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From data to knowledge



# Medical Devices & Haemovigilance



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PharmMed



## About AGES PharmMed:

On 2.1.2006 the new Austrian Medicines and Medical Devices Agency - AGES PharmMed - was founded. It is an organisation characterised by flexibility, competence and spirit of service. AGES PharmMed fulfills on behalf of the Republic of Austria, public service responsibilities related to the inspection and approval of medicinal products and medical devices. The Republic of Austria as owner of AGES PharmMed is the guarantor for objectivity and impartiality in all of the services provided. AGES PharmMed is made up of the following closely collaborating units: Pharmacovigilance, Science and Information, Medical Devices and Haemovigilance, Inspections, Marketing Authorisation and Life Cycle Management and finally the Official Medicines Control Laboratory.

## About Medical Devices & Haemovigilance:

One of the units in the AGES PharmMed is "Medical Devices & Haemovigilance". The main task is to detect threats to public health arising from medical devices, in vitro diagnostics and use of blood and blood products. By means of appropriate measures the experts focus on ensuring the health and safety of patients and users on securing and improving product quality.

**Further Information** about AGES PharmMed: [www.ages.at](http://www.ages.at)

## The tasks of Medical Devices & Haemovigilance:

- Medical device vigilance including IVD;
- Haemovigilance;
- Market surveillance, performing delineations, classifications and conformity assessments of medical devices and measures to prevent products unrightfully bearing the CE-mark;
- Assessing technical reports on the safety of medical devices containing materials of animal origin in the light of TSE risk;
- Registration and assessment of clinical trials with medical devices;
- Issuing free sales certificates for medical devices.

## Medical device vigilance, haemovigilance

Collecting and assessing reports on adverse events related to the use of medical devices, in vitro diagnostics and blood products are the main tasks of any medical device vigilance system. The assessors of the unit determine whether the risks associated with the use of a particular medical device constitute acceptable risks when weighted against the benefits. If not, appropriate safety measures are instituted and communicated by the BASG.

## Market surveillance

As many medical devices are not subject to official review prior marketing, an efficient market surveillance programme is indispensable. This surveillance requires close collaboration and exchange of information between all European competent authorities. Cooperation at this level is bound to become even more important in the near future, as future strengthening of market surveillance will be required by upcoming EU-regulations.

## Free sales certificates

The institute is in charge of issuing free sales certificates (FSC) for the export of medical devices to countries outside the EEA and Switzerland.

## Clinical trials with medical devices and performance evaluation studies with in vitro-diagnostics

Processing the registrations of clinical trials with medical devices and performance evaluation studies of in vitro diagnostic medical devices as well as the notifications on amendments is part of the responsible tasks of the unit.