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Challenges to Medical Device Accessibility following the New European Union Regulations Governing Notified Bodies for Medical Devices

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INTRODUCTION

The EU medical device (MD) regulatory structure has changed from Directives to Regulations to ascertain safety, quality, and efficacy of MDs in the EU market. The EU Regulations are complex and have increased safety partly by adapting stringent requirements for Notified Bodies (NBs). [1]

AIMS

- To analyse challenges presented from the transition between the Directives to Regulations governing Notified Bodies
- To identify reasons and manner with which Regulations are affecting Notified Bodies

METHOD

Ethical Committee approval

Study registered with Faculty of Medicine and Surgery Ethics Committee

Development of questionnaire

A self-administered questionnaire was developed to identify challenges related to:
(i) designation process
(ii)recruiting and training of experienced personnel
(iii)BREXIT
(iv)Covid-19 pandemic, and
(v) overall requirements of the Regulations

Validation and dissemination of questionnaire

A focus group consisting of four regulatory pharmacists operating at the Medical Device Unit at the Malta Medicines Authority, validated the questionnaire.
The questionnaire was distributed to a sample of 51 undesignated NBs obtained from the NANDO database on the European Commission website

Data analysis

Descriptive statistics were carried out where mean rating scores range from 0 (strongly disagree) to 4 (strongly agree).

RESULTS

Twenty valid responses were collected. Four major challenges were identified:

1. Recruiting of experienced personnel- mean rating score of 3.91, from NBs who are in the process of becoming designated. NBs who are considering to apply for designation had a mean rating score of 3.67. NBs who opted not to apply for designation had a mean rating score of 1.75, indicating that the recruiting of experienced personnel was not a main reason why they opted not to apply
2. Financial Feasibility: NBs who opted not to apply, agreed that the designation process is not financially feasible to run with a mean rating score of 3.63
3. Scientific and Technical evaluations competence: NBs who opted not to apply agreed with this challenge, mean rating score of 3.12
4. Waiting list: NBs who opted not to apply for designation perceived that the waiting list was very challenging and was one of the reasons why certain NBs opted not to become designated. NBs who are in the process of designation and NBs who are in considering to apply were neutral about this challenge, with a mean rating score of 2.09, and 1.78 respectively.

Table 1: Four Major challenges identified throughout the questionnaires (N=20)

Designation status of notified bodies: (mean rating score: statistical analysis- Friedman test)	In the process: (0- strongly disagree, 4- Strongly agree)	Considering to apply: (0- strongly disagree, 4- Strongly agree)	Opted to not apply: (0- strongly disagree, 4- Strongly agree)
Recruiting experienced personnel is problematic	3.91	3.67	1.75
Designation is not financially feasible to run	/	/	3.63
Increased competence required in terms of scientific and technical evaluations	/	/	3.12
Waiting list to apply for designation process is an issue	2.09	1.78	3.13

CONCLUSION

The results highlighted that Notified Bodies who are in the process to become designated and those who are considering to become designated under the Regulations agreed that recruiting experienced personnel is problematic.

Future studies may develop a follow up questionnaire to highlight the number of designated NBs and suggest ways how the transition could have been done differently whilst still sustaining the safety of medical devices for our patients and to ways how to assure that the medical devices affected will remain accessible to the public.

REFERENCE

1 European Commission (EC). Regulatory framework [Internet]. EU: EC; 2019 [cited 2019 Mar 14]. Available from: https://ec.europa.eu/ growth/sectors/medical-devices/regulatory-frameworken#newregulations