

2021-03-18

Covid-19 – experience from the department for medical devices at the Swedish Medical Products Agency

Helena Dzojic,
Head of the department for medical devices,
Swedish Medical Products Agency

1

Agenda for today

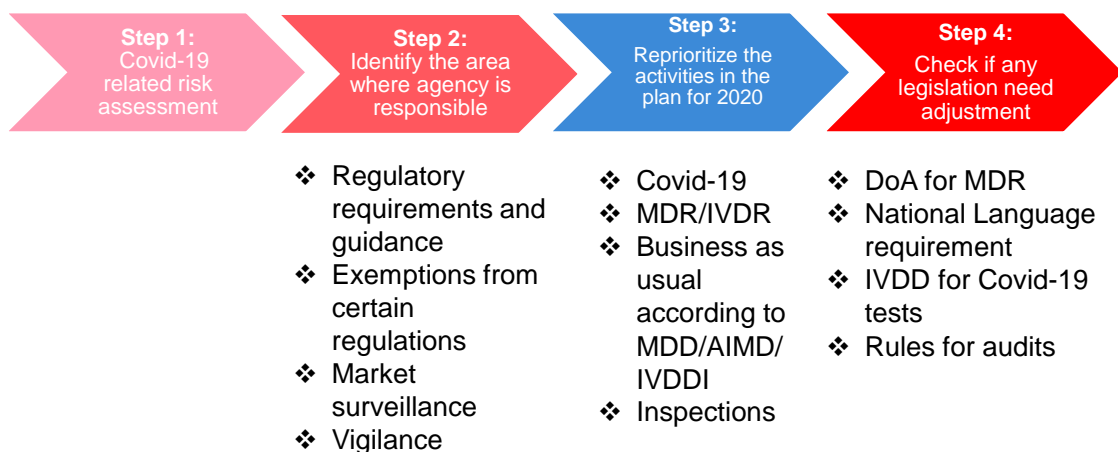
- Crisis management in the Government Offices
- The principles of responsibilities
 - Role of the Swedish Medical Products Agency (medical device department) regarding Covid-19
 - Collaboration
- Lessons learned so far

2

Crisis management in the Government Offices

- The Government's duties primarily concern matters of a strategic nature. **Responsibility for managing and coordinating operations lies with the relevant agencies.**
- At the Government Offices, as in other parts of society, crisis management is built on the **principle of responsibility**. This means that the ministry responsible for a particular matter under normal circumstances is also responsible for that matter in a crisis situation.
 - Relevant agency will as far as plausibly perform the tasks as under normal circumstances (legislation etc.)

The principle of responsibility



Collaboration (not exhaustive list, just some Covid-19 related examples)

- ❖ Regulatory requirements and guidance
 - ❖ EU Commission DG Sante (new DG for medical devices!)
 - ❖ National Board of Health and Welfare (Socialstyrelsen)
 - ❖ The Public Health Agency of Sweden (Folkhälsomyndigheten)
 - ❖ Agencies listed under the "market surveillance".

- ❖ Exemptions from certain regulations
 - ❖ The Swedish Civil Contingencies Agency (MSB)
 - ❖ National Board of Health and Welfare (Socialstyrelsen)

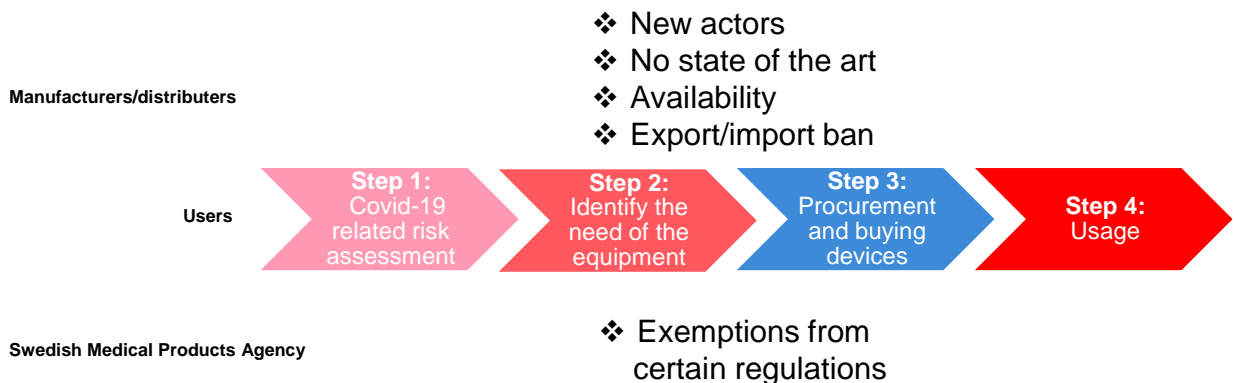
- ❖ Market surveillance
 - ❖ Swedish Customs (Tullverket)
 - ❖ Swedish Work Environment Authority (Arbetsmiljöverket)
 - ❖ Health and Social Care Inspectorate (IVO)
 - ❖ Swedish Consumer Agency (Konsumentverket)
 - ❖ EU27 competent authorities

- Website
- Newsletters
- Media
- Testing strategy

- Increase in the number of applications

- Increase in the number of opened and closed cases
- Increased number of the formal decisions to ban the products (not just Covid-19 related)

Challenges on the other side...



Lessons learned so far...

- Difficult to have good overview of the need, demand and supply among the users of the devices – more coordination at central level needed
- Challenge to make decisions if risks are acceptable – national language requirement
- National/regional recommendation which devices to be used and how to use them versus intended use by the manufacturer - regulatory support to the regions?
- Market surveillance focus on a small area of devices such as surgical masks and Covid-19 tests (information, market surveillance, media) - large effect on the market
- Proactive collaboration with Swedish Customs – ban the entry to the market for the illegal devices

For more information

- [Rapport från Läkemedelsverket \(lakemedelsverket.se\)](https://lakemedelsverket.se) (Covid-19)
- [Läkemedelsverkets Årsredovisning 2020 \(lakemedelsverket.se\)](https://lakemedelsverket.se)
- Marknadskontrollrapport 2020 (will be published soon)
- Read our newsletters [Nyhetsbrev om medicinteknik | Läkemedelsverket / Swedish Medical Products Agency \(lakemedelsverket.se\)](https://lakemedelsverket.se)
- Visit our website
 - [Medicinteknik | Läkemedelsverket / Swedish Medical Products Agency \(lakemedelsverket.se\)](https://lakemedelsverket.se)
 - [Medical devices | Läkemedelsverket / Swedish Medical Products Agency \(lakemedelsverket.se\)](https://lakemedelsverket.se)
- registrator@lakemedelsverket.se

Thank You!