SWEDISH NATIONAL AUDIT OFFICE

Summary

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Central government supervision of pharmacies and wholesale trade in medicinal products

Summary

The Swedish NAO's overall conclusion is that central government supervision of pharmacies and wholesale trade in medicinal products is not effective. This has the result that pharmacies and wholesalers are able to run businesses that do not live up to the legislative requirements in all respects, without being detected and without legal measures being taken by the supervisory authorities. Ultimately, this means that patient safety is compromised and unnecessarily large central government and regions expenditure when pharmaceutical benefits and other pharmaceutical subsidies are misused.

Audit findings

The Government has not regulated the system for supervising pharmacies and wholesale trade of medicinal products to give the Medical Products Agency, the Health and Care Inspectorate (IVO), and the Dental and Pharmaceutical Benefits Agency (TLV), in their capacity as supervisory authorities, sound conditions to carry out effective supervision. Streamlining supervision requires measures such as giving supervisory authorities better access to data in the Swedish eHealth Agency's registers, a better basis for sharing information with each other and expanded sanction options. In addition, a new regulation is needed to prevent pharmacies from overcharging for special dietary foods and medicinal products

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that are not covered by the pharmaceutical reimbursement system but are subsidised by the State or by the regions.

The Medical Products Agency needs to be better at following up that pharmacies are really taking the measures that the supervision identified the need for. The Medical Products Agency and IVO need to improve the dissemination of their supervision results than is now the case to make a greater contribution to learning and development. The Swedish eHealth Agency, in cooperation with the Medical Products Agency, needs to improve statistics on wholesale trade of medicinal products.

Recommendations

To improve supervision of pharmacies and wholesale trade of medicinal products, the Swedish NAO makes the following recommendations:

To the Government

- Introduce an opportunity for supervisory authorities to share information if needed for the receiving agency's pharmacy supervision.
- Introduce an expanded obligation for the Swedish eHealth Agency to submit data to the Medical Products Agency on pharmacies' dispensation and wholesalers' sales, allowing
    - register-based risk analysis of pharmacies and wholesalers
    - supplementing of data in ongoing supervision cases concerning pharmacies and wholesalers.
- Introduce an expanded obligation for the Swedish eHealth Agency to submit data to IVO on pharmacies' dispensation and wholesalers' sales, allowing
    - register-based risk analysis of pharmacies and their staff
    - supplementing of data in ongoing supervision cases concerning pharmacies and their staff.
- Give TLV access to data from the Swedish eHealth Agency, allowing supervision of all TLV areas of supervision.
- Introduce regulations that impose an obligation on the Swedish eHealth Agency to inform and share data with the supervisory authorities concerning suspected irregularities at the pharmacies.
- Introduce regulations that prevent pharmacies from overcharging for special dietary foods for children and for medicinal products not covered by the pharmaceutical reimbursement system but subsidised by the State or by the regions.

- Provide the Medical Products Agency with opportunities, and the TLV with expanded opportunities, to issue pecuniary sanctions.

To the Medical Products Agency

- Monitor that pharmacies adhere to the Medical Products Agency's supervisory decision.

To the Medical Products Agency and IVO

- Strengthen the broader feedback of supervisory results directed at the pharmacy market, wholesalers and the rest of society.
- Monitor developments of identified problem areas.

To the Swedish eHealth Agency and the Medical Products Agency

- Develop and ensure the quality of wholesale statistics.