



Agriculture

From healthy soil to safe food in Austria



Food

Safe food...
...and labels that tell the truth



Veterinary Medicine

Healthy animals - safe food, protection
against animal and zoonotic disease



Human Medicine

Fighting infectious diseases



PharmMed

Safe and effective medicines



Competence Centers

The lab labs rely on



Data, statistics and risk assessment

From data to knowledge

PharmMed



For further information, advice or other questions, please visit our homepage www.ages.at - our FAQs (Frequently Asked Questions) may help.

Also please do not hesitate to contact us personally:

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**Marketing Authorisation of
Medicinal Products &
Lifecycle Management**

Marketing Authorisation of Medicinal Products & Lifecycle Management

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.

One of the units in AGES PharmMed is “**Marketing Authorisation of Medicinal Products & Lifecycle Management**”.

It is our aim to become a centre of regulatory excellence within Europe – the positioning of the AGES PharmMed as important reference member state in the mutual recognition and decentralised procedure.

To achieve this goal we guarantee:

- Best organisational, regulatory and scientific standards for our clients & partners
- Consistency in scientific evaluation of Quality, Safety and Efficacy
- Predictable timelines
- Transparency of all scientific-regulatory activities

We take part in the strategy and plans of the EU and we intend to play an important role in international competition. We are also currently improving our IT-systems, which will enable us to handle electronic submissions, communication and archivation. All to be one of the best.

Dialogue and openness within our organisation and with our clients is our formula for success. The networked matrix organisation assures a flexible exchange of information outwards as well as among the six departments.

The 6 departments introduce themselves:

64% of our employees have university degrees, mostly doctors, pharmacists, but we also employ veterenary surgeons, biologists and chemists.

Regulatory Affairs – National Procedures

- Licensing procedure – human medicinal products
- Variation procedure
- Renewals

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Regulatory Affairs - MR and DC Procedures

- Licensing procedure – human medicinal products
- Project manager for RMS-activities
- LCM

Contact person: Kristof Liszka,
Head of Department
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Quality Assessment of Medicinal Products

- Scientific evaluation of the quality dossier for human and veterinary medicinal products

Contact person: Peter Platzer,
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Safety and Efficacy Assessment of Human Medicinal Products

- Scientific evaluation of the clinical and non clinical documentation for human medicinal products

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Veterinary Medicinal Products

- Regulatory affairs for veterinary medicinal products (national and MRP/DCP)

Contact person: Eugen Obermayr,
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Herbal & Homeopathic Medicinal Products

- Scientific evaluation of herbal medicinal products, traditional herbal medicinal products and homeopathics in relation to Quality, Safety and Efficacy.

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