Regulation of medical devices in Europe and Africa

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INTRODUCTION

Medical device regulation worldwide is diverse. Regulation is evolving as a result of the necessity to enhance patient safety. In Europe, the medical device directives were reviewed leading to the development of the Medical Device Regulation (EU 2017/745) which will come into force in May 2021 because of the corona virus pandemic. Scandals such as those involving the silicone breast implants and metal to metal hip implants drove the need to institute changes in the regulation that had the patient's safety and well-being in mind.

Many countries in Africa do not have medical device regulations in place or implement varied regulatory practices. The regulatory authorities are constrained in terms of human resource and funding to effectively regulate medical devices. Given this background, the quality, safety and performance of medical devices placed on the African market is not guaranteed. Research on regulation of medical devices in Africa is particularly limited.

AIMS

1. To evaluate regulations and guidelines for medical devices.
2. To assess challenges faced by regulators in Europe and selected African countries of Uganda, Kenya, Tanzania, Rwanda and Ghana.

METHOD

Five African countries, namely, Ghana, Kenya, Rwanda, Tanzania and Uganda, that are members of the Commonwealth were selected for this study. Two countries in Europe, namely, Switzerland and Germany, were included for the European aspect.

A cross-sectional study design was utilised. Questionnaires were developed and validated by a panel of experts and were subsequently administered to 20 regulatory officers from the countries included in the study. A key informant interview guide was used to interview key informants from the different regulatory agencies in the countries that participated. Questionnaires were self-administered and the key informant interviews were conducted via telephone, skype and face-to-face.

Data analysis of audio interviews, transcripts and notes based on qualitative thematic content was conducted and reviewed for consistency for qualitative data. Questionnaires were used to carry out quantitative data triangulation of the interviews.

RESULTS

The Medical Device Directives and Medical Device Regulation (EU 2017/745) apply in Europe. Revisions of medical device directives have been undertaken to make medical device regulation in Europe more robust. The procedures for market access are defined and harmonized on a European level and applied by the Notified Bodies.

Regulation of medical devices in Africa is varied, however, formulation of regulations is being undertaken in different countries and a harmonisation drive is underway to cater to the African continent.

The results of the study demonstrated different maturity levels with regards to existence of medical device regulations, guidelines and actual practice in the countries that participated in this study.

Table 1: Elements of current status of regulation and compliance in Europe and Africa

Element of compliance	Europe N=2		Africa N=5				
	Germany	Switzerland	Ghana	Kenya	Rwanda	Tanzania	Uganda
Regulation present	✓	✓	✓	×	×	✓	×
Guidelines available			✓	✓	×	✓	×
Compliance oversight	×	×	✓	✓	×	✓	×
Training	×	×	✓	✓	×	✓	✓
Reporting			✓	✓	×	✓	✓
Monitoring		√	✓	✓	×	✓	✓

40% of the questionnaire respondents indicated that the regulations in their respective countries were sufficient.

4 out of 5 of the participating African countries have import control measures at the ports of entry.

CONCLUSION

The results demonstrated that the ground is fertile for the development of regulations where none exist and the findings may support harmonization efforts and aid in adoption of improvements in regulation where they exist. This will bolster regulatory efforts and contribute towards patient access to safe and effective medical devices of good quality.