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Medical Products Agency assigned to draft new model for substance-based prescription

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Introduction

The government recently gave an assignment to the Swedish Medical Products Agency (the agency) to review the possible use of substance names for prescriptions, rather than the trade name of a medicinal product. More specifically, the agency has been assigned to prepare for substance names to be included in the register that it provides to the Swedish eHealth Agency regarding medicinal products, and that are used for prescribing and dispensing these products.

Substance name-based prescribing means that prescribers no longer prescribe the medicinal product by its trade name, and thereby a specific brand, but rather the desired substance regardless of its manufacturer. It would then be up to a pharmacist to, under the relevant law, decide which medicinal product containing the relevant active ingredient to give the patient.

The idea is for the agency to create:

- standardised designations for the substances to simplify the process and increase the convenience of the patients; and
- a uniform labelling model, regardless of the pharmacy operator.

Since there exist detailed provisions regarding the prescription and dispensation of medicinal products, including mandatory substitution to generic products, the government found it appropriate for the agency to review the current regulatory framework to propose changes that are necessary to its own, or other competent authorities' regulations, to accommodate generic prescription. This includes the Dental and Pharmaceutical Benefits Agency, the Swedish agency for pricing and reimbursement of medicinal products.

Substance names

The agency must investigate how to present substance names during the different phases of prescription, distribution and the process of follow ups with patients. To achieve this, the government has asked the agency to look over and prepare the necessary changes to its IT support needed to enable the necessary information to be entered in the relevant places in its systems and registers.

To potentially switch to a substance name-based model of prescription, the agency was also asked to investigate the possibilities to use the agency's regulations in order to include substance names on pharmacy's labelling of medicinal products for human use, when they are dispensed through prescriptions.

Another task given to the agency was to review the possibility under the current laws and regulations to prescribe a medicinal product within a substitution group with both its trade name and substance name, as well as identify whether legislative changes were needed to allow for the combined prescription, with subsequential suggestions for these changes.

The subject of a generic model of prescriptions has been discussed in Sweden prior to 2023. Both the economic benefits and the potential changes to patient safety with generic prescription has been reviewed by the agency several times during the previous ten years. The outcomes of those reviews have not been a resounding "yes", nor a definite "no" on the question of whether to introduce generic prescription. Neither review led to substance name-based prescriptions, but they did come with suggestions from the agency for changes to the labelling for prescriptions during distribution, in order to facilitate an easier conversation with patients regarding generics or otherwise substituted medicinal products (eg, parallel distributed products).

Further evidence of the governments interest in generic prescription is that the Swedish eHealth Agency, in their instructions for the year 2023, has been given an assignment to:

- ensure that information on substance names is provided for all stakeholders that have access to their register; and
- more importantly, prepare for the possibility to handle prescription through both trade names and substance names.

The government has, in the assignment to the agency, presented one reason as to why this is the appropriate time for this investigation. In 2021, a new common register over prescribed and dispensed medicinal products came into effect for parties involved along the whole process from prescribers to patients. The government seemingly views 2023 as the year to, at the very least, investigate the prospect of generic prescriptions.

The final review will be presented to the government on 31 May 2024.

Comment

Historically, the Swedish government has stopped short of proposing any changes to the prescription system, given the changes in the legislation and other regulatory framework that would be needed to accommodate for generic prescription. However, this time the government appears to be more determined to go through with a legislative proposal. It is likely that the concept of indication-based prescription will also be discussed during the review, although not explicitly mentioned in the scope of the assignment (eg, as the Dental



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and Pharmaceutical Benefits Agency has mentioned an interest in this as a concept for new therapies and otherwise). Whether such a proposal could be included is uncertain, as it would require interest also from prescribers, since it would limit the possibilities for off-label prescription for a prescriber.

Any new legislation regarding generic prescription could likely not come into effect before mid-year 2025, at the earliest.

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