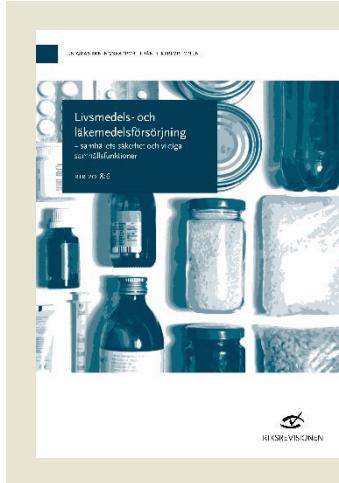


REPORT NUMBER: RIR 2018:6  
DATE: 5 MARCH 2018The image shows the front cover of the audit report. It features a collage of various food and medicinal products, including jars, bottles, and containers. A dark blue rectangular box is overlaid on the top left of the collage, containing white text that reads "Läkemedels- och livsmedelsförsörjning", "svarta och vita medicinska produkter", and "RIR 2018:6". At the bottom right of the collage, there is a small logo of the Swedish National Audit Office. The overall background of the cover is light beige.

RIR 2018:6

# Supply of food and medicinal products

– societal security and important public services

## Summary and recommendations

Safeguarding the functioning of society is one of the Riksdag's three objectives for societal security. It is included both in the civil defence objective and in one of two emergency preparedness objectives. To achieve these objectives action is required by actors throughout society, not least the Government and the agencies that play an important part in creating an overarching system.

The work of strengthening societal security has been going on for a long time in various forms and with different focuses. In recent years, however, there has been criticism of the focus and approach of national emergency preparedness. This includes deficiencies in emergency preparedness due to weaknesses in governance and problems in the interaction between legislation and principles of the system on the one hand and on the other hand the capacity and preparedness of central actors to perform their tasks. Furthermore, the work of security is more pertinent today due to a changed security situation and the renewed focus on civil defence that has accompanied the change.

In view of this, the Swedish National Audit Office has decided to conduct an audit to investigate whether the conditions exist, and the measures are taken, to contribute to robust public services. The audit focused on supply of food and medicinal products,

which are two central, citizen-related public services with high relevance for life and health and for the functioning of society. The audit focus is on supply in the event of an emergency, but the question of heightened alert has also been taken into account. The audit is thus not concerned with supply or other circumstances in a normal situation. The audit covered the Government, the National Board of Health and Welfare, the National Food Agency and the Swedish Civil Contingencies Agency.

The audit is based on two audit questions:

1. Has the Government been sufficiently clear in its governance as regards objectives, requirements and divisions of responsibility in the supply of food and medicinal products?
2. Have responsible agencies taken measures relating to governance and guidance, coordination and cooperation, as well as monitoring and analysis to promote the management of risks concerning supply of food and medicinal products?

## **The Swedish National Audit Office's conclusions**

### **Governance and division of responsibilities are not clear**

The first audit question concerns whether the Government has been sufficiently clear in its governance concerning objectives, requirements and divisions of responsibility in supply of food and medicinal products.

In its audit, the Swedish NAO made the assumption that the Government's governance should include explicit objectives, or formulations, on which the actors can base their work. These objectives/formulations should be clear enough to provide a sound basis for action. The governance should also be reasonably clear and consistent, in particular as regards the relation between different policy documents. Policy objectives or requirements should be formulated to enable follow-up. The assessment concerning divisions of responsibility assumes that there should be reasonable clarity concerning divisions of responsibility and what they entail. The division of responsibility should be clear enough to obviate the risk of responsibilities falling between two stools. The division of responsibility should also make it possible to demand accountability.

The audit shows that the Government has expressed ambitions and intentions to strengthen emergency preparedness and the conditions for vital public services. In various contexts the Government has also made reference to food supply and health and medical services as important functions for national security and for developing civil defence. The Government has also taken some measures. A good example is the National Food Agency's coordination remit for food supply, and another is the Government's

instruction to the Swedish Civil Contingencies Agency to draw up proposed performance objectives. The Swedish NAO considers, however, that even though the Government has expressed ambitions and taken measures, this has not made any clear impact on governance. Nor has the Government taken any clear action in response to the Civil Contingencies Agency's proposed objectives or otherwise made its governance more concrete.

From an emergency preparedness perspective, the supply of food and medicinal products is included at a general level in various government documents. These are for example budget bills, the Government's national security strategy, the Government's defence policy direction bill and the Government's food strategy. But in relation to the issue of safe food and medicines, for example, the difference is great. In the areas both of food and of medicinal products there are laws, supervision and forms of cooperation to prevent and limit serious crises regarding the safety of the products themselves and their management. In that sense, the system includes a clear safety dimension, but the question of safeguarding access to food or medicinal products in the event of an emergency has been given very little attention.

For the purpose of strengthening emergency preparedness, the Government has given the National Food Agency and the National Board of Health and Welfare coordinating remits. The Swedish NAO regards it as positive that there are actors in a coordinating role, and judging from the audit this has also led to some significant measures. At the same time, the audit shows that at the systemic level there is a lack of clarity that in the view of the Swedish NAO affects the conditions for the security-building work. For example, there is no agreed definition of vital public services or of sectors. Moreover, in the areas of food and medicinal products various forms of responsibility are shared between different agencies. Not least in the area of medicinal products, the division of responsibility is complex. In the area of food, the assigned coordination responsibility for an emergency is limited to downstream of primary production. In the opinion of the Swedish NAO this means that it is not clear how the National Food Agency's coordination remit relates to prolonged emergencies and heightened alert in accordance with the Government's instructions to agencies with monitoring responsibilities. Both the National Food Agency and the National Board of Health and Welfare have also pointed out that the Government needs to clarify what is included in their coordination remits.

In the past there were state emergency reserves, including food and medicinal products, which were primarily intended for a situation of heightened alert or war, but which could also be used in an emergency. These reserves have largely been dismantled (with the significant exception of anti-viral medicines for use in a pandemic situation) and

supply of food and medicinal products is dependent on the functioning of all parts of a complex chain. In particular, supply of medicinal products is internationalised, which may imply increased vulnerability. Through re-regulation of the pharmacy market in 2009 the responsibility of Apoteket AB for the supply of medicinal products in the event of heightened alert or emergencies was discontinued. As the hub of Swedish supply of medicinal products, Apoteket AB also had a greater insight than any of the current actors into the state of supply at any given time. No compensatory measures for these changes in supply of medicinal products have been taken. The Swedish NAO considers that it is not clear if the Government through this change intended that the county councils were expected to take greater responsibility.

Over the years the Government has highlighted the importance of private actors in national security, for example in the national security strategy of 2017. In the same way, the Civil Contingencies Agency and the Swedish Armed Forces have emphasised the importance of private actors in creating a civil defence. However, it is unclear in what way private actors are expected to take responsibility with regard to vital public services. The Swedish NAO is also of the opinion that there are no targets that provide conditions for agreements, for example.

Much of what the agencies highlight as important measures are financed through so-called 2:4 appropriations, and thus not within the framework of the agencies' ordinary appropriations. The National Board of Health and Welfare has also pointed out that it has refrained from implementing necessary measures with reference to insufficient resources. Both the National Food Agency and the National Board of Health and Welfare lack explicit reporting requirements and dedicated financing for the work they are expected to do as part of their assigned coordination remits. The Swedish NAO's assessment is that these factors may make it more difficult for the agencies to prioritise the measures associated with the supply aspects of emergency preparedness work in relation to other activities when they must strike a balance as to how limited resources must be used.

The Government has expressed ambitions to strengthen important public services and to achieve these ambitions the actors concerned must take responsibility and take action. This concerns sharing responsibility between many different actors at local, regional and national level. At the same time this assumes governance providing reasonable clarity regarding responsibility and levels of ambition. At present there are no clear objectives or guiding formulations for the supply of food and medicinal products and this leaves a wide margin for interpretation by the National Food Agency and the National Board of Health and Welfare as regards coordinating emergency and contingency planning, as well as by other relevant actors as regards divisions of responsibility, requirements and

levels of ambition. The Swedish NAO considers that this affects the capacity of actors in the area to take action. It also makes it more difficult to monitor the area.

There is also lack of clarity regarding responsibilities. The responsibility for a functioning supply of food and medicinal products is shared among several actors in varying degrees without any overall guidance or requirements for emergency preparedness, at the same time as the system is based on individual parts of the system functioning simultaneously and in concert. Both the National Food Agency and the National Board of Health and Welfare, as well as county councils, have called for clarifications of what their responsibilities entail and what they are expected to achieve. The Swedish NAO's assessment is therefore that there is a risk that measures will be delayed or not taken, since it is not clear who should do what and when these actions should be implemented.

## **The actions of the agencies responsible need to be developed and conditions for the work clarified**

The second audit question is whether responsible agencies have taken measures relating to governance and guidance, coordination and cooperation, as well as monitoring and analysis to promote the management of risks concerning supply of food and medicinal products.

The agencies concerned are primarily the National Food Agency and the National Board of Health and Welfare. Within the framework of its overall role, the Civil Contingencies Agency has a responsibility to act on a more general level. The Swedish NAO bases its assessment on the agencies' responsibilities under the Emergency Management and Heightened Alert Ordinance and the National Board of Health and Welfare's and the National Food Agency's respective coordination remits concerning supply. On these grounds, both agencies have a particular responsibility to make analyses, implement planning and make preparations for creating capacity to manage a crisis, prevent vulnerabilities and withstand threats and risks.

Both the National Food Agency and the National Board of Health and Welfare have taken measures concerning matters of supply and emergency preparedness. They have reported on risks and formed interactive networks, in the case of the National Food Agency including actors from the business sector. To date they have taken various initiatives and published reports as well as implementing some major projects, which is positive. However, the way in which the supply of food and medicinal products takes place in a normal situation, in combination with the lack of national emergency reserves, assumes extensive knowledge of which goods exist at a given time, how they should be reallocated and how the continued inflow of new goods is to be guaranteed at times of

crisis. Even though awareness raising activities have been conducted, the central government (through its coordinating agencies in the form of the National Board of Health and Welfare and the National Food Agency) does not have the aggregated information necessary to develop effective plans and preparations for the supply of food and medicinal products in times of crisis and heightened alert. The problems and need for action were identified several years ago, and the assessment of the Swedish NAO is that even though action has been taken, the responsible agencies have not taken sufficient measures. The agencies therefore need to continue to develop cooperation and collection of information to strengthen the conditions for planning and preparation. At the same time, it is difficult to evaluate the efforts of the agencies, since there are no clear objectives or expectations on the part of the Government.

None of the other agencies in the areas of food and medicinal products have any explicit responsibility or requirements for reporting that directly concern supply from an emergency preparedness perspective. This also applies to the Swedish Board of Agriculture and the Civil Contingencies Agency. However, the Swedish NAO considers that based on their roles and responsibilities, several of these agencies have knowledge and insight that can be used more systematically from an emergency preparedness perspective.

## The Swedish NAO's recommendations

The Swedish NAO's overall assessment is that there are not sufficiently clear conditions, and insufficient action taken, to enable supply of food and medicinal products in times of crisis or heightened alert. The Swedish NAO sees at least three overall areas that could be developed. In the first place, it is a matter of clarifying the governance inputs that the actors must take into account in their security work, both as regards divisions of responsibility and levels of ambition. Secondly, there could be development of the Government's monitoring of both areas. In the same way, the agencies responsible should increase their knowledge acquisition and follow-up to further strengthen knowledge and promote action in their own areas. In the third place, public services involve many different actors, not least private actors, with strong interdependencies. It is therefore important to have various kinds of cooperation, to be able to strengthen the work of security in the area, and both the Government and the agencies should give priority to this cooperation.

The Swedish NAO therefore recommends that the Government:

- Clarifies objectives, requirements and responsibility. This may for example concern developing and deciding on objectives.
- In particular, clarify what is expected of the agencies with coordination responsibility. This may be done by clarifying the definition of the coordination remits or by imposing specific reporting requirements concerning the Government's expectations of the coordination function.
- Ensure that cooperation continues to be developed and that the knowledge available in the areas is utilised and employed systematically and in aggregate. For example, this could be done through targeted assignments to the relevant agencies in the area.

The Swedish NAO also makes the following recommendation to the National Food Agency, the National Board of Health and Welfare and the Civil Contingencies Agency:

- Ensure increased cooperation, monitoring and knowledge acquisition to utilise the knowledge that exists in the area in a more comprehensive and systematic way.