COCIR Contribution

to the public consultation on the extended EMA mandate[1]

Introduction

COCIR – the European Trade Association representing the leading industries in the medical imaging, radiotherapy, electromedical and health ICT sectors, notes the European Commission [EC] initiative to extend the EMA mandate and reinforce its role, in line with the principles of subsidiarity and proportionality, as part of a set of measures aiming to strengthen the EU-level crisis preparedness and management, while increasing resilience and solidarity across the Union.

COCIR welcomes the **establishment of a Union-wide system** to monitor and report on potential and actual **shortages** of medicinal products and medical devices in the EU.

Encompassing data and information from all relevant stakeholders -such as the EC and its Agencies, national authorities through designated points of contact, marketing authorisation holders, and manufacturers- the proposed **harmonised framework could facilitate accurate forecast and forward planning**. Such a coordinated approach could **permit correct and timely information flow**. The use and development of IT tools should, to the extent possible, be **built upon or integrated with building blocks of the European Health Data Space**, in order to make most effective use of available high-quality data within a trusted environment.

Expert Panels on medicines and medical devices

The proposal foresees the setup of a permanent structure of **expert panels** within the Agency, aiming to quickly **provide scientific advice and technical support on demand in case of crisis and to support the assessment of certain high-risk medical devices**.
Considering that **stockpiling** should be part of the overall EU crisis strategy, EMA could contribute to the smooth functioning of the internal market in times of crisis and mitigate risks of shortages or disproportionate national stockpiling in medicines and medical devices.
Focusing on **Medical Devices**, we consider, that by **respecting the specificities of market access for medical devices, the relevant EMA expert panel could ease the access to critical medical devices**, avoiding bottlenecks in conformity assessment, and prevalence of non-compliant, unsafe or counterfeit products -as was the case in the COVID-19 pandemic.

Executive Steering Group on Medical Devices ('the Medical Devices Steering Group')

Under certain conditions, COCIR would endorse the establishment of an **Executive Steering Group on Medical Devices** tasked 'to coordinate the expert panels on medical devices, which will be involved in the assessment of specific high-risk medical devices and device types relevant for health crisis management and provide scientific advice essential in crisis preparedness and crisis management'.

However, we believe that the medical technologies industry **should be an integral part of such a Steering Group and not an occasional external guest**, since:

- with their insights and expertise, the medtech industry expert representatives would provide valuable **contributions to the discussions and the timely information flow** between the EC, the Member States and the industry – which proved to be challenging during the COVID-19 pandemic.
- they would **sustain the adoption of the necessary information, to effectively monitor the supply and demand of the medical devices** included in the **public health emergency critical devices list, the establishment of which they should also be actively involved in.**

This way cases such as those experienced during the pandemic, where **Member States placed their orders several times and at different levels** -such as hospitals, regions, national level directly to manufacturers and via joint procurement- would be avoided, and **data collection and sharing would be easier**.

[1] *Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices - COM(2020) 725 final / 2020/0321 (COD) - Link*

Medical Devices Steering Group's support groups

According to the proposal, the Medical Devices Steering Group will be mandated to support the Medical Device Coordination Group (MDCG) in order to ensure 'that those panels can efficiently and effectively provide scientific advice relevant for crisis'. **Clarification is needed on the setup and framework of activities deployed by this Steering Group's support group** 'comprised of single points of contact from national competent authorities for medical devices' which aims to assist the Steering Group in the context of the three panels -MDCG, CAMD and Medical Devices Steering Group working party- **especially in case where these panels consist of the same single points of contact**.

Shortages of medical devices

COCIR identifies some remit for further improvement regarding the **recommendations on shortages of medical devices [Article 22 (3) and (5)],** which may fall under the Medical Device Regulation – e.g. measures under COVID-19, including [i] postponement of MDR, [ii] possibility of remote audits and use of MDR Article 59. In line with this, the EC should explain **how the MDCG would be involved in this process, in addition to ensuring that the medical technologies industry is being duly consulted**.

Finally, COCIR would like to express its concern about the proposed requirement for the medical devices industry to provide some **very commercially sensitive information**, especially regarding [i] sales and market share data [Art. 23 3(e)] and [ii] mitigation plans including production and supply capacity [Art. 23 3(f(]. In other words, although we welcome the EC intention to connect health data collected by EMA to European Health Data Space, we find it very important to define for whom the data will be available and for which purposes. In this context, we **urge the EC to further clarify the purpose and processing of such data** beyond the rather general description provided in Article 24 – where point 5.b is missing.

COCIR, together with its members, will continue to contribute to this European Commission initiative, providing our full support. Moreover, we call on the European Commission to organise a specific stakeholder consultation with our member industries and look forward to becoming informed on the results of such consultation and planned next steps.