



## Biomedical Alliance in Europe

# Clinicians concerned about limited availability of medical devices

### Report of the BioMed Alliance survey conducted in cooperation with the ESC and EFORT

#### Introduction

Reports from clinicians, the European Commission and manufacturers have shown that there are issues around the availability of medical devices. This problem may soon become worse if measures are not taken to address it, since the deadline for recertification under the EU Medical Device Regulation (MDR) for a large group of devices is 26 May 2024. Many devices are at risk of being taken off the market with serious consequences for the provision of healthcare in Europe.

BioMed Alliance therefore conducted an important survey on the availability of medical devices, from August 2022. It assessed if clinicians have experienced that any devices that they normally use are no longer available on the market. The survey was developed by BioMed Alliance in cooperation with ESC and EFORT and was open until the end of September.

The survey results indeed confirm that many clinicians are increasingly concerned about the rising number of essential devices that are no longer available for use in medical care for various reasons, and they reported that this is affecting the quality of care that they can provide to their patients.

Similar surveys have been conducted by other organisations, for example by EFORT on the availability of devices used in the orthopaedic practice. Professors Melvin, Kenny, Gewillig and Fraser have recently authored a [paper](#) on ‘Orphan Medical Devices and Pediatric Cardiology – What Interventionists in Europe Need to Know, and What Needs to be Done’. The BioMed Alliance has been following this issue for some time; for more information read our [press release](#) on this topic.

This short report summarises the findings of our BioMed Alliance survey.

#### Methodology & demographics

The survey aimed to find out whether clinicians experience problems with the availability of devices, which devices are impacted, and how the problem affects patient care. It was sent to the 36 medical and research societies that belong to the BioMed Alliance and shared via internet and social media. The survey consisted of a mix of around 20 open and multiple-choice questions.

In total there were 314 replies, and the vast majority consisted of clinicians, specialists and laboratory professionals. Clinicians are active in different fields including cardiology, paediatrics, orthopaedics, gastroenterology, reproductive medicine, anaesthesiology, intensive care medicine, electrophysiology etc. Respondents work across the EU and a very small segment is from non-eu countries.

Organisations:

- 41% European Society of Cardiology,
- 18% European Society for Human Reproduction and Embryology,



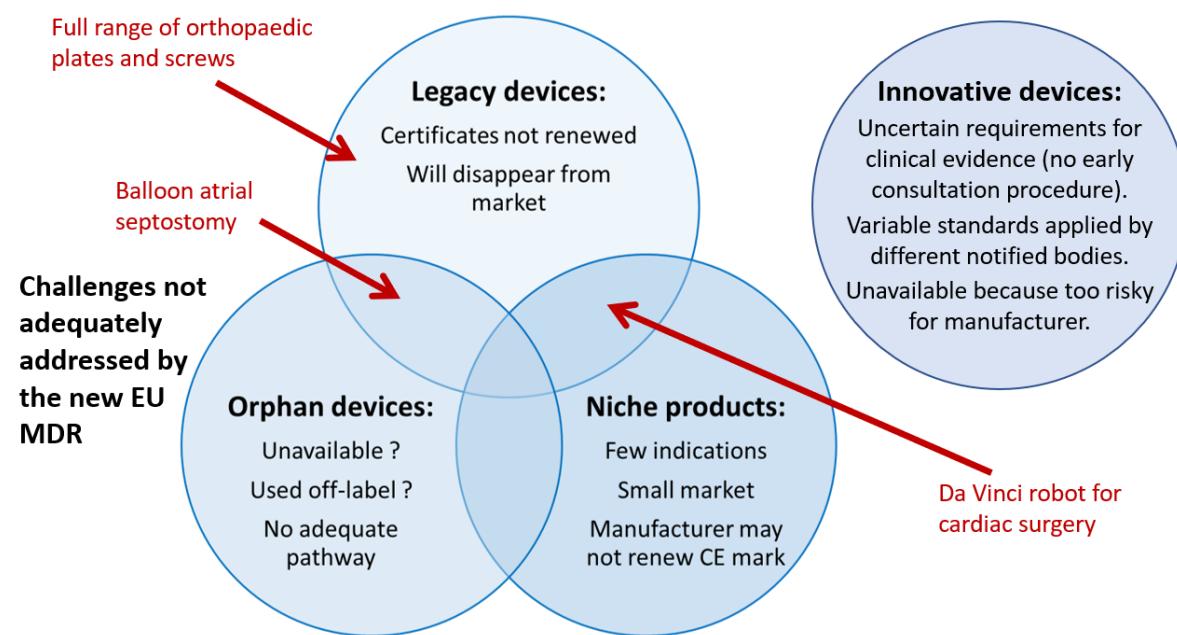
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- 12% European Association for Cardio-Thoracic Surgery,
- 6% European Society of Anaesthesiology and Intensive Care,
- 3% European Renal Association
- 1% European Alliance of Associations for Rheumatology, European Society for Paediatric Gastroenterology, Hepatology & Nutrition, European Federation of National Associations of Orthopaedics and Traumatology, European Society of Clinical Microbiology and Infectious Diseases, European Society of Radiology
- 14% Other

### Results

#### Issues with the availability of devices

Results of the survey show that a majority of 53% of all respondents have already experienced that certain medical devices are no longer available for clinical use. Examples of devices that were mentioned include the Da Vinci Robotic Systems, and different types of balloons, stents, coils, insulin pumps, respirators, pacemakers and heart valves.

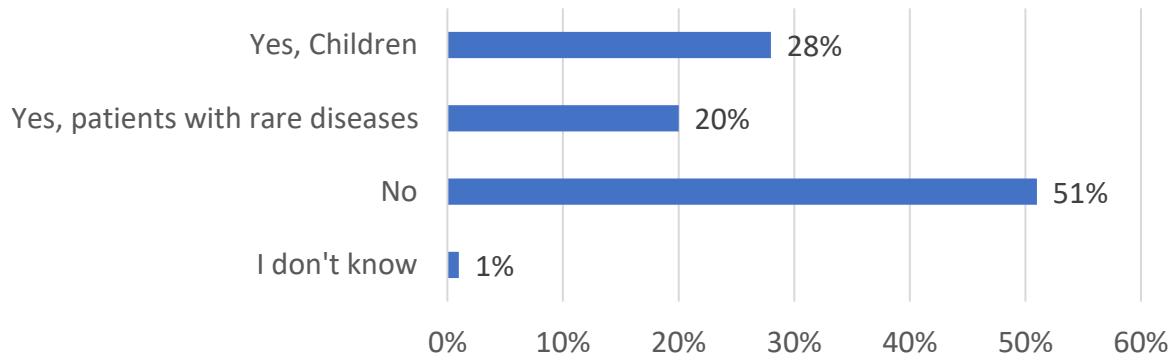


There seem to be particular issues with devices that are used on small subsets of patients, including devices used on children, orphan devices (used for treating rare conditions) and devices in odd sizes. These devices often cater to a very small group of patients and could thus for financial reasons be less attractive for manufacturers to maintain on the European market. When asked whether respondents use the device affected to treat paediatric patients or patients with a rare condition almost half of respondents confirmed this.



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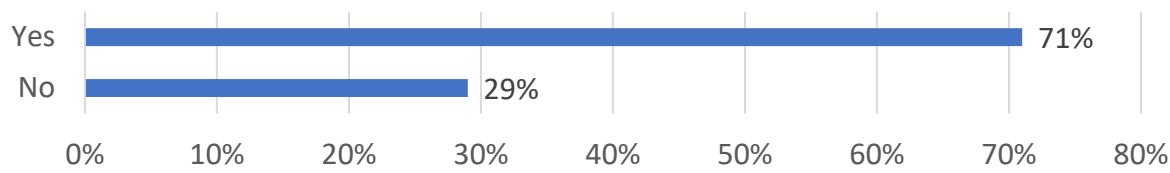
### Do you use the device affected to treat children or patients with rare diseases?



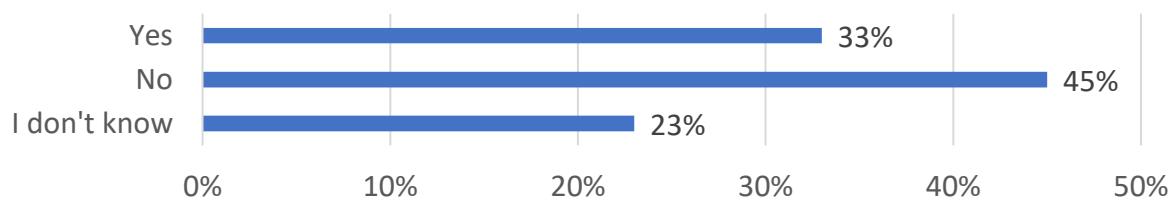
#### Impact on clinical care

Of all respondents, 71% said that they were able to use an alternative device but only 33% of those said that the device was as effective as the original device.

### Could you use an alternative medical device?



### Was it as effective as the old one?



In case there was no alternative device available, the non-availability often has a negative impact on the level of patient care. 59% of all respondents said that this reduced the level of care, showing that a limited availability of essential devices can have a disruptive impact on the European healthcare system.

#### Causes of the limited availability of devices

A variety of factors seem to cause the unavailability of devices, and this was also reflected by the answers provided in the survey.



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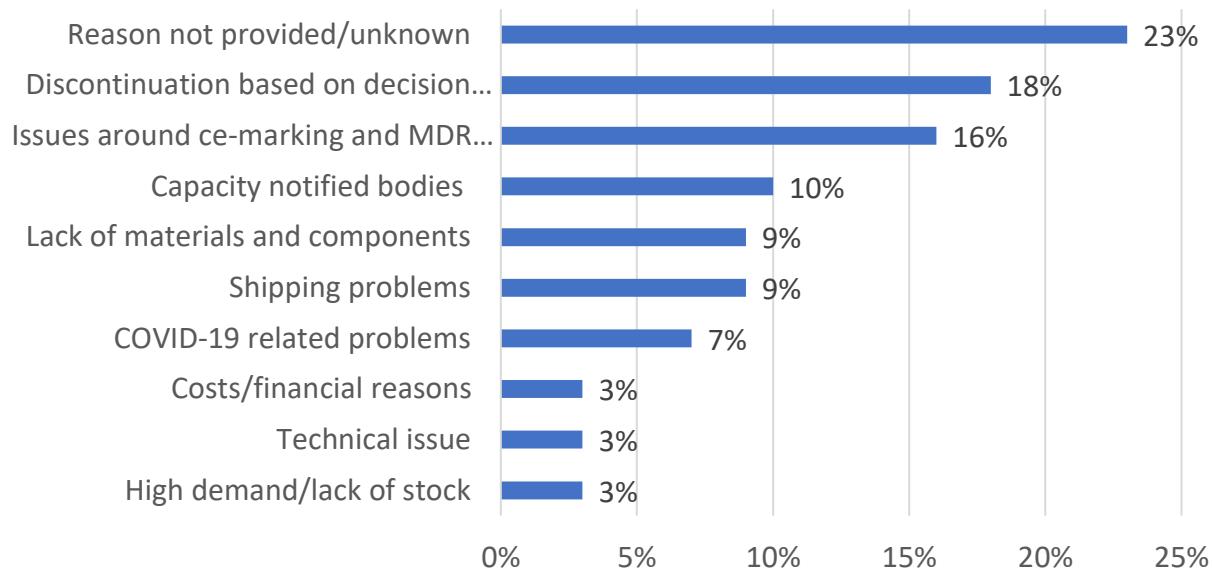
Many clinicians did not know why the device they used was no longer available, either because the responsible person in their hospital/institute did not communicate it or because the manufacturer did not provide a reason. In certain cases, the manufacturers simply informed them that the reason for the limited availability was simply 'MDR' without further specifying.

There are several MDR-related reasons that were shared in the survey. Often manufacturers decided themselves to withdraw the devices, for example because they consider the MDR certification procedure to be too lengthy or too expensive, particularly for devices that cater to a small segment of the population (including Orphan or Paediatric devices). Many respondents also compared Europe to the US and other parts of the world, and argued that from a financial perspective other markets are more attractive to manufacturers due to the bigger market sizes or less costly certification procedures. Other MDR related reasons shared in the survey were the capacity of notified bodies and lengthy or delayed certification procedures, and general issues around CE marking and MDR recertification.

Respondents also mentioned certain non-MDR related reasons. These included problems related to the COVID-19 Pandemic and the war in Ukraine, shipping problems, a lack of materials or components, technical issues and in general a lack of stock.

The majority of the reasons shared in the survey is thus MDR related, but it seems like a variety of factors all contribute to a limited availability of medical devices.

### Did the company give a reason for the unavailability of the device? What was the reason provided?





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### **What should be done?**

There is clearly an issue with the availability of medical devices, and this is already affecting patient care. The issue seems to be caused by a variety of factors including issues related to the implementation of MDR, financial considerations and a range of other external factors including the complicated geopolitical situation. It is important that a balanced package of solutions will be proposed to address the different factors that influence this issue. While regulators should put the necessary provisions in place to ensure the regulatory system is ready, manufacturers also have a responsibility to do everything they can to be prepared for the transition to MDR and to submit their applications in time and ensure applications are of sufficient quality.

### **Extension deadline for MDR recertification**

Regulators should consider extending the MDR transition period, as devices are at risk of being taken off the market since the regulatory system and manufacturers are insufficiently prepared to ensure all essential devices will be recertified before the deadline of 25 May 2024. This delay must be on the condition that the period is used to enhance notified body capacity, address issues around the MDR implementation and to ensure that additional measures are put in place to facilitate the evaluation and certification process of orphan, legacy and niche devices

### **Additional measures to support manufacturers of orphan devices and niche devices**

There seem to be particular issues with orphan devices or niche devices that cater to small patient groups. In the pharmaceutical field the [system](#) for orphan designation and the provision of incentives for manufacturers producing Orphan Medicinal Products is already well established, but a similar system is not yet in place for medical devices. The Commission should continue looking into creating certain incentives and setting up support for orphan devices, to make it more attractive for manufacturers to put them on the European market.

### **Use of registries to gather additional clinical evidence**

Registries contain a wealth of information on the use of medical devices and effects on patient care. In the pharmaceutical field [patient registries](#) already play a role in monitoring the safety of medicines, and the European Medicines Agency has implemented an initiative to make better use of registries and developed guidelines and created an inventory of registries. Similar steps can be taken to facilitate the use of registries for the evaluation and post-market surveillance of medical devices.

### **Use of expert panels for early dialogue and support to manufacturers**

MDR Article 61 paragraph 2 can play an important role in allowing manufacturers to seek advice from the expert panels prior to the clinical evaluation and investigation. This process should be supported as much as possible to help manufacturers prepare for the evaluation and certification process.

### **Explore setting up conditional approval**

Allowing conditional approval of devices in exceptional cases should be considered. This can serve as a measure of last resort for devices that are at risk of disappearance and are used to treat life threatening conditions.



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### Conclusion

The results of the BioMed Alliance survey (conducted in cooperation with ESC and EFORT) show that clinicians are increasingly concerned about devices disappearing from the market. In addition, in certain cases there were no alternative devices available or the alternative devices were not as effective as the old devices. The reasons for the unavailability vary, though the majority mentioned in this survey were MDR-related.

While the European Commission's Medical Devices Coordination Group (MDCG) has already published a transition [paper](#) highlighting a series of measures to facilitate the transition to MDR and mitigate problems, this may not be sufficient. It is therefore essential that regulators, policy makers, notified bodies, manufacturers, healthcare professionals, patients and other stakeholders continue a structured dialogue and together agree on measures to address this important issue.

An increasing number of devices is already no longer available, and with the deadline for MDR recertification of a large group of devices coming up, the problem is only expected to get worse unless sufficient measures are put in place. We must act now to limit the impact on patient care to a minimum.