

Self-preparedness for medicines and medical devices

The Swedish National Board of Health and
Welfare's assessment, recommendations, and
planned information campaign summary

Summary

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Many different products are necessary for the healthcare sector to function. A shortage of some of these products can mean serious disruptions to the ability of the healthcare sector to fulfil its mission. There is a need to strengthen the healthcare sector's level of preparedness according to several government investigations. A more secure supply of medicines and medical devices in the healthcare sector fosters resilience in everyday life as well as during serious incidents and events in times of peace, during times of heightened preparedness, and ultimately in times of war.

A robust supply system is the responsibility of the healthcare authorities and outpatient pharmacies. But patients can also contribute by ensuring that they have access to the medicines and consumables needed for the long-term treatment of their illness or other health conditions. Such access may be termed self-preparedness. By establishing self-preparedness corresponding to one month's consumption of medicines and consumables, patients contribute not only to their own safety but also to the security of supply for society as a whole. The more patients there are that are prepared, the lesser the risk of overburdening healthcare and pharmacy systems in the event of serious events during peacetime, heightened preparedness and, ultimately, in the event of war.

With this report, the National Board of Health and Welfare presents its assessment of the issue of self-preparedness. The agency also presents a

number of recommendations, which together aim to create the conditions for self-preparedness to be established to the greatest possible extent, without concomitant patient safety risks or the risk of hoarding. The recommendations will formally enter into force on 1 March 2023.

The National Board of Health and Welfare also reports that there will be an information campaign which consists of three phases of self-preparedness. Planning includes the coordination of communication efforts with others

The National Board of Health and Welfare's assessment of self-preparedness

Based on its assignment, and current statutes, as well as the assessments, conclusions and impact analyses described in SOU 2021:19, including the consultation statements to SOU2021:19, and what has emerged in the National Board of Health and Welfare's dialogues with external and internal stakeholders, the National Board of Health and Welfare has presented a summary assessment of the country's self-preparedness with regard to medicines and medical devices. This is reported here.

The National Board of Health and Welfare assesses that:

- A recommendation on self-preparedness should cover medicines and consumables pre-scribed by healthcare professionals.
- A recommendation of one month's self-preparedness is compatible with the 'pharmaceutical benefit scheme' for medicines.
- A recommendation of one month's self-preparedness is mainly achievable even taking into account regional guidelines for the prescribing of consumables outside the Pharmaceutical Benefits Scheme.
- A recommendation of one month's self-preparedness generally represents a reasonable balance between preparedness aspects, patient safety aspects and risk of wastage.
- Increased individual preparedness contributes to providing a reduced burden on the health, medical and pharmacy systems in the event of disruptions in the supply flow, and thus also makes it easier for those individuals who do not have the ability to establish such preparedness.
- It is desirable that self-preparedness be established before the supply is possibly threatened or hampered. In the event of a serious disruption to supply chains, the ability to establish self-preparedness will be strongly affected.
- Self-preparedness entails robustness in the event of disruptions to supply chains even of a more mundane nature, for example in situations when there are back orders.
- Healthcare personnel that prescribe medicines and consumables today have a responsibility to assess how much medicines and consumables a patient should have

access to at home, and based on this, consider any restrictions when prescribing.

- A recommendation of one month's self-preparedness in itself does not pose any particular safety risks for the patients/patient groups targeted by this proposal.
- The principle of self-preparedness does not apply to those patients/patient groups who receive medicines prescribed at dispense intervals.
- The establishment of self-preparedness in practice will take place gradually, partly due to the fact that the regulations pertaining to the benefit scheme impose time limitations on patients' ability to pick up their prescribed medicines. Overall, therefore, the risk of shortage situations in pharmacies arising as a result of self-preparedness being established is assessed as minimal.
- The regulations pertaining to the benefit scheme also limit the possibility of hoarding, and the risk associated with this, solely as a result of the recommendation of one month's self-preparedness, is thus small for those patients/patient groups to which the recommendation relates.
- There may be patients/patient groups who, for various reasons, may have limited opportunities of establishing and maintaining self-preparedness including the management of a personal supply of medicines/consumables. These would, for example, be patients with limitations in terms of their cognitive ability, other disabilities, or socioeconomic vulnerabilities.
- There are product areas that, due to the characteristics of the products in question, are unsuitable for storage within the framework of one month's self-preparedness. These can be, for example, products with a limited shelf life, space-consuming packaging, the need for cold storage and/or fire hazards etc.

- For products that are unsuitable for storage within the framework of a one-month self-preparedness period, the National Board of Health and Welfare recommends that the patient and the prescribing or dispensing health care professional discuss the issue to determine the level of self-preparedness that may be reasonable.
- The personal supply established for self-preparedness should be managed according to the First in, First out principle.
- A recommendation of a one-month self-preparedness period is in line with a desire on the part of the pharmacy sector, patient organisations and authorities, that patients should generally pick up medicines and consumables in good time.
- Healthcare personnel who prescribe and/or dispense medicines or consumables shall be responsible for observing and providing information about the National Board of Health and Welfare's recommendations regarding self-preparedness to those patients concerned.
- Healthcare personnel within municipal operations shall assist patients and users affected by the recommendation in setting up and providing supplies for self-preparedness.
- An increased level of self-preparedness is an important contribution to society's overall security of supply but needs to be supplemented with other measures by the state, authorities, and other actors to strengthen the overall security of supply in both the short and long term.

The National Board of Health and Welfare's recommendations regarding self-preparedness

The National Board of Health and Welfare recommends that:

- Patients who are being treated for an illness or other health condition on a long-term basis should establish their own storage for one month's consumption of medicines and consumables as prescribed by healthcare personnel.
- Healthcare personnel who prescribe medicines and consumables shall take into account the recommendation regarding self-preparedness when prescribing and prior to prescription renewal.
- Healthcare personnel who dispense medicines and consumables can inform patients about the self-preparedness recommendation in connection with dispensing.
- The healthcare sector aims to spread the information about self-preparedness that the National Board of Health and Welfare provides.
- The outpatient pharmacies aim to spread the information about self-preparedness that the National Board of Health and Welfare provides.
- Healthcare personnel within municipal operations shall, if necessary, assist patients and people in need of assistance to arrange for and provide for their own supply of medicines/consumables for self-preparedness.
- The National Board of Health and Welfare's recommendation on self-preparedness is taken into account in the design of information from the authorities that are part of the preparedness sector for health, care and social care, as well as from the Dental and Pharmaceutical Benefits Agency.

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