



## **Pandemic Preparedness - European Doctors' Recommendations to the EU -**

### **Who does What**

There must be a clear division of competences between Member States, WHO and WHO-Europe, the EU and its agencies, and OECD as to

- declarations of pandemics,
- subsequent containment or treatment measures,
- effective data collection and sharing and
- horizontal coordination on recommendations.

### **From 'just in time' to 'just in case'**

Future pandemics or severe health emergencies may look different to the current pandemic. It is possible that climate related emergencies become frequent in the European region in future.

What has become clear is that the 'just in time' rationale used in commercial sectors cannot be applied to health systems without severe risks. It is necessary to adopt a 'just in case' model. The 'just in case' model must include a baseline capacity which is sufficient to ensure Universal Health Coverage ("UHC") and surge capacities which can be deployed to deal with extraordinary situations. These structures must be based on permanent and guaranteed funding, in full acceptance that obsolescence and opportunity costs cannot be avoided.



## The health workforce is vital

- Establish a health workforce observatory to support Member States in health workforce planning, in particular data collection and monitoring of mobility flows.
- Develop concrete recommendations for ratios on resources per population unit for
  - baseline universal health coverage (UHC)
  - emergencies, including the option of pooling emergency reserves at EU level.This could include ratios for health professionals, ICU facilities, stocks of essential medicines, and local public health capacity. In format, this could mirror recommendations put to Member States for macroeconomic stability under the European Semester.
- Include a review of pandemic preparedness expenditure into the European Semester process. A multi-stakeholder working group should advise on the creation of suitable indicators.
- Review legislation and policies on health professionals' working conditions to provide safe and lawful terms of employment, including in emergency situations. This includes decent and safe PPE working conditions for professionals who form part of the surge capacity, as well as those working in the health system.
- Encourage Member States to ensure local medical capacity and competence to secure the population infection control during pandemics.
- Encourage and facilitate cross-border treatment of patients and assist health authorities in coordinating cross-border treatment, reimbursement and cross-border public health infectious tracing.

## Data are key

- Improve data collection and sharing related to infectious diseases. Member States need to align their data collection and reporting to improve data quality and comparability in the EU.
  - Develop the category of 'EU public health data' and define relevant data to be collected at national level which should be shared (e.g. PPE, medicine stock, ICU bed capacity and beds in use, ventilators and ventilators in use, testing capacity and tests performed, positive tests results).
  - Harmonise semantics of 'EU public health data'.
  - Designate national entities responsible for 'EU public health data' which report to the European Centre for Disease Prevention and Control (ECDC) in a timely manner.
  - Develop common definitions of containment measures (e.g. isolation, quarantine, tracing) to ensure comparability of data.
  - Establish better EU standards for health data interoperability.
- Enhance the role of ECDC as the competent agency receiving 'EU public health data' by increasing competences, budget and staff.
  - Enable ECDC to become the authoritative voice in developing standards, issuing recommendations and protocols to be used by the Commission and Member States in the event of a crisis, such as a virus outbreak.
  - Establish a decentralised structure of ECDC at national level, where an ECDC representative/contact point wears a double hat and works hand-in-hand with national authorities, improving data comparability.
  - Expand ECDC's geographical scope to cover also other than EU and EEA countries. This would allow better collaboration with the WHO European Region and avoid duplication of work.
- Enhance the role of the European Medicines Agency (EMA) as the competent agency providing full access to data.
  - Grant full access to Member States' data about medicine shortages.
  - Grant full access to clinical trials results also related to pandemics, while favoring open science.
- Establish an EU coordination of digital exposure notification, ensuring apps regular oversight by data protection authorities and scrutiny by civil society.
- Establish the EU Health Data Space
  - Fill EU Health Data Space with anonymised case registries enabling access to safe protocols and treatments.



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## Supplies are indispensable

- Enhance the role of the European Medicines Agency (EMA) as the competent agency to monitor and coordinate medicines' availability and supply.
- Strengthen the resilience of supply chains, increase diversification of supply sources and reduce Europe's reliance on third country manufacturing.
  - Explore EU corporate due diligence legislation<sup>1</sup> and look into potential regulatory or financial incentives to shift the production of most important active pharmaceutical ingredients and medicines back to Europe while safeguarding their affordability.
  - Exchange on procurement procedures for medicines and apply other criteria than price in tendering processes; award contracts to a number of successful tenderers instead of only to one.
- Strengthen and enforce supply and reporting obligations.
  - Review the current pharmaceutical legislation and clarify the Community Code Directive 2001/83/EC, i.e. introduce enforcement mechanisms and sanctions (e.g. license withdrawal) to hold marketing authorization holders (MAHs) accountable.
  - Require MAHs to submit shortage contingency plans while marketing a medicine in the EU.
  - Introduce an early warning system, identify best practices, and oblige all stakeholders in the supply chain to report any shortages at national and at EU level.
- Prioritize access to medicines.
  - Ensure fair pricing of pharmaceuticals to increase equitable access to innovative therapies.
  - Address the abuse of the current model of pharmaceutical incentives.
  - Revise the regulations on orphan and pediatric medicines.
  - Restructure the non-transparent R&D model resulting in a falling rate of pharmaceutical innovation and high prices.
- Ensure equitable supplies across the EU.
  - Manage stockpiling of essential/strategic medicines and other supplies (medical devices, PPE) at EU level and increase supplies from "just-in-time" to "just-in-case".
- Expand the possibility of joint procurement of medicines and other supplies (medical devices, PPE)
- Explore ways to increase the EU capacity and readiness to respond to cross-border health threats and emergencies by supporting medicines' and vaccines' development, e.g. through a new agency.

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<sup>1</sup> The EU Commissioner for Justice Didier Reynders has announced a plan for a legislative initiative on mandatory human rights and environmental due diligence obligations for EU companies. The initiative will be cross-sectoral covering the entire supply chain and all corporate-related risks, including human rights, social and environmental ones. The legislation can be a mean to ensure sustainability and strengthen the resilience of the supply chains.



## Prevention is an asset not a cost

- Invest in health promotion and disease prevention as healthy people do not burden health systems.
  - Legislate on taxation of alcohol and tobacco, unhealthy foods and drinks, alcohol and food labelling.
- Use the 'Green Deal' and the 'Farm to Fork' strategies for a "healthy recovery", i.e. reduce air pollution, shift towards cleaner and renewable energy, and change to a more sustainable and healthier food system.
- Support Member States in improving access to healthcare particularly for vulnerable groups who are disproportionately exposed to the consequences of pandemics.
  - Develop socially inclusive policies by *i. a.* ensuring equal educational opportunities and adequate health literacy skills.
  - Deliver information also to vulnerable groups.
  - Integrate mental health in any public health response to pandemics to avoid preventable psychosocial stress to individuals and communities.
- Strengthen EU cooperation against cross-border health threats and vaccine-preventable diseases.
  - Develop a common vaccination card/electronic passport.