International Journal of Advanced Engineering and Management Research

Vol. 4, No. 01; 2019

ISSN: 2456-3676

THE INNOVATION PROCESS OF MEDICAL DEVICES IN GERMANY RESPECTING THE NEW EU REGULATION

Raphaël G.D. MURSWIECK[1],Ioana CEAUSU[1],Sven IRMER[1], Vanessa JUST[1]
[1]The Bucharest University of Economic Studies,
[2]The Bucharest University of Economic Studies,
[3]The Bucharest University of Economic Studies,
[4]The Bucharest University of Economic Studies,

Abstract
Regulations create a supplementary burden for organizations when it comes to confirm compliance of innovations by third parties. On the one hand, new products cannot be developed strictly confidentially and on the other hands, marketable products have not the certainty being certified according to the regulations by the so-called notified bodies (NB) if certain conditions are not met. The present article analyses the innovation process from idea to monetarization of medical devices based on the upcoming medical device regulation (MDR) of the European Union (EU) coming into effect in May 2020. In the new framework, newmedical device ideas need to undergo a certain innovation procedure in order to be accepted by the NB. This implies the use of external stakeholders and respecting European and national laws. Looking to the German market, five steps within the innovation process can be described from idea to monetarization: research, product development, certification, reimbursement policies and finally marketing. Within each of these steps external sources are mandatory to be included along the innovation process. The present article demonstrates that the traditional internal way of innovation development and hence management is no longer applicable. Organizations are forced to open their innovation processes if they want them to promote them on the European market. Medical regulations should not only be seen as a burden but as chance to increase the innovation success by involvement of the customers.

Keywords: Innovation Management, Medical Device Directive, Medical Device Regulation, European Union

Introduction

Innovation is not only crucial for organizations within a competitive and global environment when it comes to succeed in the long-term. It is – beside the marketing aspect– a necessity for the development of economies in order to increase wealth [1]. Therefore, countries' governments support on the one hand organizations to succeed with innovations, for instance, with help of national awards in diverse categories. On the other hand, governments regulate markets with legal frameworks to ensure or increase well-being, as it is the case, for instance, for the health industry in the EU [2].

Successful organizations have implemented an innovation management strategy within their strategic long-term organizations' development targets. This also reflects the increasing number of studies about innovation as a whole but also especially regarding the process, strategy and management of innovation within literature [3-5]. In the case of product innovations in regulated

Vol. 4, No. 01; 2019

ISSN: 2456-3676

markets, as for medical devices, the innovation strategy needs to respect legal frameworks in order to being marketable and hence successful. In any case, innovations need to generate a certain value as Irmeris confirming: *"Business performance developed through innovation is materialized by creating value that is reflected in the following results: revenue growth rate, operational profit growth rate, economic return rate, inventory turnover rate, employee growth rate, consolidation position on the competitive market"*[6].The innovation process of medical devices is a challenging task: the increased legal obligations out of the EU medical device regulation (MDR) compared to the current medical device directive (MDD) constrain organizations to increase their innovation efforts. Especially the need for validated clinical evaluations prior to the certification is challenging the innovators. Therefore, the development of new products should rather be based on an iterative approach in order to respect the different stakeholders' concerns and notions. Furthermore, depending on the medical risk class, original equipment manufacturer (OEM) of medical devices have the obligation to follow strict procedures prior to market penetration as described briefly in the following chapter [7].

The medical technology sector is an important employer for the EU. Over half a million people work in the field of medical technology in the European Union [8]. Millions of EU citizens rely on medical devices every day. Medical devices such as hearing aids, eyewear, contact lenses, adhesive tape, bandages, wheelchairs and technologies such as prostheses, cardiac pacemakers, x-ray equipment, surgical instruments have a common purpose: to improve our quality of life. In terms of patent applications, medical technology has been one of the most innovative sectors in Europe for many years [9]. This goes hand in hand with high consumer expectations regarding the quality and safety of medical devices. The need for specific quality and safety processes is understandable from a consumer perspective. However, for OEM these procedures lengthen the time from idea to a certified medical device.

Innovation Management of Medical Devices

The general principles or pre-conditions for successful innovations remain, of course, the same as is non- regulated markets: an innovation-friendly ecosystem where the whole organization with all employees is driven by aso-called "excellence"-approach [10-13].Even though the involvement of the customers or end-users (in the case of medical devices such as clinics, doctors or even the patient)is not the usual way for the start of innovation it should anyway be a more promising way to succeed. By this, costly investments and product developments cycles can be reduced [14, 15] and meet the MDR requirements at the same time by generating data [7]. It can be mentioned that with this approach the traditional way of a "lonely" innovative company described by Schumpeter – the pioneer of innovation theories – is not applicable in a strict way for the medical device development [16]. In addition, Chesbrough is also mentioning that the innovation process should be rather "open" by involving external sources to increase the success chance of new ideas [17, 18].

This approach corresponds to the needs of the innovation management of medical devices, especially related to the MDR requirements, where multiple loops between different stakeholders (OEM, NB, doctors, test patient,..) are usual or even mandatory prior the placement on the market. Especially when it comes to conduct clinical evaluations as part of the conformity

Vol. 4, No. 01; 2019

ISSN: 2456-3676

assessment, OEMs need to involve end users to collect statistical data. Of course, this depends also on the type of medical device and the associated risk class [7, 19].
Respecting the governmental guidelines, EU regulations and stakeholders' interests, the following main innovation process with individual sub processes can be described as per table 1:

Table 1: Innovation process for medical devices based on EU/German legislation (adapted from VDI [20])

Research	Development	Certification	Refund	Market
Develop product concept	Specify product concept	Prepare CE certification	Define refinancing strategy	Realize sales
Identify medical needs	Create product definition	Perform risk analysis	Define health market	Form partnerships
Specify product idea	Create technical specification	Determine purpose	Define business model	Establish user networks
Perform supply analysis	Define development framework	Define risk class	Develop service packages	Build sales
Estimate innovation risk	Preparing Regulatory Affairs Strategy	Define basic requirements	Check stationary remuneration	Carry out market surveillance
Initiate research project	Define IP rights strategy	Initiate conformity assessment	Check DRG catalog	Select distribution channel
Determine research needs	Carry out development project	Define conformity assessment procedures	NUB application support	Carry out marketing
Create business plan	Create development plan	Perform clinical evaluation	Check outpatient compensation	Conduct market research
Check funding / promotion	Develop a prototype	Plan and perform clinical study	Check EBM	Develop marketing concept
Apply for funding	Design production	Submit technical documentation	Support the G-BA application	Build Market Intelligence
Carry out research project	Define manufacturing technologies	Establish Post Market Surveillance	Check fees for doctors (GOÄ)	Product clearance
Set up project management	Implement supply chain	Post Market Surveillance (PMS)	Check aid directory	Marketing Mix: Implementation of the marketing concept
Implement demonstrator	Define packaging and sterilization	Post Market Clinical Follow Up (PMCF)	Check alternative compensation paths	Drive international marketing
			Support individual case compensation	Prepare international market entry
			Negotiate selective contracts	Gain international access
				Get country specific reimbursement
				Finance export activities

Medical device innovations – as innovations in general – are to be promising when they are based on real needs or if they can arouse a need. This could be an encouraging start for any research activity. In addition, the technical feasibility should be part of the first step and ideally also the various reimbursement scenarios which applies on the different (EU) markets. Otherwise, the risk of losing money is obvious. The product development as second main innovation step is one of the most challenging part as at this point the quality and risk management system for the new medical device shall be created, as these documents will be needed already for the certification. Finally, the certification step will ensure the right to mark the device with "CE" based on all presented technical documentations and systems put into action. The main condition is that the device is compliant to the safety and performance

Vol. 4, No. 01; 2019

ISSN: 2456-3676

requirements. The forth step, the reimbursement, is of course one of the most important pre-requisitions of a medical device innovation if the device shall be accepted and paid by the health insurances based on doctors' prescriptions. The last step finally is the sales and marketing activities, which will make sure the new medical device, will be a successful innovation [20].
Within each of the five main steps of the innovation process, external sources (stakeholders) as well as regulatory affairs are involved ruling out a lonely innovation management (Figure 1):

Figure 1: Innovation sub-processes for medical devices respecting external sources and medical device regulations (source: authors)

Table 1 as well as Figure 1 demonstrate that the management of innovations within the medical technology sector needs always the involvement of third, external parties based on the MDR. In that respect the period from idea to market is rather long than short and the costs of development consequently rather high than low as well.

Conclusion

Respecting the meaning of a product innovation as an idea that is being monetarized, the present article has shown that the management of innovations for medical devices represents an open innovation approach by force of regulations. Organizations that want to develop new medical devices in the EU will need to involve end users such as doctors and patient from the beginning as well as during the clinical evaluation period prior being certified once the evaluation has been successful. The regulation frameworks are for sure challenging the organizations as they need to include different stakeholders. However, two promising aspects can be derived: Firstly, with increased regulations, as it is the case with the upcoming EU medical device regulation, the entry barrier for more organizations will increase and will consequently ensure a longer profit period for organizations committing to the EU market and having the necessary fund for the development. Secondly, involving end users from the beginning of the innovation process is not

Vol. 4, No. 01; 2019

ISSN: 2456-3676

only mandatory: it is also promising a much higher success rate than without end users. In this sense, regulations within the medical sector are both an increasing safety factor for humans and a promising business market for innovative organizations.

Bibliography

Leaven good, S. (2011), *Identifying Best Quality Management Practices for Achieving Quality and Innovation Performance in the Forest Products Industry, Portland State University*

European Commissions' strategy 2018, accessed December 3,2018 [https://ec.europa.eu/info/strategy_en]

Maier A., Brad S, Nicoară D., Maier D. (2013), *Innovation by developing human resources, ensuring the competitiveness and success of the organization*, 2nd World Conference on Business, Economics and Management–BEM 2013, April 25 – 28 2013, Antalya, Turkey

Olaru M., Hohan A., Maier A., Maier D. (2013) – *Metrics for innovation of product – the basis for continuous improvement of an organization, Science Journal of Business and Management*, Vol. 1, nr 1, p. 26-30, SUA

Olaru M., Maier D., Maier A., Nicoară D., (2013 b),*Establishing the basis for the development of an organization by adopting the integrated management systems: comparative study of various models and concepts of integration*, 2nd World Conference on Business, Economics and Management–BEM 2013, April 25 – 28 2013, Antalya, Turkey

Irmer S., Murswieck R., Kurth B. L., Floricel T.-B (2017), *Innovation management as part of the general management of the organization*, International Journal of Advanced Engineering and Management Research, vol. 2, no. 6, pg. 2404-2412, ISSN 2456-3676 http://ijaemr.com/view1.php?issue=6

Benad, N., Backhaus, C., Lau, H.-J., Pleiss, T. (2017), *MDR & Co.: Eine Vorschriftensammlung zum europäischen Medizinprodukterecht (Praxiswissen Medizintechnik),* ISBN: 3740602066, TÜV Media GmbH TÜV Rheinland Group

European Commission statistics, accessed December 3, 2018 [https://ec.europa.eu/growth/sectors/medical-devices_en]

European Patent Office, accessed December 3, 2018 [https://www.epo.org/about-us/annual-reports-statistics/annual-report/2017/statistics/patent-applications.html#tab3]

Ceausu, I., Murswieck, R., Kurth, B.L., Ionescu, R. (2017), *The organizational culture as a support of innovation processes, International Journal of Advanced Engineering and Management Research Vol. 2 Issue 6. ISSN: 2456-3676.*

Bayó, E., Camps, X. (2015), *how to become an innovative company, ISBN: 978-84-606-5937-2*

Hochmeier, A. (2012), *Kritische Erfolgsfaktoren im Innovationsmanagement. Aktuelle Handlungspraxis und Werkzeuge zur Identifikation von Handlungsbedarfen, Springer Gabler Wiesbaden*

Vol. 4, No. 01; 2019

ISSN: 2456-3676

Chesbrough, H. W. (2006), *Open Business Models: How to Thrive in the New Innovation Landscape, Harvard Business Review Press*

Murswieck R., Fortmüller, A., Dünnweber, M., Arp, A-K. (2018), *The early stage of the innovation process from a marketing perspective (case study),*International Journal of Advanced Engineering and Management Research, vol. 3, issue 6, pg. 86 – 96, ISSN 2456-3676, http://ijaemr.com/view2.php?issue=6

Classen, M. (2015), Marktorientierung in Business-to-Business-Märkten. Eine empirische Untersuchung von mehrstufigen Marketingstrategien. Springer Gabler Verlag: Wiesbaden

Schumpeter, J. A. (1934), The theory of economic development. Cambridge: Harvard University Press.

Chesbrough, H. W. (2003), Open innovation: The new imperative for creating and profiting from technology. Boston: Harvard Business School Press.

Chesbrough, H. W. (2006), Open Business Models: How to Thrive in the New Innovation Landscape. Boston: Harvard Business Review Press.

Murswieck, R., Stiller M. (2018), *MDR – Kompaktratgeber. Praxisbezogener Einstieg für Hersteller von Medizinprodukten in die Medical Device Regulation (MDR) inklusive deutscher Fassung*, HEYDELBERGER Institut (ed.), ISBN 978-3-7469-8238-0, Tredition Verlag: Hamburg

VDI Technologiezentrum GmbH (2018), accessed December 3, 2018 [https://medizintechnologie.de/innovation-im-fokus/innovationslotse/]