BASG / AGES
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Information on Named Patient Use (Heilversuch) in Austria

Cave: English translations of Austrian legal documents are not authorized and therefore not legally binding. The original, legally binding, German text passages are included in the text for reference.

Definition and Framework:

The Austrian Medicinal Products Act (Arzneimittelgesetz, AMG), as outlined in § 8 para. 1 Z 2 AMG permits the treatment of patients with medicinal products that are not licensed in Austria when specific requirements are met:

> *§ 8. (1) Arzneispezialitäten bedürfen keiner Zulassung, wenn …*
>
> *2. ein zur selbständigen Berufsausübung im Inland berechtigter Arzt, Zahnarzt oder Tierarzt bescheinigt, dass die Arzneispezialität zur Abwehr einer Lebensbedrohung oder schweren gesundheitlichen Schädigung dringend benötigt wird und dieser Erfolg mit einer zugelassenen und verfügbaren Arzneispezialität nach dem Stand der Wissenschaft voraussichtlich nicht erzielt werden kann*

> § 8. (1) Medicinal products do not require a license, if…
>
> 2. a medical doctor, dentist or veterinarian, licensed for independent exercise of profession in Austria, confirms, that the medicinal product is urgently required to avert a life threatening situation or severe health damage, and that successful treatment likely cannot be achieved with a licensed and available medicinal product according to the scientific state of the art.

In contrast to compassionate use programs that apply to a group/cohort of patients, named patient use, as the name implies, refers to a single individual. Named patient use in Austria does not require notification to or approval by the Austrian Federal Office for Safety in Health Care and lies in the sole responsibility of the treating physician.

In the special case of a named patient use with a product that falls under the scope of the Austrian Gene Technology Act, an approval by the Federal Ministry of Health is required (see http://www.bmg.gv.at/home/Schwerpunkte/Gentechnik/)

As outlined in § 8 para. 1 Z 2 AMG, named patient use is intended to facilitate the urgently needed treatment of a specific patient to avert a life-threatening or chronically debilitating situation. A

systematic collection of data on safety and efficacy of the medicinal product used is not legally acceptable in this framework. Systematic collection of these data is only possible in the framework of an authorized clinical trial (see **L_I209_Guidance_CT_submission_en**)

The Compassionate Use Program (Härtefallprogramm), in contrast, provides a framework where data (primarily on safety) on the medicinal product, can be collected (according to a treatment plan) after approval by the Agency. A Compassionate Use Program can be applied for either by the manufacturer of the medicinal product, if the manufacturer is sponsor of an approved clinical trial, or by the applicant for licensing according to Article 6 of Regulation 726/2004. An outline of the application procedure and information required can be found in document **L_I217_Compassionate_use_AT_en**.

Import of medicinal products:

For the importation/shipment of a medicinal product that is not licensed in Austria, the Austrian Medicinal Products Importation Act 2010 (AWEG, BGBl I Nr. 79/2010, as amended) needs to be applied. If the criteria of § 8 para. 1 Z 2 AMG apply, the exemption of § 11 para. 1 Z 2 Medicinal Products Importation Act 2010 applies for importation/shipment.

The exemption of § 11 para. 1 Z 2 Medicinal Products Importation Act 2010 requires the following: A medical doctor, dentist or veterinarian licensed for independent exercise of profession confirms that the respective medicinal product is **urgently** needed for the treatment of specific patient to avert a life-threatening or chronically debilitating situation and that successful treatment with licensed or available medicinal products cannot be achieved based on the scientific state of the art.

Urgency as referred to § 8 para. 1 lit 2 AMG applies, if the need for the medicinal product to avert a life-threatening or chronically debilitating situation which is not foreseeable, respectively plannable, and if it is required without delay. Only if these criteria apply importation can proceed without the involvement of the Austrian Federal Office for Safety in Health Care.

Import or shipment of the medicinal product lies in the responsibility of the treating physician. Release by customs needs to be based on the medical justification provided.

Hospital doctors need the co-operation of the hospital pharmacy or the public pharmacy, which supplies the hospital. The applicable procedure may vary depending on the hospital and needs to be clarified in consultation with this pharmacy.

Resident practicing physicians need cooperation with a public pharmacy.

In absence of urgency according to § 8 para. 1 lit 2 AMG, import of a medicinal product which is not authorized in Austria but is required for medical, dental or veterinary treatment for a specific patient must follow the requirements of the Medicinal Products Importation Act 2010. As a consequence, an application for importation authorization or a shipment notification is necessary as applicable, whenever the need for the medicinal product is foreseeable or plannable.

Detailed Information on the requirements of the Medicinal Products Importation Act 2010 can be found on the BASG homepage: http://www.basg.gv.at/en/inspections/importing-medicinal-products-to-austria/

Pharmacovigilance obligations:

All suspected adverse reactions of a medicinal product applied in Austria need to be documented and notified to the Austrian Federal Office for Safety in Health Care. The pharmacovigilance reporting obligations also concern medicinal products which are not licensed in Austria, including those which are applied in the framework of named patient use.

According to § 75 g AMG , members of the health care professions are obliged to notify all suspected adverse drug reactions that come to their notice as part of their occupation. These notifications must be made without delay.

Marketing authorization holders are obliged to electronically report suspected adverse drug reactions according to § 75 j AMG. The reporting obligation is within 15 days of the event becoming known for suspected serious adverse reactions and 90 days for suspected not serious adverse reactions.

Further information on pharmacovigilance can be found on our homepage: http://www.basg.gv.at/en/pharmacovigilance/