FOLLOW-UP MEETING ON RAMPING-UP PRODUCTION OF MEDICAL EQUIPMENT
19.05.2020

The purpose of the meeting was to follow up and gather more in-depth information after the discussion held on 4 May concerning existing supply and increase of production for medical equipment, including obstacles and bottlenecks.

The meeting, chaired by two members of the Clearing House, was attended by around 120 participants, including the national contact points and the members of the Competitiveness and Growth Working Party. Colleagues from different Commission services also joined the call.

As in previous meetings, to facilitate interaction Sli.do was used during the meeting (please see PDF file attached with results of Sli.do polls for more details). Member State representatives also provided input through the Webex chat function.

After a short introduction providing the context of the meeting, two Member States delivered presentations of best practices at national level, and more specifically 1. Bulgaria on an information tool for businesses with short notes and links to all Government anti-crisis measures to address the economic impact of COVID-19; 2. Belgium on the European platform Organised by Enterprise Europe Network Flanders for match-matching and sharing of useful information and support measures.
(For more information on the two tools, please see the attached PPTs)

GR asked to receive the participants' list. The Clearing House will look into the feasibility of this, as explicit consent for dissemination of sensitive data would need to be collected.

The discussion then moved to the detailed questionnaire, previously shared with participants, which was shown through Sli.do. Please see here below the main findings from the poll results:

On Existing supply

- Most MS indicated that they are measuring their own supply of PPE, ventilators, test kits and medical equipment. How is this monitoring done?
Most popular answer: regular surveys (50%), but also ad hoc contacts with industry (one-third). No use of national statistical offices.

Comments
ES: scorecard where the autonomous communities transfer their stock and consumption to the government
DK: IT-infrastructure that allows for upload of inventory to a national database. As of now, it is required to upload data on a daily basis.
IE: Health Service procurement databases
MT: data collection on a daily basis and verifies the data weekly both with respect to demand/supply and financial forecast

- More specifically, are you monitoring the supply of the following medical equipment in your country? (
Most popular answer: masks, but also tests, gowns and gloves (al above 70%), but less so on medical devices (only-half)

- For which products you currently have domestic production?

Most popular answer: surgical masks/FFP masks by far (88%)

- Two-third of MS indicated that they have strategic reserves. Which products do these cover?
Most popular answer: personal protective equipment by far (93%)

Comments
LV: a small reserve of face masks

LT: PPE; medicines

NL: no current strategic reserves but plans for PPE

On ramping up production

- Most MS indicated that they are incentivising the domestic production of medical protective gear, test kits and active substances. Which incentives are MS using?
Most popular answer: public tenders/calls (50%), but also matchmaking platforms (46%)

Comments

LT: matchmaking platform; several times negotiated procedure without publication

IT: for information, issues and measures by Italy: https://www.invitalia.it/cosa-facciamo/emergenza-coronavirus/incentivi-curaitalia

BE: Provision of additional funding for R&I. Initiative from the health cluster (BIOWIN) providing a matchmaking platform around a wide set of topics: https://biowin-cooperation-platform-covid-19.b2match.io/ Main goals:

1. Gather and structure the initiatives around urgent themes,
2. Foster interaction between industrial, academic players and other contributors,
3. Consolidate critical masses around these themes in order to catalyse and strengthen project development.

Topics addressed:

1. Basic research: physiopathology and molecular studies
2. Epidemiology and modelisation
3. Biobanking
4. In vitro & In vivo diagnostic approaches (research & clinical validation)
5. In vitro & In vivo diagnostic approaches (industrial production)
6. Treatment/Vaccines (research & clinical development)
7. Treatment/Drug repurposing (research & clinical development)
8. Treatment/Novel therapeutic approaches (research & clinical development)
9. Manufact Belgium - (end of message) 9. Manufacturing of drugs (including biologics and vaccines)
10. Medical devices (research & clinical validation)
11. e-health & Digital Applications (research & clinical validation)
12. Data science & artificial intelligence
13. Manufacturing and recycling of Personal Protection Equipment (masks, disinfectants and

sanitizers)
14. Behaviour and mental health
15. Fundig
16. Others

- Do you plan incentivising your domestic production of diagnostic test kits?
Most popular answer: no (70%)

Comments

IT: some Public regional laboratories are improving their own production of diagnostic test kits

FR: on diagostic test kits, possible intention to manufacture swabs by a local company with a derogation to CE marking (although tests will be made at national level). FR also provided information on CE marking national certification process
https://www.entreprises.gouv.fr/files/files/home/ProtocoleDGA.PDF

On obstacles and issues encountered when trying to ramp-up production

- Production input

Most popular answer for testing kits components: sample collection consumables (44%) but closely followed by consumables and accessories (39%)

Comments
DE: still assessing the situation with respect to testing; not yet identified any shortages, but cannot exclude the possibility.

HR: speaking of Sample collection consumables, the users signaled a lack of nasopharyngeal swab sticks. According to the information received from the distributor, the supply chain has not been interrupted, but the available quantities are hardly sufficient. One business entity announced the start of such production in the Republic of Croatia using additive technologies (3D printing). To our knowledge, the products are in the preparation phase for the validation of their performance in relation to classically produced sticks.

ES: companies had problems for the supply of reactive substances, enzymes, etc, as well as some other components such as swabs. They did not have extraction kits, and the supply came from abroad. According to the information we have received from economic operators, the main problem has been the gas flow electronic valves. There are very few valid alternatives worldwide. The semiconductors supply was also an obstacle.

CZ: regarding swab sticks one Czech company is currently producing new swabs with perfect results - still CE certification is pending.

Most popular answer on ventilators: components and parts (45%)

Comments

FR: different problems: filters & components and parts; subcontractors problems; on masks: customs problems

PL: components and parts, masks and accessories

HR: we can add that there are currently two companies in Croatia dealing with ventilators. One of them is contracted manufacturer of Spain's manufacturer, where products are placed on the market. The second manufacturer has developed the prototype of the product. The certification process is ongoing.

LT: one manufacturer who developed prototype and now is under certification process

NL: production of the whole machine.

On other medical devices (open question):

Supply of infusion pumps has been challenging since the beginning of pandemic.
Syringe drivers
Components and parts
Automated infusers and infusion pumps
Shortage on infusion pumps and disposables Humidifier

After the first block of questions, a representative from OECD delivered a presentation on the policy brief "The Face Mask Global Value Chain in the COVID-19 Outbreak: Evidence and Policy Lessons"

- Cover different types of facemasks in report, focus on disposable face masks (surgical masks (FFP1/FFP2, N95 respirators), and not community masks.
- Core of the analysis is the whole value chain, to understand the variety of steps and possible bottlenecks: (1), Packaging (2) Meltblown polypropolene is not manufactured by so many countries and companies (3) now woven fabric, (4) Ultrasonic welding; assembly lines for masks are very specific and in shortage.
- Prioritization and organisation of the distribution of PPE is a relevant element of complexity.

The OECD colleague gave full availability to receive questions and comments (please see PPT attached for more details).

After the OECD presentation, the last block of the questionnaire was completed.

Other issues: which is the most pressing issue in your country?

Most popular answer: lack of capacity of Notified Bodies for certification of products (78%)
Comments: the issue of notifying bodies was present already pre-pandemic, let alone now, but mainly for medical devices, as for PPEs not mandatory.

Conclusions

The Clearing House thanked all participants and in particular those who delivered presentations, reiterated the invitation to Member States delegations to pursue technical exchanges at bilateral

level and invited other Member States to indicate possible interest to present national best practices at future meetings.
The Clearing House indicated the functional mailbox to reach out in case of further questions or any other need for information: 5.1.5 @ec.europa.eu