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Reclassification of medicinal products from dispensing category D to E: evaluation concluded

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As part of the revision of the Therapeutic Products Act (TPA), self-medication is to be made easier for patients: access to medicines will be simplified, but without endangering patient safety. Under the new legislation, the current dispensing category C is to be discontinued. In addition, dispensing category E will be expanded. The evaluation of all medicinal products currently listed in the current dispensing category C was concluded in mid-November 2018, and the evaluation of medicines in dispensing category D as well as their suitability for reclassification to category E has now also been completed.

Medicinal products in dispensing category E are dispensed on a self-serve basis without expert advice. The reallocation of a medicinal product to dispensing category E hinges on whether patients are able to evaluate symptoms of illness and decide if a medicine is appropriate or not without the need for expert advice. The scientific criteria were defined and the dispensing categories reviewed with the participation of external experts.

Criteria: Therapeutic areas limited by patient safety considerations

Of the almost 1,800 medicinal products in dispensing category D, around 540 were evaluated for possible reclassification for sale on a self-serve basis. They were selected based on the following criteria:

- The strict requirements which the government has defined in its therapeutic products legislation for medicines that may be dispensed in all sales outlets; according to the Therapeutic Products Act, these must be safe and not require any medical/pharmaceutical or other expert customer counselling (Art. 23 para. 2 TPA).
- Elimination of existing inconsistencies in dispensing categories D and E (comparable preparations can currently be found in both categories).

The possible therapeutic areas in which medicines can in principle be dispensed without expert advice were defined on the basis of these requirements. The corresponding medicinal products in dispensing category D that were possible candidates for reclassification were then identified.

The actual review was carried out in consultation with the commission of external experts. The same experts had previously advised Swissmedic during the evaluation of the reclassification of dispensing category C, thereby ensuring consistent assessment of the medicines.

The expert group included representatives from various dispensing outlets, the Swiss Medical Association FMH, the Swiss Pharmacists' Association Pharmasuisse, the Swiss Druggists' Association SDV, the complementary medicine umbrella organisation Dakomed (therapists) and the retail industry stakeholder group IG Detailhandel, as well as patient organisations and cantonal supervisory authorities (Association of Cantonal Pharmacists). Representatives from the two leading associations of the manufacturers of the relevant medicinal products (Association of the Swiss Self-Medication Industry ASSGP and the Swiss Association for Complementary Medicinal Products SVKH) were also consulted.

Each individual medicine was reviewed by the commission of experts on the basis of the previously defined and published list of criteria. The scientific evaluation was based on the latest packaging texts for the medicinal products to be evaluated (indications, side effects, restrictions on use, etc.).

Results

Most of the reviewed medicines are not suitable for dispensing on a self-serve basis since they are intended to be used for illnesses requiring expert advice.
For one thing, a layperson cannot always assess a patient's clinical picture; for another, expert advice is required for correct administration.

Although the composition of many of the reviewed medicinal products gives no cause for concern, their indication wording suggests that they are not suitable for dispensing without expert advice. Information such as: "their effect can be weakened by the concurrent administration of oral anticoagulants (blood thinners)" or "may not be used for Duhring's dermatitis herpetiformis (rare, herpes-like illness)" must be explained by a healthcare professional (doctor, pharmacist, druggist).

After in-depth discussions, the decision was also taken not to reclassify any homeopathic or anthroposophic agents as self-serve products. Since these medicines form part of a holistic therapeutic concept, the appropriateness of their use should be explained and communicated by an expert trained in the field concerned.

Of the medicines reviewed in dispensing category D, just under 17% were ultimately suitable for reallocation to dispensing category E. As a result, the current dispensing category E will be expanded by around 60%, from its current 146 (excluding veterinary medicines) to approx. 240 medicinal products.

Next steps

The actual reclassification will take place in the course of regular administrative procedures. These will be initiated from April 2019, once the revised Therapeutic Products Act has entered into force and the procedure for the medicines in dispensing category C has been started. Information about the process was provided to the industry at information events and in published documentation.

Following the entry into force of the new Therapeutic Products Act, the new dispensing categories applicable as of January 2019 will be as follows: A (Dispensed once on medical or veterinary prescription); B (Dispensed on medical or veterinary prescription, though pharmacists can dispense certain medicinal products in dispensing category B without a medical prescription); D (Dispensed after expert advice from healthcare professionals); and E (Dispensed without expert advice).

Related documents

List of intended reallocations of medicinal products for human use in dispensing category E (PDF, 222 kB, 21.11.2018)
(/dam/swissmedic/en/dokumente/marktueberwachung/abgabekategorien/liste_vorgesehene_umteilungen_ham_abgabekategorie_e.pdf.download.pdf/20181204-Entscheide-Abgabekategorie-E-HAM.pdf)

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