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A WATCH-LIST – OVERVIEW ON THE EXPECTED SHORTAGES/NEEDS OF MEDICAL EQUIPMENT AT EU LEVEL

Results of the 4th online survey

EUSurvey

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1. RESULTS OVERVIEW/MAIN MESSAGES

At the beginning of December, the Commission conducted the fourth online survey on needs of medical equipment during the COVID-19 pandemic. The main results of the survey among 32 countries (27 Member States, UK, NO, IS, LI, CH) are as follows:

- Overall, the **situation has slightly deteriorated** in comparison to the third survey and to September: there is now one product category in acute shortage (red in the first column of the watchlist) and still ten products in moderate shortages, but not exactly the same one.
- The situation seems to have improved notably in the EU for:
  - Surgical **masks;**
  - Hand **sanitisers**; and
  - **Reagents.**
- The situation seems to have deteriorated in the EU for:
  - **Medical gloves**
  - **Oxygen therapy delivery devices**
  - **Needles and syringes**
  - **Rapid antigen tests** (RAg)
  - **Pipette tips, tubes & other lab consumables**
- In the very short term (December 2020), the EU seems to experience a shortage of **pipette tips, tubes & other lab consumables**.
- In the short term (January-February 2021), **medical gloves, PCR automated tests (kits) and PCR point of care tests** are likely to be in shortage.
- In the mid-term (March-April 2021), **medical gloves** are expected to continue to be in shortage, together with **needles and syringes.**
- At this stage, **moderate shortage** are expected for some Personal protective Equipment only for the period beyond May 2021 in the EU.
- Overall, **medical goggles/protective eyewear, ventilators**, most **medical devices and hospital supplies**, as well as **antibody tests ('serological')** or **PCR machines** are not expected to be in shortage in the EU in the short, mid or longer

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term.

- The situation for **surgical masks** and **reagents** has improved.
- The **level of knowledge/understanding of the situation on shortages** for medical equipment seems to be rather high. However, this is not so much the case for **vials** (for around a third of them) and for some types of tests **(antigen/antibody).**

The main message to policy-makers and manufacturers therefore would be to continue to focus on the following medical equipment:

- Medical gloves;
- Needles and syringes
- PCR tests (both 1) automated tests (kits) and 2) point of care tests); and
- Pipette tips, tubes and other lab consumables.
- To a lesser extent, the situation for FFP masks and gowns/overalls/aprons should be looked at carefully in the mid to longer term.

You will find below more detailed information. The one pager (the **'watch list' colour-coding one pager**), is also annexed to this explanatory note.

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2. RESULTS PER CLUSTER

Cluster 1 – Protective Equipment (PPE and devices) - Main trends

Overall, the situation does not seem to have really improved when it comes to possible shortages of protective equipment (both PPE and medical devices) in Europe in comparison to the post summer period (September), and some types of equipment are still in high demand.

There seems to be no real shortage for **medical goggles and protective eyewear**, and limited shortages of **surgical masks**. For **face shields**, **gowns/overall/aprons**, **caps/shoe covers** and **FFP masks** shortages are moderate in the EU overall. For **Medical gloves** expected shortages are very high, especially for the first four months of 2021 and only seven countries indicate that they expect no shortage at all of these products and only two of them do not know what will be the situation.

In comparison to the previous survey, the situation for **medical gloves** has much worsened, the one of **face shields** and **FFP masks** slightly deteriorated, the one of **gowns/overall/aprons** slightly improved, and for **surgical masks** the situation got better.

In addition, the level of certainty of the replies provided is high on average for all the listed categories of protective equipment, with, at the two extreme sides, a very high level of certainty for **medical gloves** and much lower for **caps/shoe cover**.

The overall anticipation pattern resembles the one of September with no expected shortages for six out of seven categories, with only three categories with no shortage in the short term, only one on March-April and forecast getting brighter again for May-August 2021.

- **In the very short-term (December),** there is no immediate shortage for protective equipment overall, except for medical gloves where the needs are moderate (expected shortages in six countries).
- **In the short term (January-February 2021),** medical gloves are expected to be in acute shortage in the EU (expected shortages in twelve countries), while gowns/overalls/aprons, caps/shoe covers, and FFP masks should be in moderate demand. There should be no shortage for medical goggles/protective eyewear, for face shields and surgical masks.

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- **In the mid-term (March-April 2021),** medical gloves are still expected to be in acute shortage in the EU (expected shortages in ten countries), while face shields, gowns/overalls/aprons, caps/shoe covers, surgical masks, and FFP masks are expected to be in moderate shortage. No shortage are expected for medical goggles/protective eyewear.
- **In the long term (May-August 2021),** moderate shortages are expected for face shields, gowns/overalls/aprons, FFP masks and medical gloves, while no shortages are expected for all the other types of protective equipment.

Further comments:

It seems that some stocks of gloves are low for health care professionals (for the next six months) and the pressure on the global market (notably for medical nitrile gloves) and fierce competition between procurers makes it difficult to make precise estimates or to have access to suppliers' bids. In this context, the production of gloves in Europe seems to be envisaged. In addition, a country indicated a shortage for FFP3 masks and another some tensions for sterile surgical gowns given an overuse in the first wave.

Cluster 2 – Ventilators – Main trends

Overall, the situation does not seem to have substantially improved when it comes to possible shortages of ventilators and their accessories in Europe in comparison to the post summer period (September): replies are rather consistent as there is overall limited shortages expected for these types of products, although the situation for oxygen therapy delivery devices and to a lesser extent for accessories of ventilators seems to have worsened.

Most countries indicated that there is no expected shortage for **invasive ventilators** and for **non-invasive ones** (twenty-three and twenty-two, respectively). The situation of **oxygen therapy delivery devices** seems however to be more concerning in the short term (December 2020 to February 2021 included).

In addition, the level of certainty of the replies provided is high on average for all the listed categories in this cluster, especially for **ventilators** and **their accessories** and lower for **oxygen therapy delivery devices,** which accentuates the concern for this category.

- **In the very short-term (December),** there is no expected shortage of ventilators but moderate shortages for both their accessories (four countries) and the oxygen therapy delivery devices (six countries).

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- **In the short term (January-February 2021),** oxygen therapy delivery are still expected to be in moderate expected shortage (four countries) while neither of the other categories should be in tension.
- **In the mid-term (March-April 2021),** no shortage are expected in Europe overall for these categories of products (still concerns in a couple of countries for the ventilators and the oxygen therapy delivery devices, and in three for their accessories though).
- **In the long term (May-August 2021),** no shortage are expected in Europe overall for these categories of products (still concerns in on country for the ventilators and in a couple of them for their accessories and the oxygen therapy delivery devices though).

Further comments:

A couple of countries underlined the difficulty to plan the needs for these products due to the unpredictability of the disease and reliability of the regular supply chains. They stress that there are currently a sufficient number of ventilators but that they cannot totally exclude future shortages of these categories of products. As the epidemiological situation evolves, an increasing number of treatment facilities have to set up COVID-19 beds and the need for additional ventilators therefore arises. Additional purchases are made by medical institutions and the government reimburse the incurred costs. Lastly, one country specifically indicated a Shortage of high flow oxygen devices.

Cluster 3 – Other medical devices – Main trends

Overall, the situation does not seem to have substantially improved when it comes to possible shortages of medical devices and hospital supplies in Europe in comparison to the post-summer period (September 2020): replies are consistent as there are limited (or very limited) shortages expected for these types of products, at the noteworthy exception of needles and syringes (only eleven countries do not expect shortages of the latter).

According to current expectations in the Member States and associated countries, there seems to be no or very low expected shortage of medical devices of hospital supplies in the very short, long and very long terms in Europe, excepted for hand sanitisers and needles and syringes. Some moderate shortage are expected January-February for needles and syringes (in six countries), probably given the expected start of the vaccination campaigns with the first COVID-19 vaccines for some parts of the population, and even more in spring

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(eight countries). Hand sanitisers could also be in moderate tension in spring (four countries only though).

In addition, the level of certainty of the replies provided is not very high on average for all the listed categories in this cluster. As this was the case in September, the situation for vials (and stoppers) seems to be quite unclear in the different countries and quite high for pulse-oximeters, endotracheal tubes and patient monitors - and to a lesser extent for needles and syringes.

- **In the very short-term (December),** there are no expected shortages for most of the categories of medical devices and hospital supplies (still concerns in three countries for infusion pumps and patient monitors).
- **In the short term (January-February 2021),** there are no expected shortages for most of the categories of medical devices and hospital supplies (still concerns in three countries for infusion pumps), but moderate shortages expected for syringes and needles.
- **In the mid-term (March-April 2021),** there are no expected shortages for most of the categories of medical devices and hospital supplies (still concerns in three countries for infusion pumps), but moderate shortages expected for hand sanitisers (all types), and possibly high tensions for syringes and needles (eight countries).
- **In the long term (May-August 2021),** there are no expected shortages for most of the categories of medical devices and hospital supplies (still concerns in three countries for infusion pumps).

Further comments:

A couple of countries stress that procurement procedures are in place, as well as requests through the EU joint procurement agreements and that limited shortages are therefore expected.

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Cluster 4 – Tests and testing materials – Main trends

Overall, the situation remains to have slightly deteriorated when it comes to possible shortages of various types of tests kits and machines, consumables and various other types of materials used for testing of individuals for COVID-19 in Europe in comparison to the post-summer period (September). Some types of equipment are still in high demand but uncertainties on needs are much lower than in the past. It should also be stressed that four countries do not use antibody tests or rapid antigen tests.

According to current expectations in the Member States and associated countries, there seems to be no or very low expected shortage for antibody tests ("serological"), automated antigen tests (but a very high number – fourteen – countries indicate some uncertainty in this respect), and PCR machines in Europe. Some moderate shortages are expected for PCR tests, pipette tips, tubes and other laboratory consumables and for swabs. Acute shortages should be experienced in Europe for both PCR automated and point of care tests, as well as for pipette tips, tubes and other laboratory consumables, but only in some moments in time. Interestingly, the situation for reagents seems to have improved.

For rapid antigen tests specifically, only half of the countries (fifteen) expect no shortage while eight are uncertain about possible shortages and four do not use them.

- **In the very short-term (December),** there is low expected shortage for most categories of tests and testing materials, except for PCR tests (both PCR automated and point of care tests) where the shortages are expected to be moderate (in six and seven countries respectively) and for pipette tips, tubes and other laboratory consumables for which shortage are expected to be high (in nine countries).
- **In the short term (January-February 2021),** acute shortage are expected for PCR automated and point of care tests (in twelve and ten countries respectively), and for reagents. Moderate shortages are expected for rapid antigen tests, reagents, pipette tips, tubes and other laboratory consumables and swabs.
- **In the mid-term (March-April 2021),** moderate shortages are expected for PCR automated and point of care tests and swabs.
- **In the long term (May-August 2021),** the responding Member States and associated countries seem to expect no or very low shortages for all categories of tests and testing materials.

Further comments:

European countries identified possible shortages for regular popular PCR tests like Roche COBAS 6800/8800 and Hologic Panther, while stressing that less popular alternatives are however still available on the market. Point of care molecular tests, for example Cepheid GeneXpert and LIAT Roche. Cepheid Xpress point of care tests used in hospitals also seems in tension (in one country, the estimated need is 10 000 per month while the need for laboratory PCR tests is around 240 000 per month). Laboratory consumables are specifically mentioned by four countries, including pipette tips for Hamilton extraction robots and plastic consumables for RT-PCRs. For this cluster again, possible shortages of the above-mentioned products highly depend on the development of COVID-19 cases in the upcoming months and the reliability of the regular supply chains. Therefore, future shortages cannot be fully excluded at this very moment. In particular, in the context of the upcoming mass testing in some European countries, it is not possible to estimate the imminent shortage of antigen rapid tests.

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3. CONTEXT

Throughout the COVID-19 pandemic, the Commission faced a lack of real-time, comparable and reliable data on Member States' demand and needs of medical equipment. To try and rapidly get some insight on the unprecedented surge of the demand of some medical equipment, the Clearing House for medical equipment (COVID-19) worked through a series of proxies and ad hoc tools to identify the possible demand and supply. For the analysis of the demand, one of the instruments identified was a forecasting system, to be regularly updated. Operating in times of crisis, the tool had to be simple to allow swift replies and straightforward interpretation.

The survey

Regarding the demand of medical equipment in the EU, the SG-Clearing House asked the designated national contact points in Member States and associated countries to complete a short EU online survey on their respective needs and shortages in the coming weeks and months.

The fourth survey was conducted from 25 November until 11 December 2020. All the countries replied (response rate: 100%): 32 countries, including 27 Member States, UK, NO, IS, LI, and CH.

This survey consisted again of a simple question ('Looking at your own country, do you see a shortage of these products in your country in the next weeks and months?').

To provide their answers, the respondents were asked to identify **shortages and expected needs of medical equipment** over four periods:

- ***In the very short term***: upcoming/ongoing month (December);
- ***In the short term***: early 2021 (From January to February 2021);
- ***In the mid-term***: end of winter/early spring (March-April 2021); and
- ***In the long term***: spring and early summer (May-August 2021)

Member States and associated countries had to provide an answer for each of the twenty-seven categories of medical equipment listed (thirty-two in the previous edition, twenty-eight in the second version and twenty-four in the first "watchlist"). These categories are regrouped into four of the five clusters of the Clearing House as pharmaceutical products were removed for this survey given the ongoing work the at EMA/Commission on this. Since the third edition in September, the part on testing was revamped substantially to adapt to a rapidly evolving situation (i.e. "RAg" or "RAT").

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The objective of the 'watchlist' or forecasting system

The survey helps developing and updating a 'watch list' - or forecasting system – fitting into a simple one-pager traffic light (three colour coding system).

It aims at providing a swift understanding of the expected shortages, and demand and needs of Personal Protective Equipment (PPE), medical devices and in vitro diagnostics at EU level. It helps identifying the priority areas for EU action during this COVID-19 outbreak.

Limits and advantages

The watchlist is a **subjective instrument** since the attribution of a colour to a specific box can vary much depending on the value initially determined for the ceilings. The same ceilings were kept compared to the three first surveys conducted in end April, end May and September to enable comparisons over time.

An advantage of the tool is the system of compulsory answers for each of the categories. Member States and associated countries had indeed to select a category: type of possible shortage according to a timespan/no shortage/do not know. This allows a systematic analysis of the replies.

By simply clicking on some replies, respondents are not required any specification of either quantified data, or qualitative explanations (open questions). In other exercises where comprehensive and - at the same time - more specific information is asked, countries are not necessarily providing a reply and the assessment of the replies and the presentation of the results of those questionnaires are often impossible.

This 'traffic light' tool is neither intended nor designed to serve for the **quantification of shortages** and needs in each product category. It attempts to identify needs according to specific time spans at EU level and could help policy-making in times of crisis. It should be read as an indication of the current and likely shortages of medical equipment needed in the management of the COVID-19 pandemic and for preparedness purposes.

It must be stressed that, when starting this exercise in spring, some countries had wanted the survey to be conducted in an anonymous way. Yet, this time again (as for the third edition), no country has replied anonymously, which could indicate that respondents are now used to the functioning of the survey.

In addition, there is currently no other tool which enables to get a systematic overview of the expected shortages of COVID-19-related medical equipment at EU level (at the exception of medicines), with answers provided in a coherent and consistent way, according to a breakdown of categories of medical equipment and a clear timespan. The categories chosen for this survey are to some degree "arbitrary" as they may not match some individual experiences at national level, but they correspond to a European experience and

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to the products the Commission attempts to monitor at EU level - the colour coding is also subjective.

For this edition, the results of the "watchlist" will only be presented to Member States and associated countries through this note and email. For the time being, no further horizontal meeting of the Clearing House (last one: 24 September) is planned.

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Annex – One pager with a colour coding system: 'the watch list'