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The Medical Devices Sector in Morocco: Current Situation and Patients Safety

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Abstract
The medical devices represent a very important link in the care pathway or in the medical coverage because we cannot imagine a medical or surgical covery without support of a medical device of all categories I, IIa, IIb, III. In this case their importance, their usefulness, the medical devices have acquired a particular attention and an avowal on the part of professionals and the sanitary deciders in terms of management, legislation, regulation, and also quality, in order to insure and guarantee an optimal quality care for the patients and with minimal risks or errors during the use of medical devices.

The aim of the actual article is to make a current situation of the institutions operating in the medical devices sector and to highlight their respect and conformity with the norms of specific quality with the medical devices and with their regulation so as to guarantee the security of the patients during the use of any medical device of all kinds and of all confused categories.

Among the settings tackled in this article, the action of the establishments operating in the medical device sector, their different legal forms, the respect of the continued formation, the establishment of traceability systems of medical devices, the respect of medical device reporting (Materiovigilance), the respect of the norm ISO 13485[1], and of the legislation in effect to know the law 84-12 relating to the medical devices [2].

Keywords
Medical devices, Regulation, Traceability system, Medical device reporting (MDR), Materiovigilance, Morocco

INTRODUCTION

Regarding its importance, the market of medical devices attracts increasingly the Moroccan and foreign investors; it also generates more than 236 millions of dollars including 181 millions for importations .Hence, the increase of only 7% during the period 2018-2021 [3].

The market of medical devices, however, witnesses perturbations linked to the medical devices management within the enterprises of manufacturing, importation, exportation, maintenance or distribution .Moreover, the medical devices market is also related to the respect of the medical device regulation which is recent since the medical devices sector had been regulated only by a circular dating from 1997 .The circular doesn't have the power of the law nor does it cover aspects such as medical device reporting , medical devices advertising ,and the management of donations and waste . Then appeared the law 84-12 which took place only in 2013, and its four decrees which came in 2015.

Following the official data basis of consulted medicine and pharmacy direction in the date of February10,2024,only 746 companies of all confused legal forms are cited [4]; establishments of manufacture ,exportation, importation, maintenance and distribution ; whereas the market of medical devices sector counts more than 3000 establishments [5].

We notice that the medical devices sector encompasses establishments that are declared at once in the medicine and pharmacy direction and in the local authorities .There are others which are declared only in the local authorities but not in the medicine and pharmacy direction. Sometimes the companies are open without prior declaration neither in the local authorities, nor in the medicine and pharmacy direction.

MATERIALS AND METHODS

In a perspective of drawing up a current situation of the operating establishments in the medical devices sector, a questionnaire has been elaborated containing eight questions.

According to the data basis of the medicine and pharmacy direction relating to health ministry, this data basis which is accessible though the platform of the same direction, counts 746 companies declared and to which the questionnaire is addressed.

The investigation took place for 7 months in two phases, quantitative and qualitative .The first consists of sending a questionnaire to 288 establishments specimens acting in the medical pharmacy field, calculated according to the formula of Cochran (formula of Cochran is a statistical formula used to calculate or determine the sample size required to represent a population with a specific margin of error and confidence level), this in a random way. The second comprises a telephonic interview with the regulatory affairs office, if not, with the accountant or administrative affairs manager, aiming at obtaining any useful information related to the exercise of any activity that brings into play a medical device either an activity of manufacture ,importation, exportation, maintenance or of distribution.

RESULTS

The nature of establishments in the medical devices sector

The medical devices sector in Morocco is characterized by the diversity of establishments that vary according to the type of activity exercised and often according to the type of the declared activity, since the whole activities declared are not necessarily activities concretely exercised.

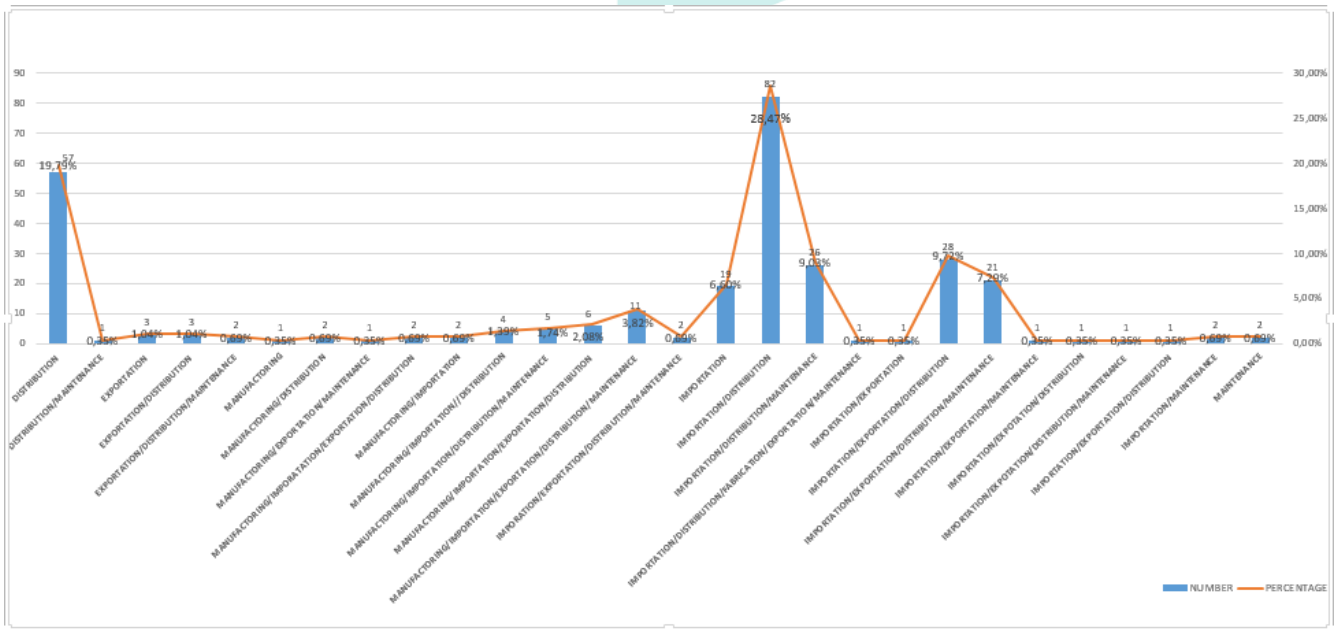

Fig.1 Type of establishments active in the medical device sector by activity (***Source*:** Author)

Among the 288 establishments questioned

- 82 establishments declared exercising as an activity the importation and the distribution of medical devices (28. 47%).
- 57 establishments declare that their main activity is the distribution of medical devices (19. 79 %).
- 28 establishments declare exercising as an activity importation, exportation and distribution of medical devices (9. 72 %).
- 26 establishments declare exercising as an activity importation, distribution and maintenance of medical devices (9. 03%).
- 21 establishments declare exercising as an activity importation, exportation, distribution and maintenance of medical devices (7.29%).
- 19 establishments declare that their main activity is importation of medical devices (6. 60%).

- 11 establishments declare exercising as an activity manufacturing, importation, exportation, distribution and maintenance of medical devices (3. 82 %).
- 6 establishments declare exercising as an activity manufacturing, importation, exportation and distribution of medical devices (2. 08%).
- 5 establishments declare exercising as an activity manufacturing, importation, distribution and maintenance of medical devices (1. 74%).
- 4 establishments declare exercising as an activity manufacturing, importation and distribution of medical devices (1.39%).
- 3 establishments declare that their main activity is exportation of medical devices (1.04%).
- 3 establishments declare exercising as an activity exportation and distribution of medical devices (1.04%).
- 2 establishments declare exercising as an activity exportation, distribution and maintenance of medical devices (0. 69%).
- 2 establishments declare exercising as an activity manufacturing and distribution of medical devices (0. 69%).
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- 2 establishments declare exercising as an activity importation and maintenance of medical devices (0.69%).
- 2 establishments declare that their main activity is maintenance of medical devices (0. 69%).
- 1 establishment declare that its main activity is distribution and maintenance of medical devices (0.35%).
- 1 establishment declare that its main activity is manufacturing of medical devices (0. 35%).
- 1 establishment declare that its main activity is manufacturing, exportation and maintenance of medical devices (0.35%).
- 1 establishment declare that its main activity is manufacturing, importation, exportation, distribution and maintenance of medical devices (0.35%).
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The legal form of the different establishments

The legal form adopted by each establishment remains a choice, but sometimes a legal obligation conditioned by the nature of the activity exercised or declared, the size of the establishment and its social capital.

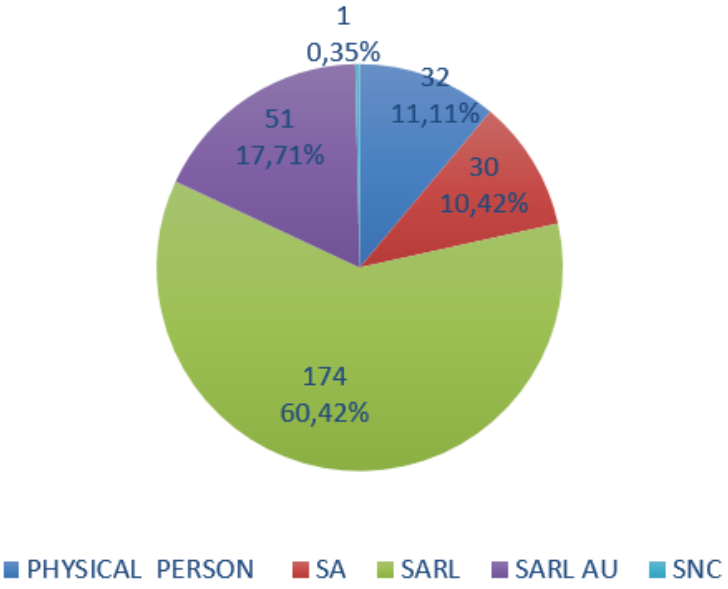

Fig. 2 The legal form of the establishments (***Source*:** Author)

- 32 establishments have adopted the legal form of physical person (11. 11%).
- 30 establishments have adopted the legal form of anonymous company SA (10. 42%).

- 174 establishments have adopted the legal form of limited responsibility company SARL (60.42%).
- 51 establishments have adopted the legal form of limited responsibility company with unique associate SARL AU (17.71%).
- 1 establishment has adopted the legal form of a collective noun company SNC (0.35%).

Reporting of incidents and accidents related to Medical Device Reporting (MDR) or materiovigilance to the medicine and pharmacy direction

The medicines and pharmacy direction, related to the Moroccan ministry of health, has made available to the operating establishments in the medical devices sector a form to fill and to address to the same direction in case of the discovery of any type of incident or accident linked to the use of medical devices, and this, in order to take the necessary procedures imposed, and to guarantee the security of the patients and the users of medical devices.

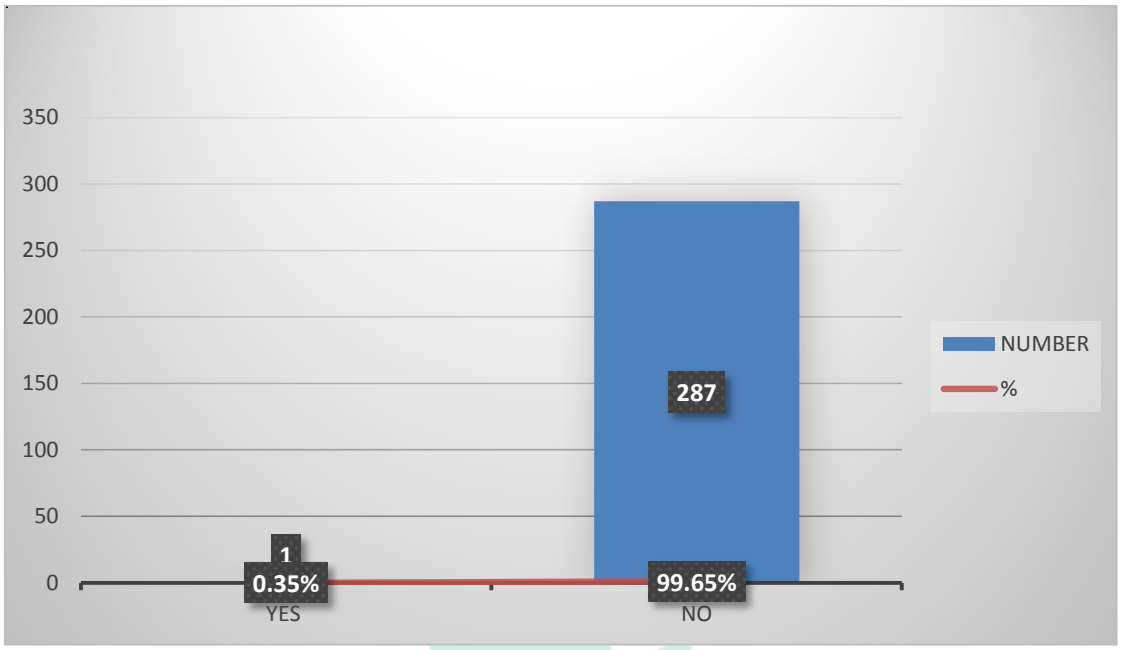

Fig. 3 Declaration of an incident or accident related to medical device reporting (Materiovigilance) to the medicine and pharmacy direction (***Source*:** Author)

- 287 establishments have reported no incidents or accidents linked with Materiovigilance to the medicine and pharmacy direction over the two last years (99. 65%).
- 1 establishment only has reported an incident or accident linked with Materiovigilance to the medicine and pharmacy direction (0.35 %).

Medical device reporting (MDR) or Materiovigilance

The materiovigilance constitutes a very important link of the life cycle of each medical device, and more accurately, during the cycle after the post market so as to detect any undesirable side effect, and thus report it to the instances and to the people concerned.

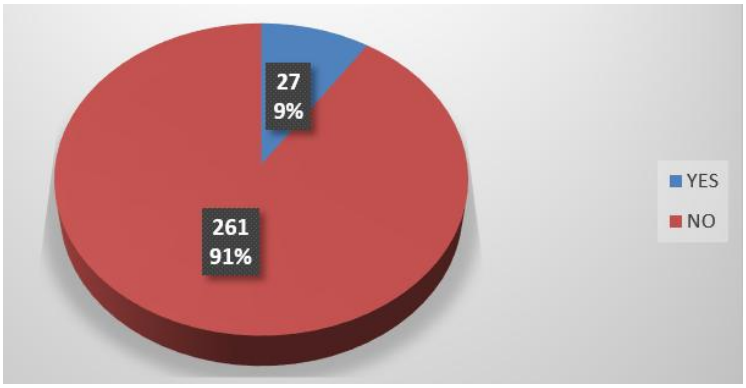

Fig. 4 Percentage of establishments having received from their collaborators a declaration of medical device reporting (Materiovigilance) (***Source*:** Author)

- 261 establishments have declared that they were recipients of a declaration linked with MDR from one of their collaborators (91%).
- 27 establishments have declared that they were recipients of a declaration linked with MDR from one of their collaborators (9%).

Person specifically in charge of medical device reporting (MDR) or materiovigilance

To have a person, particularly dedicated to the materiovigilance system, has become an obligation in several regulations such as the European regulation on medical devices (MDR 745/17) [6].

In Morocco, this does not constitute a legal obligation with the law 84-12, and that requires a revision of the said law so as to make it chime with the international regulation on the medical devices.

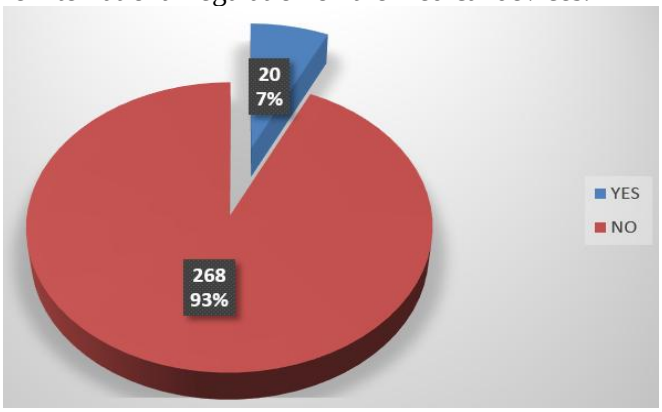

Fig. 5 Detention percentage of a person responsible for Medical device reporting MDR (Materiovigilance) within establishments operating in the medical devices sector (***Source*:** Author)

- 268 establishments do not detain a person particularly responsible for materiovigilance (93%).
- 20 establishments only have declared having a person responsible for materiovigilance (7%).

Cabinet of consulting or accompaniment

The cabinet of consulting or accompaniment plays an important role in helping the establishments set up a management system of quality, taken from their expertise, in order to solve specific problems and establish strategies adapted to their organization and to their needs.

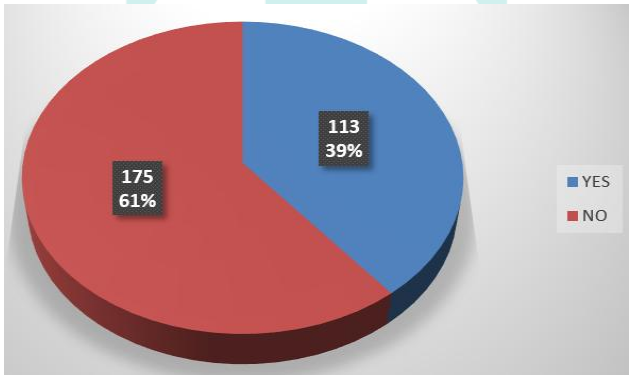

Fig. 6 Percentage of establishments that have been in contact with a consulting or accompaniment cabinet for the implementation of a quality management system ISO 13485 (***Source*:** Author)

- 175 establishments have declared being in contact with a consulting cabinet for the implementation of a quality management system in accordance with the norm ISO 13485(61%).
- 113 establishments have not yet contacted a consulting or accompaniment cabinet for the implementation of a quality management system ISO 13485 (39%).

Certification ISO 13485

The norm ISO 13485 is an international one that determines the essential requirements for a management system of quality of medical devices in order to ensure that the establishments implied in manufacturing, importation, exportation, maintenance and distribution of medical devices, are compatible with the requirements of security and performance.

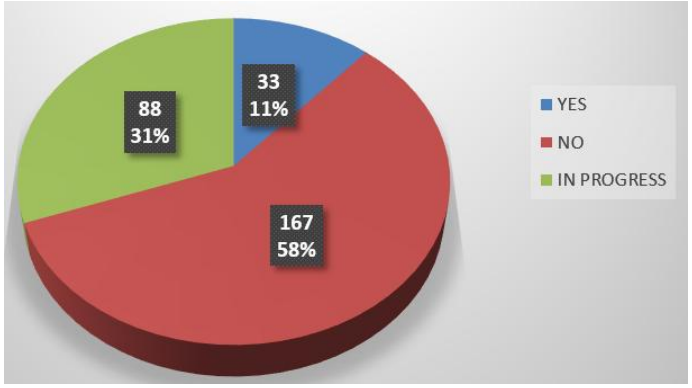

Fig. 7 The percentage of establishments which have got the certification ISO 134851 (***Source*:** Author)

- 167 establishments operating in the medical devices sector do not have the certification ISO 13485(58%).
- 88 establishments are in the process of obtaining the certification ISO 13485(31%).
- 33 establishments only have got the certification ISO 13485(11%).

Traceability system of medical devices

The traceability system of medical devices is crucial for ensuring a follow- up of the medical devices from their conception and manufacturing until their post market and their usage, thereby helping determine the levels of responsibility.

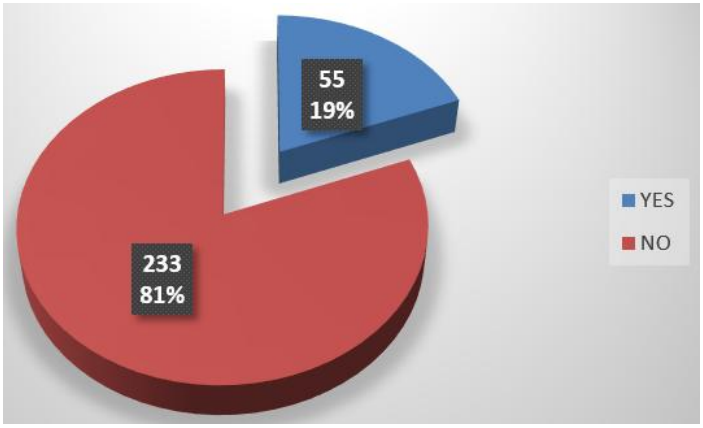

Fig. 8 Detention percentage of the traceability system of medical devices (***Source*:** Author)

- 233 establishments do not possess a traceability system of medical devices (81%).
- 55 establishments only own a traceability system of medical devices (19%).

Continuous training

Like all the enterprises, the operating establishments in the medical devices sector are in need of establishing, as far as possible and in necessary cases, a plan of formation in favor of their personnel so as to respond to the market's requirements, to reduce the losses related to ignorances, and to keep their current personnel in close contact with the regulatory and technological innovations.

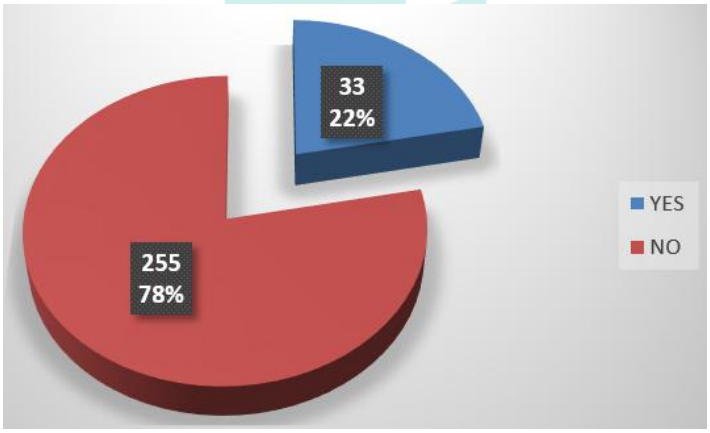

Fig. 9 Personnel training percentage (***Source*:** Author)

- 255 establishments do not have a formation program for their personnel (78%).
- 33 establishments have only a formation program for the whole personnel (22%).

DISCUSSION

This descriptive study with an analytic vision of establishments exercise operating in the medical devices sector in Morocco has allowed setting up current situation of its institutions and of its different activities, those of manufacture, importation, exportation, maintenance and distribution.

The principal activity of the questioned establishments is, in fact, mostly limited to the importation and the distribution of medical devices.

It is noticeable that the activities vary according to the declaration of the establishment ,since one declaration can comprise one activity, two activities ,three activities and sometimes even the five activities to know ;the activities of manufacturing, importation ,exportation, distribution and maintenance .In addition, the real activity of the establishments is limited to importation ,distribution or distribution and maintenance ,and it is seldom limited to manufacturing .

60.42 % of the establishments have adopted the legal form SARL " society with limited responsibility" ,and 17.71% have adopted the legal form SARL AU "society with limited responsibility with unique associate " .The choice of these two forms is mainly explained by the fact that these establishments are a simple organization that counts a very limited number of the personnel ,without forgetting that their administrative constitutions are very simple ,and do not require a great capital [7].

10.42% of the establishments have adopted the legal form SA" anonymous society" as the majority of them declared having exercised principally the activity of medical devices manufacturing, beside the activities of importation, maintenance, and distribution, this legal form which is compatible with the enterprises that recruit a great number of employees and that are of a complicated organization " directory and supervision council plus one or many auditors in charge of the control function ,and the social accounts monitoring in the conditions anticipated by the article 159 of the law 17-95 [8] ", and which require a great social capital not inferior to three million dirhams if the company publicly resorts to savings .In the other case this capital must not be less than 300000 dirhams " the article 6 of the law 17-95". These shareholders must not be inferior to five "first article of the law 17-95".

11.10 % of the establishments have adopted for the legal form of the physical person given that this type of establishment is of a simple organization. It is mostly constituted and represented by one person who is himself the owner of the establishment.

0.35% of the establishments are represented by one establishment which has declared an incident related to MDR to the medicine and pharmacy direction, whereas 99.65 % of the whole interrogated establishments have not declared to medicine and pharmacy direction any incident related to MDR. This is explained by the fact that the majority of establishments do not own a traceability system of medical devices or do not give importance to the different declarations stemming from the users of medical devices or from others.

91% of the interrogated establishments did not receive any declaration linked to MDR, neither from their clients, nor from their suppliers or others. Nevertheless 9% stated they were recipients of a declaration related to the MDR from their suppliers, their clients, and others.

93% of interrogated establishments do not employ or retain a person in specific charge of MDR, whereas only 7% of establishments declared having a person responsible for MDR in spite of his authentic duty as an accountant. This is interpreted by the fact that most establishments are of a small size and of a small capital .Thus they cannot recruit a person particularly responsible for materiovigilance and regulatory watch .This function is often occupied by the accountant or the person in charge of the administrative affairs. The latter remains unqualified for this task.

81% of the interviewed establishments do not possess a traceability system of medical devices since the arrival from the suppliers until the final clients, and just contented with having paper records, whereas 19% of the questioned establishments own only an ordinary traceability system used commonly in trade and in management, mostly of excel and SAGE types .These soft wares do not allow a precise and rigorous traceability ,taking into account the particularity of the medical devices sector .That is why the actor establishments in the medical devices sector must agree and proceed in order to have an installation of a common and normalized traceability system for insuring security and traceability of the whole medical devices presented for sale in the market .

19% state that they have a formation program and ensure a regular formation for its personnel in the domain of devices concerning maintenance, marketing, and management ,while 78% of the establishments do not propose nor ensure a formation program for their personnel and this may affect the quality of the service carried out by this establishments, considering that the medical devices sector is in increasing development, thus necessitating an actualization of knowledge of the personnel in terms of applied technologies ,legislation …etc.

39% of the establishments stated that they contacted the consulting cabinet for the implementation of the management system of quality ISO 13485 .This contact is explained by the fact that the medicine and pharmacy direction has obliged the establishments operating in the medical devices sector to provide an attention of contact with a consultation cabinet for the setting up of the said management system of quality .This is like a transient period to allow the establishments continue to import and distribute the medical devices .However , 61% of the questioned establishments did not contact a consulting or accompaniment cabinet since the majority of them ,from their part, are needless of the ISO 13485 certification so far, taking into account that their activities are essentially restricted to distribution or maintenance of medical devices and that ,according to them ,the ISO 13485 certification must be an obligation for the establishments of importation and manufacturing of the medical devices which are an organization of an important size.

58% of the establishments do not own a management system of quality related to medical devices ISO 13485.

11% of the establishments only have a management system of quality ISO 13485 and 31% are on the way of implementing this system. This is explained by the fact that the setting up of management system of quality and the obtaining of the certification ISO 13485 are quite costly and their price can reach 400000 dirhams besides the technical and organizational difficulties that witness most of the establishments.

CONCLUSION

The medical devices field remains a major sector to ensure the implementation and the success of any sanitary strategy and patient care, hence a good quality of care however, the medical devices sector in Morocco knows many difficulties ,among these are:

- ✓ Some medical devices of class III are stocked and maintained randomly, thereby threatening the sanitary security of the patient.
- ✓ Some establishments of the parapharmacy type are sometimes open without being declared to the medicine and pharmacy direction, and are, in some cases, contented with having a simple permission or not having it, in most cases from the local authorities.

- ✓ The majority of the establishments that operate in the medical devices sector are not inspected since their opening.
- ✓ Some establishments import products such as gloves declared at the authorities as hygiene products and which they resell as medical devices, thereby endangering the patient's security.
- ✓ The majority of the establishments are of a small or average size. Thus their competitive appeal is limited in comparison with high sized establishments of a SA type, the latter possess a management system of quality ISO 13485.
- ✓ The existence of conflict of interests between the establishments operating in medical devices sector and the pharmacies, the latter sell medical devices of all confused categories without installing a management system of quality according to the norm ISO: 13485. As for the other establishments, the implementation of this system has become a legal necessity .Hence, to impose this system on a category and exonerate another is considered as the creation of an environment of unlawful and unconstitutional competition, since, from a scientific viewpoint the security of medical devices is the same as in the pharmacies or in the parapharmacies, or in the establishments operating in the medical devices sector.

In order to guarantee a good security of medical devices and hence optimal patient care ,the supervisory ministry which is health ministry must optimize the reinforcement of legislation respect concerning the medical devices through regular inspections of different establishments of manufacturing ,importation ,exportation ,maintenance and distribution and therefore through boosting its legal arsenal in order to be harmonious with the international legislation , and the European one in particular , since Europe constitutes a major actor of exchange with Morocco in terms of medical devices .

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DECLARATION OF LINK OF INTERESTS
The authors declare that they have no links of interest

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