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Circular to pharmacies on the conditions for prescription of medicinal products for ADHD and Sic notations

Fimea's competence

According to Section 76 of the Medicines Act (395/1987), general planning, control and supervision of pharmaceutical services falls within the purview of the Finnish Medicines Agency Fimea, which operates under the Ministry of Social Affairs and Health.

With this circulation, Fimea instructs pharmacies on conditions for prescription of medicinal products for ADHD in connection with prescribing or dispensing prescriptions, and using the Sic notation for exceptional dosage instructions or exceptional purpose of use in prescriptions.

Background

There have been challenges with compliance with conditions for prescription because some of them have left room for interpretation as to what kind of specialisation or familiarity is required from the prescribing physician. Especially conditions for prescription of ADHD medication have caused problems with interpretation. At the same time, the question has been raised whether a Sic notation can be used to override a condition for prescription.

Regulatory background

Conditions for prescription of medicinal products

According to Section 21(2) of the Medicines Act (395/1987), the Finnish Medicines Agency may incorporate conditions to the marketing authorisation of a medicinal product may when these are necessary to ensure the correct and safe use of the medicinal product.

A summary of product characteristics (SPC) in line with the marketing authorisation may already include similar text to a condition for prescription. In certain cases, the content of a separate condition for prescription imposed by Fimea may conflict with the text of the SPC. This is usually due to the fact that in a decentralised procedure, it is not possible to deviate from the common text of the SPC binding to all countries applying for a marketing authorisation. In these cases, the conditions for prescription imposed by Fimea must be respected.

Prescription of drugs

According to Section 10(3) of the Ministry of Social Affairs and Health Decree on the prescription of medicines (1088/2010, "Prescription Decree")(1459/2016), restrictions based on the marketing authorisation or restrictions imposed by a competent authority must be respected in the prescription of drugs. Prescribers must also take into account possible clinical guidelines that are based on research evidence.

According to Section 9 of the Prescription Decree (1088/2010), the prescriber must cooperate, when necessary, with the pharmaceutical staff of the pharmacies the patients usually use to ensure medication counselling for patients as well as safe, efficient and cost-effective pharmacotherapy.

Dispensing of medicines

According to Fimea administrative regulation 2/2016 on dispensing of medicines:

- Prescription and dispensing of medicines from a pharmacy should constitute a safe and appropriate entity from the perspectives of the medication user, prescriber, pharmacy and the rest of the health care system.
- If the pharmacy has reasonable grounds to suspect that the prescriber does not comply with the regulations governing the prescription of drugs or that prescribing is not appropriate, the pharmacy must contact the prescriber. If this practice continues nonetheless, the pharmacy must contact the employer of the prescriber. If the contact is unsuccessful, the pharmacy may contact the authority supervising professional activities of health care professionals or veterinarians.
- A chemist or pharmacist checks that prescription drugs are ready to be dispensed and dispenses them to the customer, and they must make sure that instructions, regulations and conditions of the marketing authorisation concerning the medicinal product to be dispensed have been considered. It must be made sure that other conditions of the marketing authorisation are also respected.

Sic notations

According to the Prescription Decree (1459/2016), a “Sic” notation must be used when the prescriber exceeds the dosage instructions provided in the approved summary of product characteristics, when the dose of an ex tempore drug exceeds the dosage instructions of a corresponding authorised medicinal product or a maximum dose provided in another well-known source, or if the prescription deviates from widely accepted clinical practices.

The above section of the Decree was updated to the current form in 2016, and the Memorandum concerning the amendment to the Decree (STM101:00/2016 and STM/4478/2016; 22 December 2016) states the following:

“Subsection 5 of the Section would be clarified to say that a “Sic” notation should also be included in a prescription when the prescription deviates from widely accepted clinical practice in a way not specified in the Section. The objective is that the pharmacy dispensing the medicinal product has no need to enquire as to whether the prescriber has intentionally written the prescription or if it is a mistake, requiring the prescriber to be contacted. At the same time, this reduces the number of contacts between pharmacies and prescribers.”

Guidance on conditions for prescription concerning prescription and dispensing

Prescription of drugs

Due to uncertainty concerning the conditions for prescription of ADHD medication, the Ministry of Social Affairs and Health, Supervisory Authority for Welfare and Health Valvira, and Fimea clarify the principles to be taken into account in the updating of the conditions for prescription of ADHD medication. The aim of this work is to update the product-specific conditions for prescription in line with the below principle.

Medication can be started by:

- For children and adolescents, a child or adolescent psychiatrist, paediatrician, child neurologist, or other physician familiar with the mental and physical development of children and adolescents and treatment of ADHD, when non-pharmacological modes of treatment alone are not sufficient.

- For adults, a specialist in psychiatry or neurology, when non-pharmacological modes of treatment alone are not sufficient.

In a stable phase, to implement further treatment, the prescribing physician should consult a physician familiar with ADHD treatment, when necessary.

In addition to psychiatrists, specialists in psychiatry include child, adolescent and forensic psychiatrists. In addition to neurologists, specialists in neurology include child neurologists.

A physician specialising in the above specialities can start ADHD medication in the place of specialisation. If the pharmacy has reasonable grounds to suspect that prescribing has not taken place at the place of specialisation concerning the above specialities, the pharmacy must contact the prescriber.

The authorities do not comment on progressive patient care and ADHD medication.

Valvira provides more detailed instructions to prescribers on its website.

Dispensing of medicines

Pharmacies must ensure that clear conditions for prescription are respected, for example, if the conditions for prescription require a specialist or the maximum amount of medicine to be prescribed at one time is restricted.

If the conditions for prescription require, for example, that the physician is familiar with the treatment of a certain illness, pharmacies are, as a rule, not able to verify if the condition has been met, and responsibility for compliance remains with the prescriber.

Implementation and continuation of appropriate pharmacotherapy must be ensured.

Guidance on Sic notations

A prescriber may use a Sic notation to inform that a deviation in the prescription, as referred to in the Prescription Decree (1459/2016), is intentional and not a mistake. This additional information helps to reduce the number of contacts from the dispensing pharmacy to the prescriber.

The Ministry of Social Affairs and Health, Fimea and Valvira agree that a Sic notation in the prescription cannot be used to override a condition for prescription of a medicinal product that is based on ensuring the correct and safe use of the medicinal product.

Cooperation between prescribers and pharmacies

If a prescription is not appropriate and does not comply with the conditions for prescription, the pharmacy must contact the prescriber. When necessary, the prescriber must cooperate with the pharmaceutical staff of pharmacies to ensure medication counselling for patients as well as safe, efficient and cost-effective pharmacotherapy.

Cooperation between physicians and pharmacies must ensure implementation and continuation of appropriate pharmacotherapy.

For further information, please contact:

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Distribution

Pharmacies
National Supervisory Authority for Welfare and Health Valvira
The Ministry of Social Affairs and Health
The Association of Finnish Pharmacies

For information

The Finnish Medical Society Duodecim
The Finnish Medical Association
Working group on ADHD, Current Care Guidelines
Kela
The Finnish Institute for Health and Welfare

Further information

Valvira's website: ADHD and prescribing of medication (in Finnish)