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Post-approval Studies in France, Challenges Facing Medical Devices

Karine Levesque[1], Claire Coqueblin[2], Bernard Guillot[3] and participants of round table N°3 of Giens XXIX: Lucie Aubourg[4], Bernard Avouac[5], Cédric Carbonneil[6], Michel Cucherat[7], Patricia Descamps-Mandine[8], Serge Hanoka[9], Marcel Goldberg[10], Anne Josseran[11], François Parquin[12], Séverine Pitel[13], Christelle Ratignier[14], Odile Sechoy[15], Karine Szwarcenstein[16], André Tanti[17], Emmanuel Teiger[18] and Nicolas Thevenet[19†]

1 Abbott Vascular, Rungis, France
2 DGCIS, Service de l'industrie, Ivry sur Seine, France
3 CHU de Montpellier, Montpellier, France
4 LDR Medical, Rosières Près Troyes, France
5 La-Ser, Paris, France
6 DGOS, Paris, France
7 UMR CNRS 5558, Service de pharmacologie, Lyon, France
8 Direction générale de la santé, Paris, France
9 WL Gore & Associés, Roquevaire, France
10 INSERM, Villejuif, France
11 SNITEM, Courbevoie, France
12 Hôpital Foch, Suresnes, France
13 Qualissima, Marseille, France
14 CNAMTS, Paris, France
15 Direction de la recherche et de l'innovation, Toulouse, France
16 Johnson & Johnson, Issy les Moulineaux, France
17 Comité économique des produits de santé, Paris, France
18 AP-HP, CHU Henri Mondor, Créteil, France
19 ANSM, Saint Denis, France

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Abstract – Medical devices are characterized notably by a wide heterogeneity (from tongue depressors to hip prostheses, and from non-implantable to invasive devices), a short life cycle with recurrent incremental innovations (from 18 months to 5 years), and an operator-dependent nature. The objective of the current round table was to develop proposals and recommendations concerning the prerequisites needed in order to meet the French health authorities expectations concerning requests for post-approval studies for medical devices, required in cases where short and long-term consequences are unknown. These studies, which are the responsibility of the manufacturer or the distributor of the medical device, are designed to confirm the role of the medical device in the therapeutic management strategy in a real-life setting. There are currently approximately 150 post-approval studies underway, mainly concerning class III devices, and the majority face difficulties implementing the study or meeting the study objectives. In light of this, the round table endeavored to clearly identify the conditions for implementation of post-approval studies specific to the characteristics of medical devices. Various areas of progress have been envisaged to improve the performance of these studies, and by consequence, the efficiency of reimbursement of medical devices by the national health insurance. These include providing manufacturers with the opportunity to better anticipate post-approval requirements, defining a study-specific primary objective, integrating a phase allowing dialogue between the manufacturer, the health authorities and the scientific committee, and increasing awareness and training of health professionals on the impact of post-approval clinical studies in terms of the reimbursement of medical devices by the national insurance.

Abbreviations: see end of article.

† The articles, analysis and proposals from the Giens Workshops are the sole responsibility fo the authors and do not represent the position of the organisations to which they belong.

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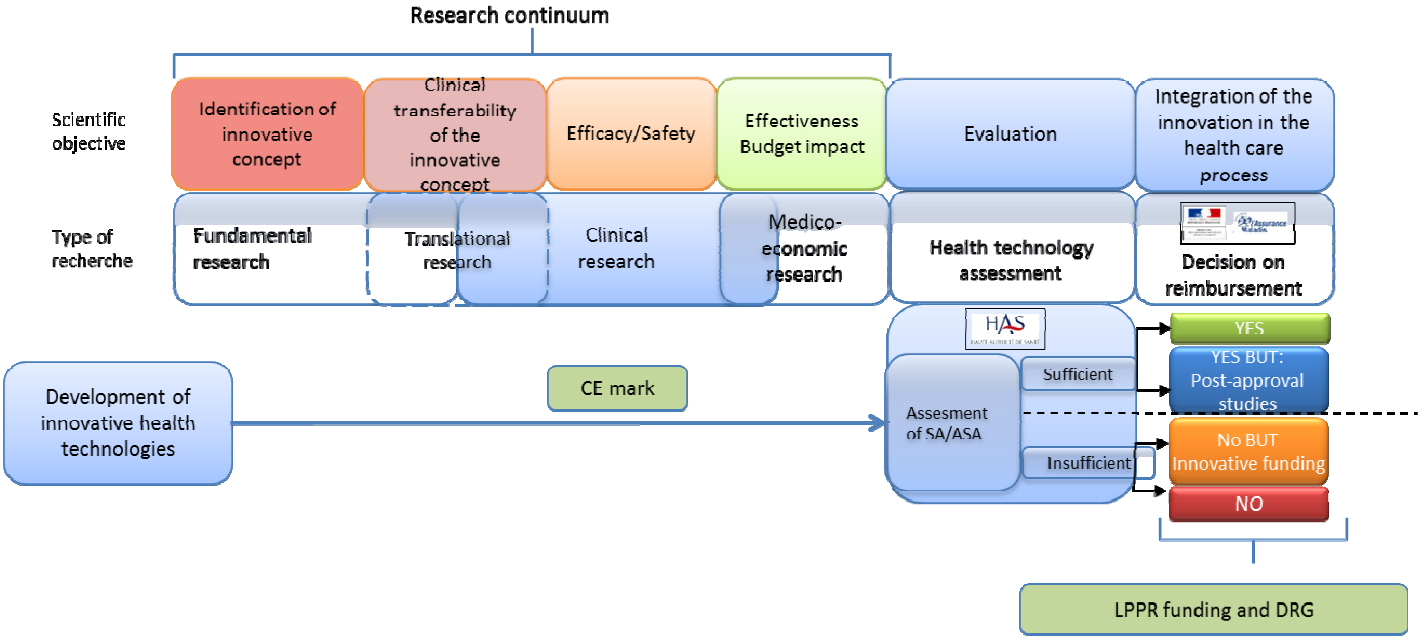

Fig. 1. Processing of a medical device. Source: with courtesy of Directorate General for Healthcare Provision (DGOS).
DRG: disease related group; **LPPR**: products and services reimbursement list (*liste des produits et prestations remboursables*); **SA/ASA**: expected service improvement of expected service (*service attendu/amélioration du service attendu*)

1. Background

In the French Public Health Code, a medical device is defined as "any instrument, apparatus, material, equipment, or product which is not of human origin, or other article used alone or in association, including accessories or software involved in its functioning, designed by the manufacture to be used in humans for medical purposes and which does not achieve its purposes through pharmacologic, immunologic or metabolic activity, but the functioning of which may be assisted by such a device".[1]

This definition encompasses thousands of products of highly diverse origins in terms of their weight, size, and production costs, but all of which fulfill the same purpose: prevent, diagnose, manage, or minimize an injury, illness or handicap.

In order for a medical device adhering to the European Directive 2007/47/CE and conforming to the requirements of the French Social Security Code to be made available to health professionals and patients, companies are required to demonstrate, *via* quality clinical data, the safety and benefit of their product. Following evaluation of this clinical data by the health authorities, the medical device may receive CE marking for marketing in Europe. In France, medical devices eligible for the product and services reimbursement list (*liste des produits en prestations remboursables*, LPPR) are reviewed by the National Commission of Evaluation of Medical Devices and Health Technologies (*Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé*, CNEDiMTS) of the National Health Authorities (*Haute autorité de santé*, HAS) for eligibility for reimbursement by the national health insurance (figure 1). Registration of a medical device brand name on the LPPR is temporary and lasts a maximum of 5 years.

On the basis of the data presented, the CNEDiMTS will conclude that either the device can provide adequate assistance meriting possible reimbursement by the national health insurance, or is inadequate and registration on the LPPR will be refused. Nonetheless in some cases, while the CNEDiMTS may consider the device to be of interest and as having a role to play in the therapeutic management strategy, uncertainty over the short or long-term consequences of its implementation on patients' health may still exist. These uncertainties generally concern a number of parameters such as efficacy or tolerance of the medical device in the clinical setting, its long-term effects on the therapeutic management strategy, real-life conditions of use, or its impact on the organization of care and from a medico-economic perspective.[2] In the latter case, studies are evaluated by the Commission for Economic Evaluation and Public Health (*Commission d'évaluation économique et de santé publique*, CEESP) from the HAS.

For renewal of registration of a medical device on the LPPR,[3] post-approval studies may be required, as requested by the CNEDiMTS, the CEESP, or the Economic Committee on Health Care Products (*Comité économique des produits de santé*, CEPS). In this case, the company has to complete these studies during the approved registration period. New efficacy and safety data will be used to