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

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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

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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

Step 1: Covid-19 related risk assessment

Step 2: Identify the area where agency is responsible

- Regulatory requirements and guidance
- Exemptions from certain regulations
- Market surveillance
- Vigilance

Step 3: Reprioritize the activities in the plan for 2020

- Covid-19
- MDR/IVDR
- Business as usual according to MDD/AIMD/ IVDDI
- Inspections

Step 4: Check if any legislation need adjustment

- DoA for MDR
- National Language requirement
- IVDD for Covid-19 tests
- Rules for audits

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".	➢ Website ➢ Newsletters ➢ Media ➢ Testing strategy
❖ Exemptions from certain regulations ❖ The Swedish Civil Contingencies Agency (MSB) ❖ National Board of Health and Welfare (Socialstyrelsen)	➢ Increase in the number of applications
❖ Market surveillance ❖ Swedish Customs (Tullverket) ❖ Swedish Work Environment Authority (Arbetsmiljöverket) ❖ Health and Social Care Inspectorate (IVO) ❖ Swedish Consumer Agency (Konsumentverket) ❖ EU27 competent authorities	➢ 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…

Manufacturers/distributers

- ❖ New actors
- ❖ No state of the art
- ❖ Availability
- ❖ Export/import ban

Users

Step 1: Covid-19 related risk assessment → **Step 2:** Identify the need of the equipment → **Step 3:** Procurement and buying devices → **Step 4:** Usage

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- ❖ Exemptions from certain regulations

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) (Covid-19)
- Läkemedelsverkets Årsredovisning 2020 (lakemedelsverket.se)
- Marknadskontrollrapport 2020 (will be published soon)

- Read our newsletters Nyhetsbrev om medicinteknik | Läkemedelsverket / Swedish Medical Products Agency (lakemedelsverket.se)
- Visit our website
  - Medicinteknik | Läkemedelsverket / Swedish Medical Products Agency (lakemedelsverket.se)
  - Medical devices | Läkemedelsverket / Swedish Medical Products Agency (lakemedelsverket.se)
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Thank You!