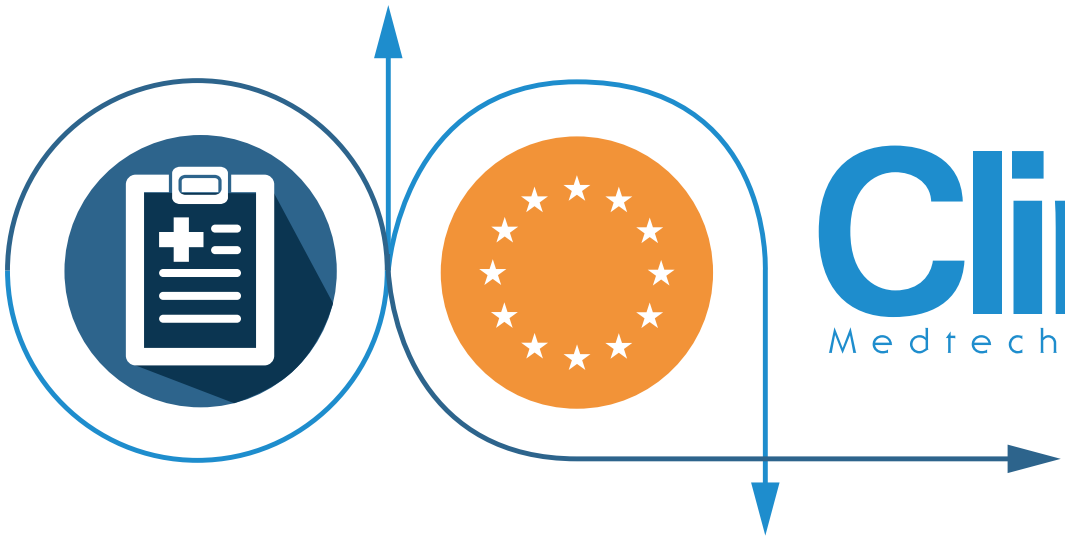

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REIMBURSEMENT UNRAVELLED: Will new French medtech innovation plans hit the spot?

by Corinne Lebourgeois, 22 June 2015

SECURING REIMBURSEMENT FOR INNOVATIVE MEDICAL DEVICES in France calls for high levels of human and financial input. Yet the often cumbersome and misfiring adoption procedures deter manufacturers from approaching this ostensibly attractive medical device market – Europe's second largest. But Corinne Lebourgeois* explains that a revamped "forfait innovation" might provide the much-needed change

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The medical device reimbursement process in France can be complex and long. Applicants' dossiers are examined by two committees, one after the other, in a process that supposedly lasts 180 days. But in practice, it takes much longer, extending to almost a year, according to the 2012 annual report of the tariff and price-setting body CEPS (Comité Economique des Produits de Santé).

This has prompted users of the system to wonder if France is losing touch with others operating elsewhere in Europe, and whether it can now ever catch up.

The fact is that reimbursement of innovative devices in France has become even more complex over the last few years, leading many manufacturers to introduce their innovative devices in other countries around Europe before thinking of France. But changes are at last on the horizon, thanks to a new review of the overall issue of market access for innovative devices that has been underway in 2015. Its aim is to make France more competitive.

Improving on the past

Prior to 2009, reimbursement was a ponderous process, whereby innovative devices underwent a procedure that involved years of discussions among numerous stakeholders that may or may not lead to a positive result.

In 2007-08, the launch of Edwards Lifesciences' percutaneous valves prompted a first attempt by the Haute Autorité de Santé (HAS), the government's reimbursement and professional healthcare standards body, to manage innovative devices and procedures differently.

Percutaneous valve replacement was a procedure that was recognized as having a high impact on patient treatment generally and on the survival of those who were not eligible for open surgery in particular.

According to Edwards Lifesciences' executive Raymond Lauret, this pilot project represented the first time that appraisals for a device and for a procedure were issued around the same time. "After several months of negotiations, special funding for the both the device and the procedure was granted for a limited time, enabling the implementation of a clinical trial in selected centers and the collection of additional data. It took around two years to obtain temporary reimbursement of percutaneous valves," said Mr Lauret, who is Edwards' vice-president, economic and government affairs, Europe.

In 2009, based on the success of percutaneous valves pilot project, a new procedure called "forfait innovation", embracing

product appraisal, clinical studies and funding, was created in L165-1-1 of the LFSS – Loi de Financement de la Sécurité Sociale (2009). Starting on 1 March 2010, eligible innovative devices could receive temporary funding for a specified period during which a clinical study was to be carried out in selected centers, aiming to collect additional data.

In total, 10 "forfait innovation" dossiers have been submitted to date, but only two products/procedures have benefited from this new procedure. The president of CNEDiMTS (Commission Nationale d'Evaluation des Dispositifs Médicaux et des Technologies de Santé) Professor Jacques Belghiti explains why. "The main issue was that the process definition was too general and too broad, with no defined timeline, no clear definition of what innovation means and no guidelines on how to conduct clinical or economic studies," he said at a HAS meeting, held on 5 June 2015. CNEDiMTS evaluates medical interest and benefit.

The growing consensus has been of the need to review the whole process, including redefining the terms, which is what finally prompted a re-examination of the "forfait innovation".

Forfait innovation – a revamped version for 2015

The new 2015 version of the "forfait innovation" aims to improve on the original version by removing the major hurdles that have stood in the way of it working effectively. A new *Arrêté* was published on 18 February 2015, and its *Décret d'application* is to be published soon. The objective remains unchanged: namely the temporary funding of innovative devices and procedures to facilitate their introduction onto the French market. As in the original version, the temporary funding will be subject to conducting a clinical or an economic study in order to collect the additional data that confirms the medical or economic interest of the device/procedure.

The submission of a "forfait innovation" dossier will henceforth follow a new procedure, for which a guideline document is soon to be released. A first draft was presented during the HAS' 5 June meeting.

Under the draft, device manufacturers, distributors, healthcare establishments or physician groups can simultaneously submit a dossier for innovative medical devices, in vitro diagnostic devices or procedures to the HAS (Direction de l'Evaluation Médicale, Economique et de Santé Publique –DEMESP) and the Ministry of Health (Direction de l'Offre de Soins – DGOS). The dossier is to be reviewed by a new commission in less than 120 days.

Two questions – device eligibility and data needs

The first question that needs to be asked is whether or not the device or the procedure is eligible. Four criteria must simultaneously be met:

1. Is the innovation a true innovation?

Only "breakthrough" innovations are within scope, not incremental developments

2. Has the device/procedure already been launched outside France?

Only a limited launch will be considered.

3. What are the risks for patients?

Only CE-marked devices are eligible, and risks for patients and users must be still be described

4. What is the value of the innovation?

Does it bring important clinical benefits (ASA I, II or III) or reduce healthcare costs? (See also REIMBURSEMENT UNRAVELLED: Get to grips with France's new value assessment rules, Clinica, 29 September 2014)*

* Amélioration du service attendu – expected benefits rendered

The second question is what additional data are needed in order to convince the authorities that the device/procedure is of major clinical or economic interest? A clinical or economic study protocol must be presented in the dossier. The reviewers will assess the study design and the budget.

The "forfait innovation", in its 2015 edition, allows simultaneous (and collaborative) work between the HAS and the DGOS, leading possibly to temporary funding for several years (generally 2-5 years). The funding covers the device's cost, fully or partially, and hospitalization costs. The cost of the study implementation is borne by the manufacturers/distributors or physician group.

Once the study is completed, the new dossier can be submitted following the current, traditional procedure. It is foreseen that a post-study budget will be established to ensure proper patient follow up while the new dossier is under review.

With this new version of the "forfait innovation", it is hoped that France might be regain some of its lost status and be considered once more by device innovators as an attractive and leading market for launching new and innovative technologies.

Mr Lauret's view is that, in theory, the new "forfait innovation" seems very appealing and represents a process that can be managed more effectively than its predecessor. But he also acknowledged that preparation of the new dossiers is becoming complicated, as it requires manufacturers to collect cost data (treatment and hospital costs) that are not easily accessible.

The "forfait innovation" may take a few years to take off and be fully effective, because a situation has arisen whereby many device manufacturers have developed strategies that lead to the launch of innovative technologies outside France first, while at the same time they have been collecting additional data to meet the HAS' high level clinical requirements. This strategy – first launch outside France – is now in some ways defunct, because it is considered by the HAS as a non-eligibility criterion under the new "forfait innovation".

Medical device companies will have to reassess their market access strategies based on the 2015 legislation if they expect that their new innovative technology could benefit from the new "forfait innovation" and be adopted in France, a country that has a long history of medical innovation.

We eagerly await the publication of the *Décret d'application* and the guideline document, in order to be able to fully exploit this new opportunity to address the French market, which is most likely to be published this summer.

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