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Divergent evidence requirements for authorization and reimbursement of high-risk medical devices – The European situation

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Abstract
Background: Unsafe and dangerous medical devices have entered the European market during the last decade, raising public awareness. Consequently, regulatory processes and their requirements for evidence are under discussion.
Objective: This research aims to explore the authorization and reimbursement processes and associated evidence requirements for high-risk medical devices in four regions: Europe, the United States, Australia and Canada.
Methods: A literature search in PubMed about the authorization and reimbursement processes in the four regions was performed. Seven high-risk medical devices were selected as examples, and their authorization and reimbursement status were analyzed. Information was extracted from publicly available summaries of the authorization agencies of the regions, from the Controlled Clinical Trial Database, supplemented by information from HTA and reimbursement organizations.
Results: The evidence required for the authorization and reimbursement processes differs strongly in the four regions regarding the levels of methodology and scrutiny. All seven devices have been authorized in Europe, three in Australia, one in the USA, and one in Canada. Currently none of the devices is recommended for reimbursement in the regions except one, in the USA. Devices that have been authorized in more than one region show that authorization has been two to three years earlier in Europe.
Conclusion: Huge differences and gaps in the evidence required for market authorization and for reimbursement were observed, especially between the two processes (authorization and reimbursement) in Europe. To ensure the high quality and safe provision of medical devices, harmonization of requirements and transparency in processes are needed.

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Introduction

In the last decade, the healthcare sector has been inundated with a great variety of new and increasingly complex medical devices. Many patients have benefitted from those devices and their availability has significantly improved the quality of life of many users [1,2]. Yet, as devices are evolving and their technical characteristics are becoming more and more complex, regulatory processes seem outdated and incapable of assuring the safety and efficacy of all products entering the market. Recent examples of unsafe and risky devices on the market are the Trilucent™ breast implants and the metal hip-to-hip implants. Those unsafe and dangerous medical devices entered the European market and raised public awareness only recently [3,4]. Consequently, the regulatory processes and their evidence requirements are under debate, particularly for high-risk devices.

The term medical device covers a broad range of technologies, referred to in the European Union Directive 2007/47/EC as "any instrument, apparatus, appliance, software, material or other article, … used specifically for diagnostic and or therapeutic purposes" [5]. All medical devices, but especially high-risk devices must fulfill certain evidence requirements including safety, performance and efficacy depending on the region for premarket authorization (approval) and reimbursement. The evidence requirements for authorization are defined through a risk-classification approach, based on the risk the devices pose to the patient. Depending on the region the risk categories can range from one to five categories. Evidence requirements needed for reimbursement are always country-specific and can range from only clinical studies to rigorous cost data [6–9].

Following a series of device failures and recalls, numerous weaknesses have been identified in the European approval process. They relate to very low safety standards for market access, the exclusion of efficacy assessments and the lack of transparency of regulatory processes and their evidence requirements. As a result, the call for the development of new regulatory frameworks with stricter evidence requirements and more transparency has never been stronger. However, while stricter regulatory frameworks will lead to higher safety, this will on the other hand limit the early access to market of some devices. Overall there is a clear tension between the fast accessibility to new, often innovative products and the provision of a high level of safety to patients [10,11].

This study aims to understand and compare the regulatory processes for the authorization and reimbursement of high-risk medical devices in four high impact regions, namely Europe, the United States, Australia and Canada, the major markets for medical devices in the western world. The study takes a broader approach to the topic than the current literature [4,7,12]: first, by including Australia and Canada in the comparison of regulatory processes and second in comparing authorization requirements next to requirements for reimbursement. Specifically, we have three objectives: [1] to explore and explain the authorization and reimbursement processes for high-risk medical devices in the four regions, [2] to learn about the evidence requirements for authorization and for reimbursement of seven selected high-risk devices and finally [3] to compare the available evidence of the seven high-risk medical devices at the time of authorization and of reimbursement recommendation.

Methods

First, we conducted a literature search on the authorization processes for high-risk medical devices in the four high impact geographical regions: Europe, the United States, Australia and Canada. The selection of regions was based on the inclusion of western countries and therefore major markets for the high-risk medical devices in question. In addition, a literature search was conducted on the reimbursement decision-making processes in the respective regions. As the healthcare systems and the reimbursement decisions in Europe are regulated under country sovereignty, (only) four European countries – based on language and public accessibility of documents – have been selected for the analysis of the evidence requirements for reimbursement: Germany, the United Kingdom, Austria and the Netherlands. The literature search was performed in PubMed and information until July 2013 is included in this research. Information on authorization was then analyzed and presented according to authorization instrument, standard for approval, evidence required, approval granted and transparency of information on the approval process. Information on reimbursement was analyzed according to the clinical information used and recommendations given by the HTA institutions having major impact on reimbursement decisions in the respective regions and European countries (Table 1).

Second, we selected seven exemplary high-risk medical devices from a broad range of disease indications that depend on the usage of medical devices (Table 2). The choice for the case studies was also influenced by the fact that five of the seven devices have been assessed by the authoring agency LBI-HTA.

For analyzing the evidence available at the time of market authorization and at the time of reimbursement decision, a literature search was performed in PubMed (June 2013) using the device (product) "brand" name in combination with its disease indication and supplemented with a search in the clinical trial registry – clincialtrial.gov – for ongoing or completed clinical trials of the seven high-risk devices. We are confident that with this search combination we have found all relevant information and trials on the seven devices. Predefined inclusion and exclusion criteria have been applied to both searches. Upon request the full search strategy and the criteria can be made available.

Third, the websites of the respective agencies were searched for assessments on the selected seven medical devices. Information from official reports and summaries from the authorization agencies and HTA bodies advising and recommending on reimbursement was analyzed with an evidence pyramid, ranking clinical evidence according to its trial design. All information is presented within these evidence pyramids and complemented with timelines on years of approval and years of evolving clinical evidence. Since the MDS reports are not publicly available – a major hurdle for transparency – only those MDS could be used that