Forfait Innovation. Last, the French Ministry of Health did not select the multitechnologic solution considering the heterogeneous position of the HAS for the compounds of the multitechnologic solution (the HAS did not request Forfait Innovation for the whole multitechnologic solution, but only for one compound: the associated procedure). Taken together, these elements demonstrate that the weak number of innovative products covered by Forfait Innovation was not due to a lack of political will (for economic or other reasons) but rather due to the former CED scheme failure itself in terms of 1) absence of a clear definition of innovative health technologies eligible for Forfait Innovation, 2) difficulties in agreeing on data requirements and study design, 3) lack of coordination among partners and bodies overseeing data collection, and 4) no well-defined regulatory framework governing coordination. Interestingly, most of these criteria were previously identified by the European Network for Health Technology Assessment (EUnetHTA) as barriers to the implementation of access with evidence generation schemes [3]. The improvements in Forfait Innovation introduced by law [2] and by decree [4] in 2015 clearly aimed at addressing these barriers. As reported by Martelli et al. [1], improvements were thus focused on the definition of innovation (selection/prioritization criteria), on the access process to Forfait Innovation (improvement in coordination between the HAS and the Ministry of Health, introduction of processing deadlines), on transparency of the selection process (systematic publication of assessments and decisions), and on methodological assistance (provided by the HAS or by hospitals through clinical investigators or innovation and clinical research supporting structures).

A dedicated “innovation track” for Forfait Innovation was created by decree [4]. Thus, direct applications to Forfait Innovation are not submitted to CNEDIMTS assessment but to a dedicated committee that has been specifically created within the HAS.
Evidence generated in the context of Forfait Innovation must meet high-quality criteria. Therefore, study design should be comparative. A comparative study, however, does not systematically mean randomized controlled trial. In agreement with Martelli et al. [1], the HAS will accept alternative comparative study designs when relevant.

Last, dedicated funding is of course a critical point of all CED schemes [3]. From the initial version of Forfait Innovation, a dedicated funding based on a co-payment system was stated by law [2]. Thus, dedicated funding of Forfait Innovation covers medical device and/or procedure costs as well as medical consultation and hospitalization costs when required. Conversely, study-related costs are not covered and are funded by the industry or medical professional societies. Initially, funding was restricted to in-hospital medical devices and procedures. Improvements in Forfait Innovation have extended its dedicated funding to out-of-hospital medical devices and procedures to cover a broader set of innovative health technologies. Considering the important financial constraints on health care expenditure in France, Martelli et al. [1] were concerned about the availability of substantial and sustainable funding for Forfait Innovation. Because innovation policy is one of the utmost priorities for the French Ministry of Health, dedicated funding for Forfait Innovation will be sufficient to allow the CED of selected innovative medical devices and procedures.

REFERENCES