SWEDISH NATIONAL AUDIT OFFICE

Summary

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Pharmaceutical prescription

– central government governance and supervision

Summary

The central government grant is not an effective instrument for more cost-effective pharmaceutical prescription

The assessment of the Swedish National Audit Office (Swedish NAO) is that the Government's governance of pharmaceutical prescriptions through the central government grant for the pharmaceutical benefits scheme etc. is not effective. In theory, the structure of the grant gives the regions incentives to keep pharmaceutical costs down. However, the regions proceed only to a minor extent on the basis of the size of the central government grant when drafting their pharmaceutical budget. The reasons given by the regions is that they have not been given the means to plan their pharmaceutical budget based on the central government grant. Firstly, the size of the central government grant is usually announced after the regions' pharmaceutical budget for the coming year has already been decided. Secondly, the frequent changes to the grant structure have made it difficult for the regions to forecast the size of the central government grant for the coming fiscal year. Since 2021, the Swedish Association of Local Authorities and Regions has been providing forecasts to the regions on the forthcoming central government grant to facilitate budgetary planning. Nevertheless, the regions base their pharmaceutical budget chiefly on factors other than the central government grant. The central government grant can therefore be regarded as general budgetary support for the regions rather than a policy instrument.

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The agencies' governance through knowledge has a limited effect on the prescription of pharmaceuticals

Furthermore, the Swedish NAO considers that the efforts of the National Board of Health and Welfare, the Medical Products Agency and the Swedish Agency for Health Technology Assessment and Assessment of Social Services within knowledge management documentation is largely satisfactory, but that knowledge management nevertheless has a limited impact on the prescription of pharmaceuticals. The agencies' knowledge-enhancement resources are coordinated, but following up on knowledge management and returning its results to the regions could be improved. The knowledge-enhancement resources are based on science and proven experience, have sound quality assurance processes and support the needs of various professions. The agencies perform a thorough conflict of interest assessment of the experts who take part in developing the knowledge-enhancement resources. The National Board of Health and Welfare and the Medical Products Agency need to take greater account of the needs of the responsible authority in preparing the documentation. The Medical Products Agency needs to involve patients and users to a greater extent.

Supervision of improper prescriptions is not effective

The Swedish NAO's assessment is that the Health and Care Inspectorate's (IVO) processing times for cases of improper pharmaceutical prescriptions do not meet the requirement in the Administrative Procedure Act for prompt processing. Processing times, the volume of incoming cases and the case backlog at IVO have increased over time. Processing times at the Medical Responsibility Board (HSAN) are also year-long which, taken together with IVO's processing times, leads to unreasonably long processing times. During the processing time at IVO and HSAN, prescribers can continue their improper prescriptions unless HSAN has taken an interim decision to limit or revoke their prescription right or withdraw their certification at the request of IVO.

IVO does not have the regulatory means to conduct effective supervision of pharmaceutical prescription, since IVO lacks the possibility to use register data to search for prescribers who engage in improper prescription. This poses a risk of serious malpractice going completely undetected.

The Swedish NAO's assessment is that IVO's authority to impose sanctions is effective. Most professionals who have been issued with a decision containing criticism cease their improper prescriptions. About three in four professionals who have been issued with a decision on a probationary period complete this period.

Major deficiencies in the regulation of improper use of the pharmaceutical benefits scheme and disease control subsidies

There are also considerable shortcomings in the regulation of how prescriptions that lead to improper use of the pharmaceutical benefits scheme and subsidies under the Disease Control Act are to be managed. An example of improper use is when pharmaceuticals are prescribed as being free of charge to the patient under the Disease Control Act even though they are not used to treat a communicable disease. Another example is when pharmaceuticals that are only covered by the pharmaceutical benefits scheme for certain groups or certain conditions are also prescribed under the scheme beyond these restrictions, such as diabetic medicinal products prescribed for slimming and emollient creams. Improper prescription of narcotics-classified and other desirable pharmaceuticals like botulinum toxin against wrinkles, growth hormones for body builders and potency-enhancing products also have the side effect of burdening the pharmaceutical benefits scheme.

The Dental and Pharmaceutical Benefits Agency (TLV) and IVO both have supervisory responsibilities in this area, but neither agency has the capacity to conduct effective supervision. TLV does not have access to medical records or other information about individual prescribers' prescriptions and no possibility to supervise individual prescribers. IVO focuses its supervision on patient safety and not on the pharmaceutical benefits scheme or disease control subsidies. Neither is it possible for IVO to find out from the eHealth Agency whether a pharmaceutical has been prescribed with a disease control subsidy or under the pharmaceutical benefits scheme.

When the regions discover improper use of the pharmaceutical benefits scheme or disease control subsidies, their prospects of stopping the prescribers and recovering the disbursed funds are limited. One way for regions to prevent exploitation of the benefits scheme is to revoke a care provider's workplace code. A workplace code is needed to enable prescribing pharmaceuticals under the pharmaceutical benefits scheme. In many cases, the clinics appeal the revocation of the workplace code to the National Board of Health and Welfare. In many cases, the National Board of Health and Welfare considers that care provider's workplace code should be reinstated, entirely in line with the Ordinance (2002:160) on Pharmaceutical Benefits etc. Under the ordinance, all parties that have a workplace and are authorised to prescribe pharmaceuticals have the right to receive a workplace code. Neither are the regions able to obtain compensation for undue costs under the benefits scheme that have already been disbursed. Some regions have claimed damages, as injured parties, for costs incurred through the pharmaceutical benefits scheme in connection with prescribers being prosecuted

for crimes. However, the claims were dismissed when the defendants were acquitted by the courts.

Recommendations

To the Government

- Transfer the central government grant for the pharmaceutical benefit scheme etc. to general government grant for regions within the appropriation for the local government financial equalisation system.
- Clarify the agencies' supervisory responsibility for improper use of the pharmaceutical benefits scheme.
- Investigate how improper use of pharmaceutical subsidies can be prevented and how the regions can be compensated for undue payments.
- Clarify the rules for awarding and revoking workplace codes.
- Enable IVO to use the information about prescriptions of specific pharmaceuticals and other medicinal products needed to identify deviant prescription patterns and high-risk individuals ahead of, and during, supervision of the pharmaceutical prescribers.
- Investigate opportunities for HSAN to shorten processing times, or alternatively enable IVO to revoke or provisionally limit prescription rights during ongoing supervision.

To the Medical Products Agency and the National Board of Health and Welfare

- Perform continual follow-up on knowledge management and return the results to the regions.
- Take into account the perspective of the responsible authority – that is, the regions – ahead of work on drafting treatment recommendations and national guidelines.

To the Medical Products Agency

- Develop patient and user participation in the work on the treatment recommendations.

To the Health and Care Inspectorate (IVO)

- Improve efficiency in processing cases relating to deficiencies in pharmaceutical prescription to cut processing times.

To the Health and Care Inspectorate (TLV)

- Continue to develop and systematise follow-up of prescribers' compliance with the restrictions of the pharmaceutical benefits scheme.
- Review the decision on the benefit if compliance with the restrictions of the pharmaceutical benefits scheme is low or if the cost-efficiency assumptions that formed the basis for the decision have changed.