



For further information, advice or other questions please visit our homepage www.ages.at or contact us personally:

Contact:

Andrea Laslop

Head of Unit
Tel.: +43 (0) 50555 36800
Fax: +43 (0) 50555 36809
E-Mail: andrea.laslop@ages.at

Silvia Wulz

Assistant to Andrea Laslop
Tel.: +43 (0) 50555 36801
Fax: +43 (0) 50555 36809
E-Mail: silvia.wulz@ages.at

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Health. Nutrition. Safety. Our Concern.



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



Science and Information

Science and Information

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 Science and Information:

One of the units of AGES PharmMed is "Science and Information". The aims of the unit are to ensure a high scientific level and to strengthen the organisation's position within Europe's leading centres of excellence in the centralised procedure and scientific advice on a national and international level.

Further Information about AGES PharmMed: www.ages.at

What does the Institute "Science and Information" do?

- Assessing the quality, efficacy and safety of human and veterinary medicinal products in European centralised procedures;
- Scientific advice on a national level (EMEA);
- Registration and approval of medicinal products;
- Research;
- Representing Austria in international committees and boards;
- Coordinating the implementation of national measures with experts;
- Training and development of staff;
- Communications and public relations.

Department for International Affairs

How does the Institute work?

- with the highest scientific standards;
- with adequate management structures;
- with and within an expert network;
- by developing core competencies.

The Science and Information unit has launched a research project in cooperation with the Data, Statistic and Risk Assessment division of AGES and the Institute for Medical Statistics, Medical University of Vienna, evaluating the use of adaptive designs in clinical phase I studies. Projects dealing with process optimisation and basic research are in the pipeline.

The Science and Information unit consists of two closely cooperating departments:

Department for International Affairs

The focus of this department lies on processing applications for scientific advice on the international and national level. The assessment of centralised applications for marketing authorisation will be strengthened as a second major task.

Contact: Thomas Lang, Head of Department

E-Mail: thomas.lang1@ages.at

Department for National Affairs

The department is primarily responsible for assessing requests for authorisation of clinical trials and processing adverse event reports arising from these trials. As a result of the expertise of the department one focus is the evaluation of biologics and their complex manufacturing processes.

Contact: Ilona Reischl, Head of Department,
Deputy Head of Unit

E-Mail: ilona.reischl@ages.at