IMDRF - DITTA Joint Virtual Workshop

What to learn from COVID-19?

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Reflections on medical devices from the perspective of the European Commission

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Health

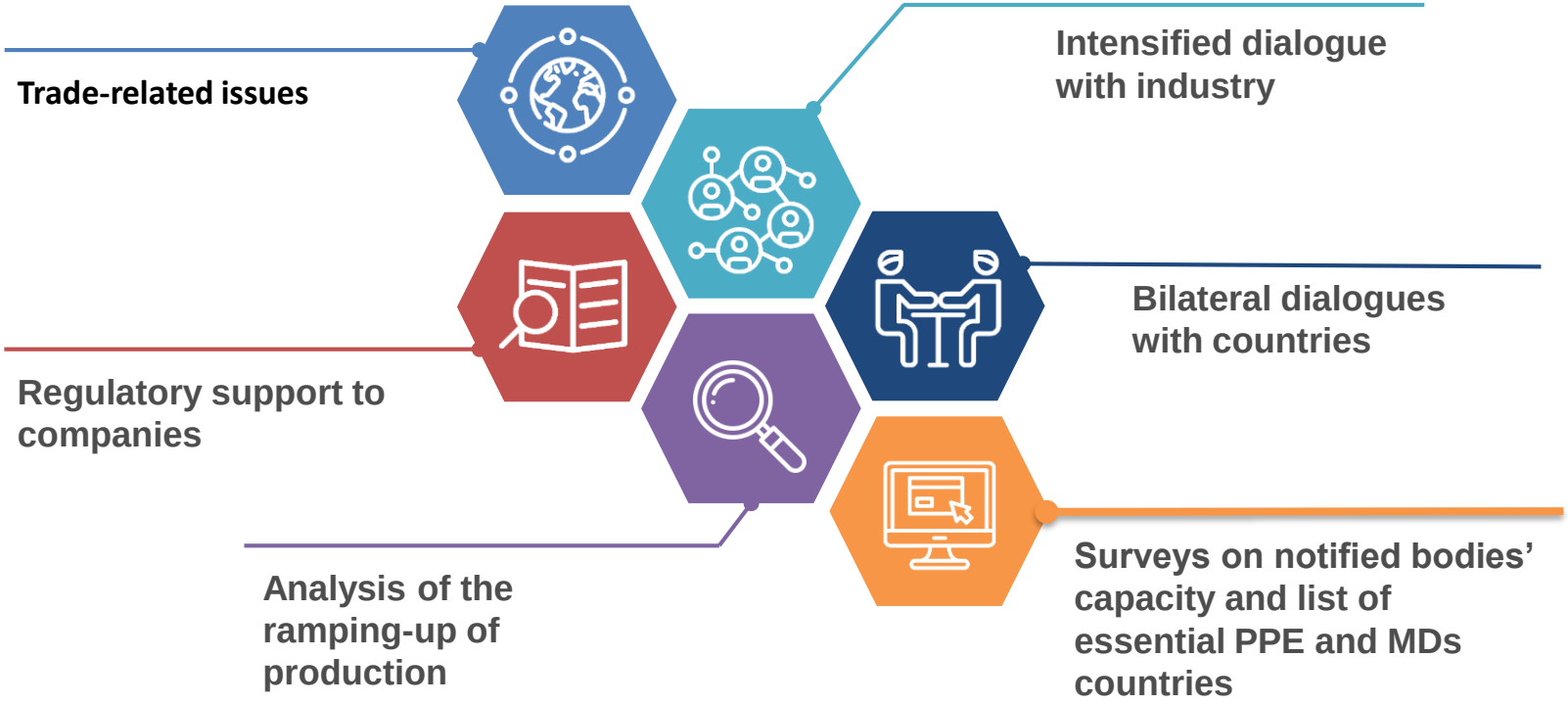
European Commission

Priority actions:

A. Counteract shortages

- Ramping up of production (ventilators, face masks..)
- Availability of Covid-19 IVD tests
- Many European Standards made freely available
- Combatting export restrictions
- Derogations (MDD, IVDD)
- Joint procurement Agreement: masks, gloves, gowns, laboratory equipment, ventilators, intensive care units
- Clearing House (next slide)

Overview of Clearing House activities



B. Regulatory measures

- Regulation (EU) 2020/561 adopted on 23 April 2020 amending MDR, as regards the dates of application of certain of its provisions
- Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies
- Commission notice of 11 January 2021on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment

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C. Guidance documents (selection)

- Guidance on placing medical devices and PPE **on the EU market**
- Guidance on Medical devices, Active implantable medical devices and in vitro diagnostic medical devices **in the COVID-19 context**
- Guidance to increase production of **PPE, hand gel, 3D printing**
- Guidance on regulatory requirements for **ventilators**
- Commission guidelines on **Union-wide derogations**
- Guidance on temporary measures on **notified body audits** during COVID-19 quarantine orders and travel restrictions + renewal designations.
- Guidelines on COVID-19 IVD **tests** and their performance
- Working document on **performance of** COVID-19 **test methods**
- Database of publ. available **performance data COVID-19 IVD tests**

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Some experiences on ramping up medical equipment production

- Importance of **keeping trade flows open**, both within the Single Market and with main trade partners.
- Importance of having **pre-existing structured communication channels** with industries.
- **Main bottlenecks:** increased prices for raw material and production input; lack of components and parts for ventilators; lack of consumables for testing kits; capacity of Notified Bodies for certification of products.
- Importance of policy for **strategic reserves** (striking the balance between production capabilities and strategic reserves is key), mostly for PPE, but in some cases it was pre-existing to the COVID-19 crisis.
- Importance of **sustainability aspect** as pivotal to deal with the ramped-up production of medical equipment.

General political initiatives:

A stronger European Health Union

- Build on first lessons from the health crisis:
- Strengthen crisis preparedness and management of cross-border health threats.
- Strategic stockpiling to address supply chain dependencies, notably for pharmaceutical products.
- Reinforce and empower the agencies ECDC and EMA (- monitoring and mitigating the risk of shortages of critical medicines and medical devices)
- Build a European Health Emergency Response Authority (HERA) for coordination across the whole value chain on medical countermeasures
- Increased funding through future proof EU4Health programme
- Question of health competences (Conference on the Future of Europe).
- Learn the global lessons: Global Health Summit in Italy.

Thank you for your attention !

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