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Post market surveillance in the german medical device sector – current state and future perspectives☆

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ABSTRACT

Medical devices play a central role in the diagnosis and treatment of diseases but also bring the potential for adverse events, hazards or malfunction with serious consequences for patients and users. Medical device manufacturers are therefore required by law to monitor the performance of medical devices that have been approved by the competent authorities (post market surveillance). Conducting a nationwide online-survey in the German medical device sector in Q2/2014 in order to explore the current status of the use of post market instruments we obtained a total of 118 complete data sets, for a return rate of 36%. The survey included manufacturers of different sizes, producing medical devices of all risk classes. The post market instruments most frequently reported covered the fields of production monitoring and quality management as well as literature observation, regulatory vigilance systems, customer knowledge management and market observation while Post Market Clinical Follow-up and health services research were being used less for product monitoring. We found significant differences between the different risk classes of medical devices produced and the intensity of use of post market instruments. Differences between company size and the intensity of instruments used were hardly detected. Results may well contribute to the development of device monitoring which is a crucial element of the policy and regulatory system to identify device-related safety issues.

1. Introduction

1.1. Background

Medical devices provide healthcare benefits to millions of people but can also lead to adverse events and incidents with serious consequences for the affected patients and users [1–3]. In order to reduce medical device associated risks, manufacturers are obliged by law to observe systematically the safety and performance of those medical devices which have already been approved and are now being used in clinical care. This applies to Europe, but also to other markets such as the USA or Japan [4–6]. According to European law, medical device companies have to implement a quality system that shall include "an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase" [7]. This has to be verified and approved by a notified body. The implementation and operation of such a post market surveillance system can also be found in the directives for active implantable medical devices (AIMD) [8] and in vitro diagnostics (IVD) [9]. In this way, the medical device companies should receive structured information both on device-related adverse events and equipment defects and on rare problems, outcomes and complications occurring throughout the whole product lifecycle. This information can then be analyzed, evaluated and used for risk prevention. Some high-profile device recalls in recent years – such as artificial metal-on-metal hip implants [10,11], breast implants [12–14] or implantable cardioverter/defibrillators (ICD) [15–17] – illustrate the importance of this regulatory measure both for the risk management of the manufacturer and for a stronger patient and user safety.

Although regulation for medical devices has been discussed in literature for a long time [18–23] and despite the broad consensus on the importance of post market surveillance activities to collect safety-related information on medical devices and processes [5,6,24], we discovered a lack of empirical data so far. Our aim was to find out how medical device companies which are engaged in

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Table 1
European classification system for medical devices, AIMD and IVD groups [9,25], with medical device, AIMD and IVD examples.

Risk class/group	Risk level	Medical device examples
I	Low	reading glasses, stethoscope, wheelchair, hospital bed, dressings, scalpel
IIa	Low-moderate	hearing Aid, blood pump, ultrasound device, MRI Scanner, contact lens, Positron emission tomography, dental implant
IIb	Moderate-high	intraocular lens, ventilator, infusion Pump, anaesthetic machine, defibrillator, X-ray machine
III	High	Prosthetic heart valve, cardiac catheter, coronary stent
AIMD	High	implantable cardiac pacemaker, implantable cardioverter defibrillator
IVD group		IVD examples
IVD Annex II List A		blood groups of the AB0 system, blood groups of the Kell system, irregular anti-erythrocyte antibodies, markers of HIV infection, Hepatitis B, C und D
IVD Annex II List B		congentital infection with rubella or toxoplasma, hereditary diseases phenylketonuria and Down syndrome (trisomy 21), tumor marker PSA
IVD Products for self-testing		systems for measurement of blood glucose
IVD General		cholesterol, blood clotting or thyroid function tests

AIMD, Active implantable medical devices; IVD, in vitro diagnostics; Annex II, see IVD listed in Annex II – List of Devices referred to in Article 9(2) and 3 of the Directive 98/79/EC.

the German market perform their post market activities in daily practice.

1.2. Objectives

The present study had two objectives:

i) To evaluate and analyze the intensity of use of post market surveillance instruments and measures in the German medical device sector.
ii) To check whether the intensity of use of post market activities is associated with the company size or the risk class of the medical devices produced, as we assumed that this is mainly influenced by the manufacturer's resources or the device-related risk.

2. Material und methods

2.1. Study sample

We first considered manufacturers organized in one of the following trade associations for medical technology in Germany: German Medical Technology Association (BVMed), German High-tech Industry Association (SPECTARIS) and Association of the Diagnostics Industry (VDGH) (total n = 466, Date: 03/31/2014). This allowed to include in the study sample manufacturers with different company sizes from all over the country. Moreover, we considered companies with medical devices of all risk classes as well as AIMD and IVD. Device risk classes and IVD groups are as defined by the European Commission (see Table 1, [9,25]). Companies only distributing or repairing medical devices or having an authorized representative on the German market etc. (and therefore not subject to post market requirements) were not included. As a result, there was a sample of n = 324 medical device companies (as shown in the flowchart in Fig. 1).

2.2. Questionnaire design and measures

With regard to the first objective, medical device manufacturers were asked to assess how often they used each of a total of 24 instruments for post market surveillance. The instruments were identified on the basis of a systematic search in the legal and regulatory requirements for post market surveillance as well as the relevant international regulatory and device-related literature and then categorized into two main sections: internal and external knowledge sources. Internal sources were further subdivided into production monitoring and quality management. External sources were subdivided into customer knowledge management, market observation, literature observation, regulatory vigilance systems, Post Market Clinical Follow-Up (PMCF) and health services research. The data collection was based on a six-point Likert scale ranging from 0 ("never") to +5 ("very often/always").

Regarding the second objective, we were interested in company-specific characteristics. We were particularly interested in the risk class(es) and type(s) of produced medical devices as well as in the size of the company (turnover, balance sheet total and number of employees, all in 2013), company classification as defined by the European Commission for SMEs [26]. To assess the quality of data collected, respondents were asked to provide information on their position in the company and their professional work-experience in the field of post market surveillance in years. All questions could be skipped by answering "not specified".

Prior to the final survey, six experts, each responsible for post market surveillance of medical devices, were asked to participate in a pre-test. To cover the heterogeneous spectrum of medical devices, we asked representatives of medical device manufacturers from various product areas (anaesthesia devices, intraocular lenses, artificial hip joints, surgical equipment, IVD, etc.). Based on the pre-test, the wording and layout of the questionnaire was finalized. We also added examples of knowledge sources to the different post market knowledge categories in order to achieve a uniform understanding among the participants and therewith better data quality.

2.3. Data collection and analysis

Data were collected between April and June 2014, based on a nationwide online survey. We used a two-step approach: first, telephone contact with a post market expert in each of the sampled companies and second, personalized invitation to participate in the survey via e-mail. We made up to three telephone contact attempts on different days of the week and times of day in order to avoid systematic or accidental bias in the survey. A week before the end of the survey we conducted a follow-up mailing to increase the response rate.

We analyzed data using descriptive analysis. To identify differences in the use of post market surveillance instruments regarding the company size and the highest reported risk class, we analyzed the local significance of the mean differences between company subgroups by using the two-sided non-parametric Kruskal-Wallis-Test ($p = 0.05$). This test was chosen for independent, non-parametric testing, as the manufacturer (sub-) groups we assumed to be not normally distributed. Collected data was analysed by software package SPSS® Statistics (22.0), IBM Corporation®, Armonk, New York, USA, for the operating system Windows® 7, Microsoft Corporation®, Redmond, Washington, USA.