

List of questions concerning COVID-19 measures

Medicines

Have measures been put in place at a national level to secure supply and availability of medicines?

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Do you have a national list of essential medicines?

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Does your NCA play any role in the distribution of medicines? If so, how?

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Has your NCA or health authority put any measures in place to:

- *ensure continuity of procedures for medicines approval (CAPs and NAPs);*
- *prioritize regulatory continuation for specific categories of medicines;*
- *considered the impact and consequences of delaying regulatory procedures?*

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Medical devices

Have measures been put in place at a national level to secure supply and availability of medical devices?

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Do you have a national list of essential medical devices?

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Does your NCA play any role in the distribution of medical devices?

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Oversight

What measures has your NCA taken with regards to GxP inspections?

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How do you decide which GxP inspection to do and which not?

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Business continuity

What measures has your NCA or health ministry taken to enable working from distance?

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Do you have any best practices for sharing virtual business meetings you can share?

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What are your scenarios for preventing collapse of the digital infrastructure due to peak-usage?

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Do you have scenarios in place for temporary unavailability for a proportional amount of your work force?

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Do you foresee any challenges in performing the usual regulatory processes (CAPS and NAPS) due to urgent COVID19 tasks?

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