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Safety of Medical devices

Medical device vigilance and Reporting

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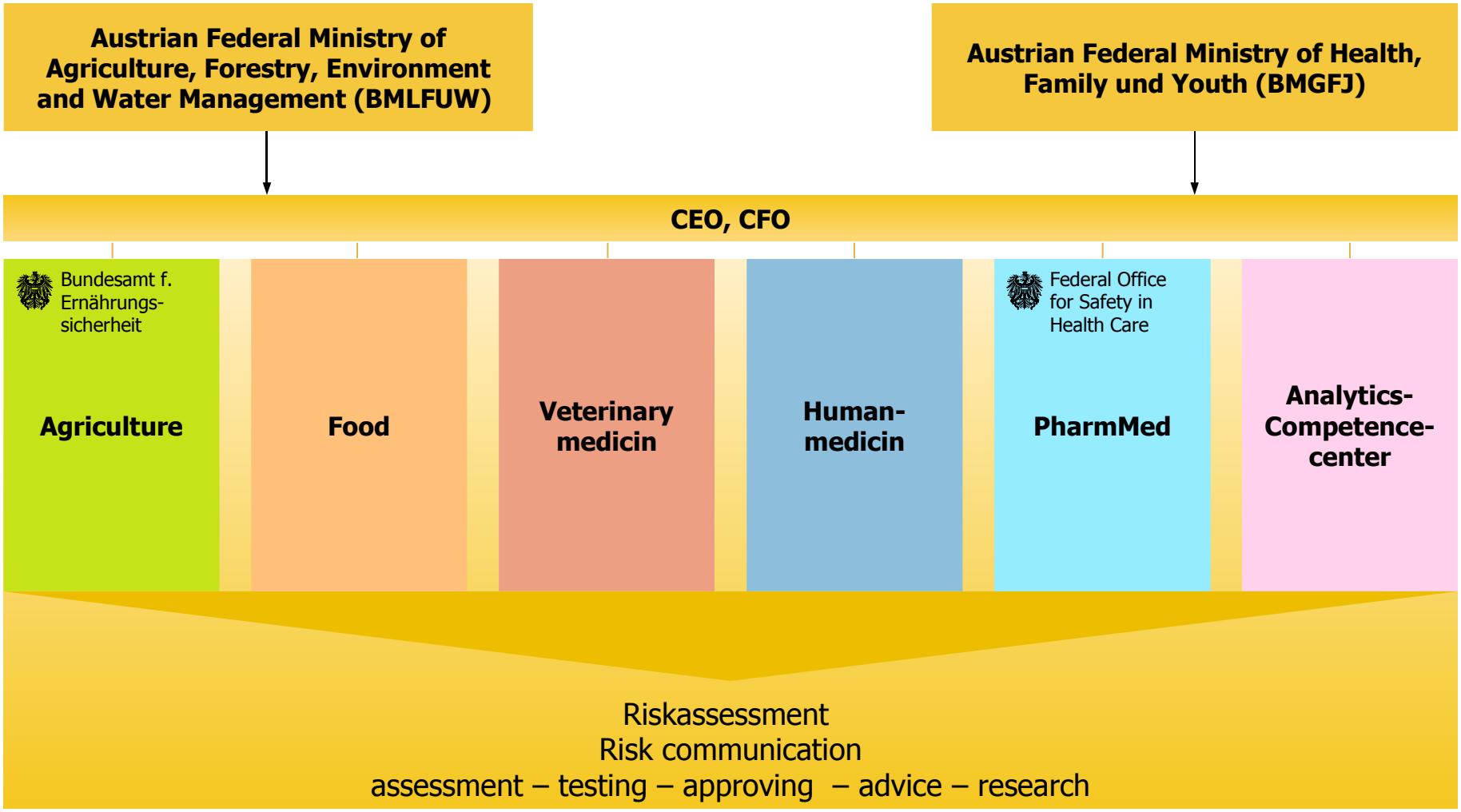
Disclaimer: The content of this presentation does not necessarily conform to the official position of AGES PharmMed and of the Bundesamt für Sicherheit im Gesundheitswesen

1. AGES and PharmMed Austria
2. CE – mark

   PMS, medical device vigilance, assessment

   European coordination amongst Competent Authorities

Organization chart AGES



risk control – the AGES cycle

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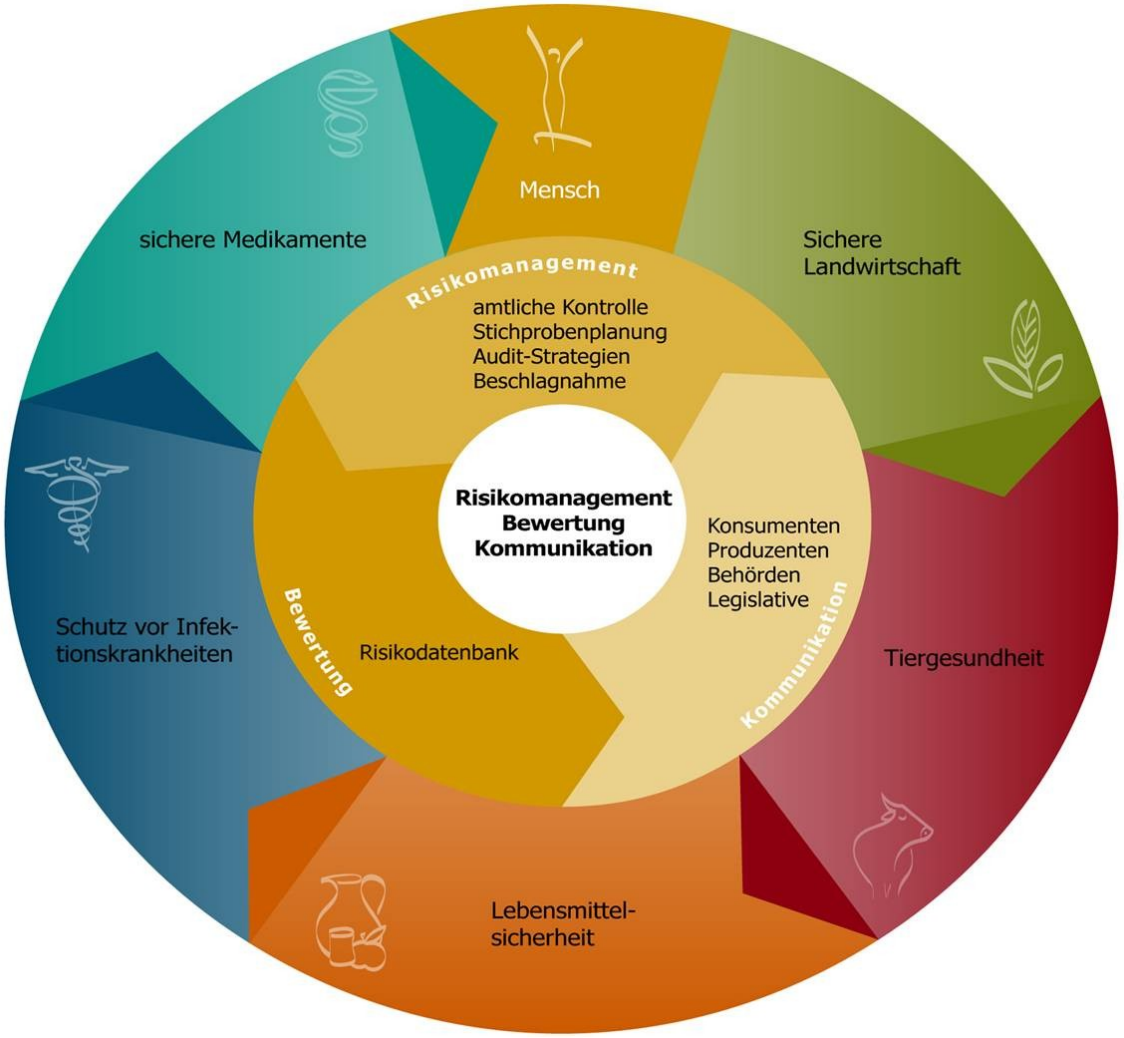

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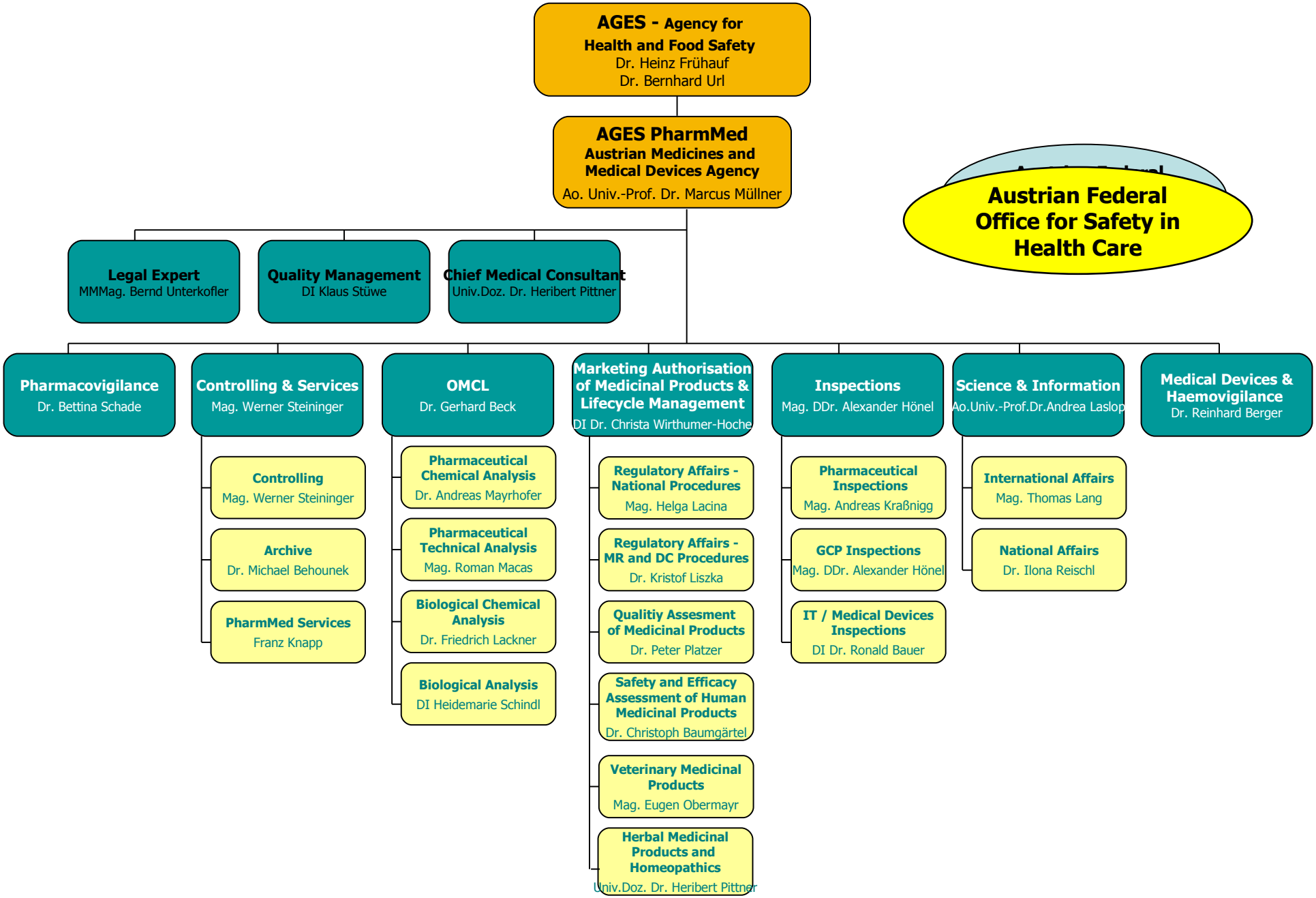
- 153. Federal law, changing and amending the *Gesundheits- und Ernährungssicherheitsgesetz (GESG)* and related legislation

Issued on December 28th 2005

→ Thus transferring tasks and responsibilities from the BMGFJ to the **Federal office for Safety in Healthcare**, and to AGES – PharmMed Austria as operating unit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AGES PharmMed
Austrian Medicines and Medical Devices Agency
Ao. Univ.-Prof. Dr. Marcus Müllner
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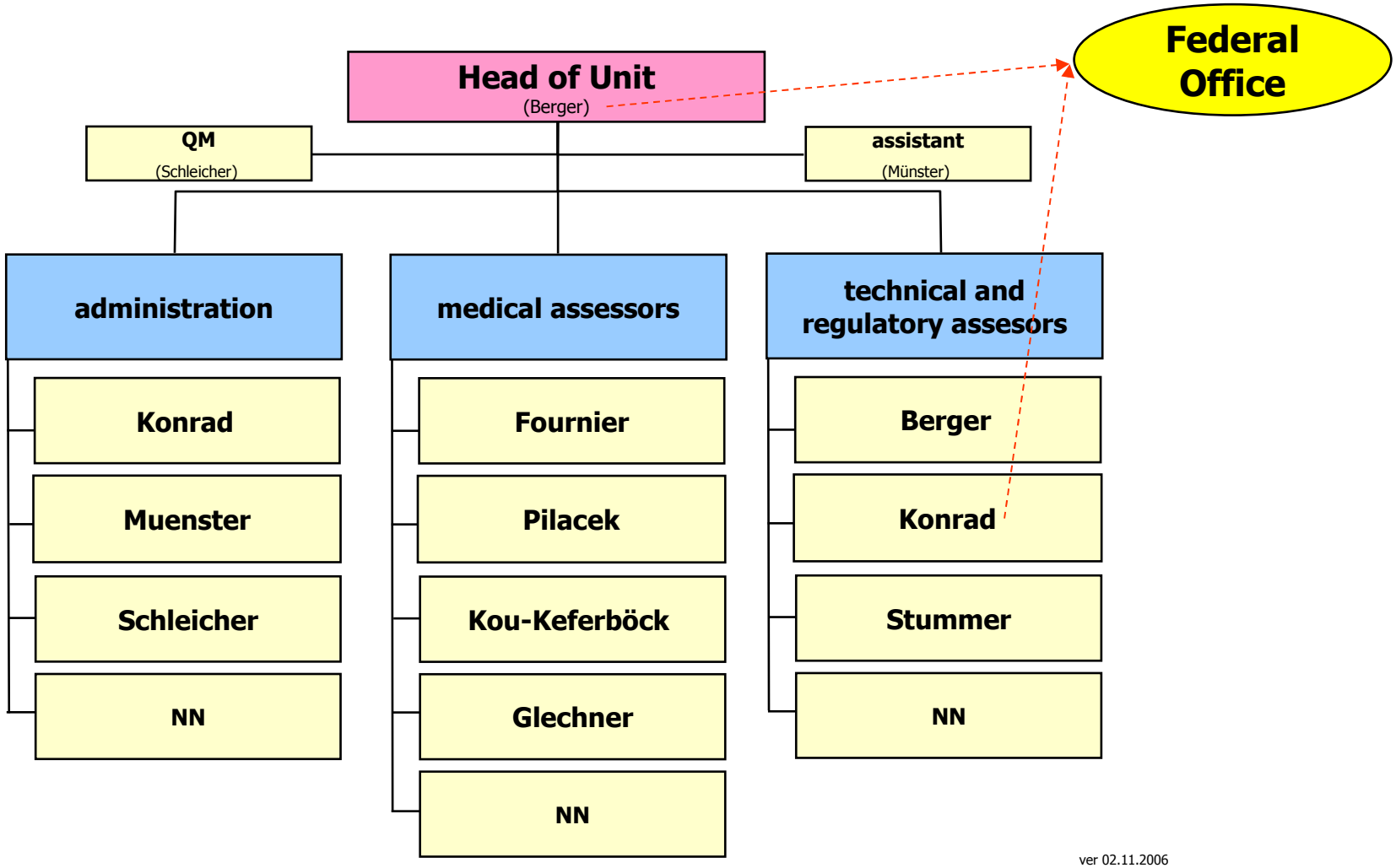
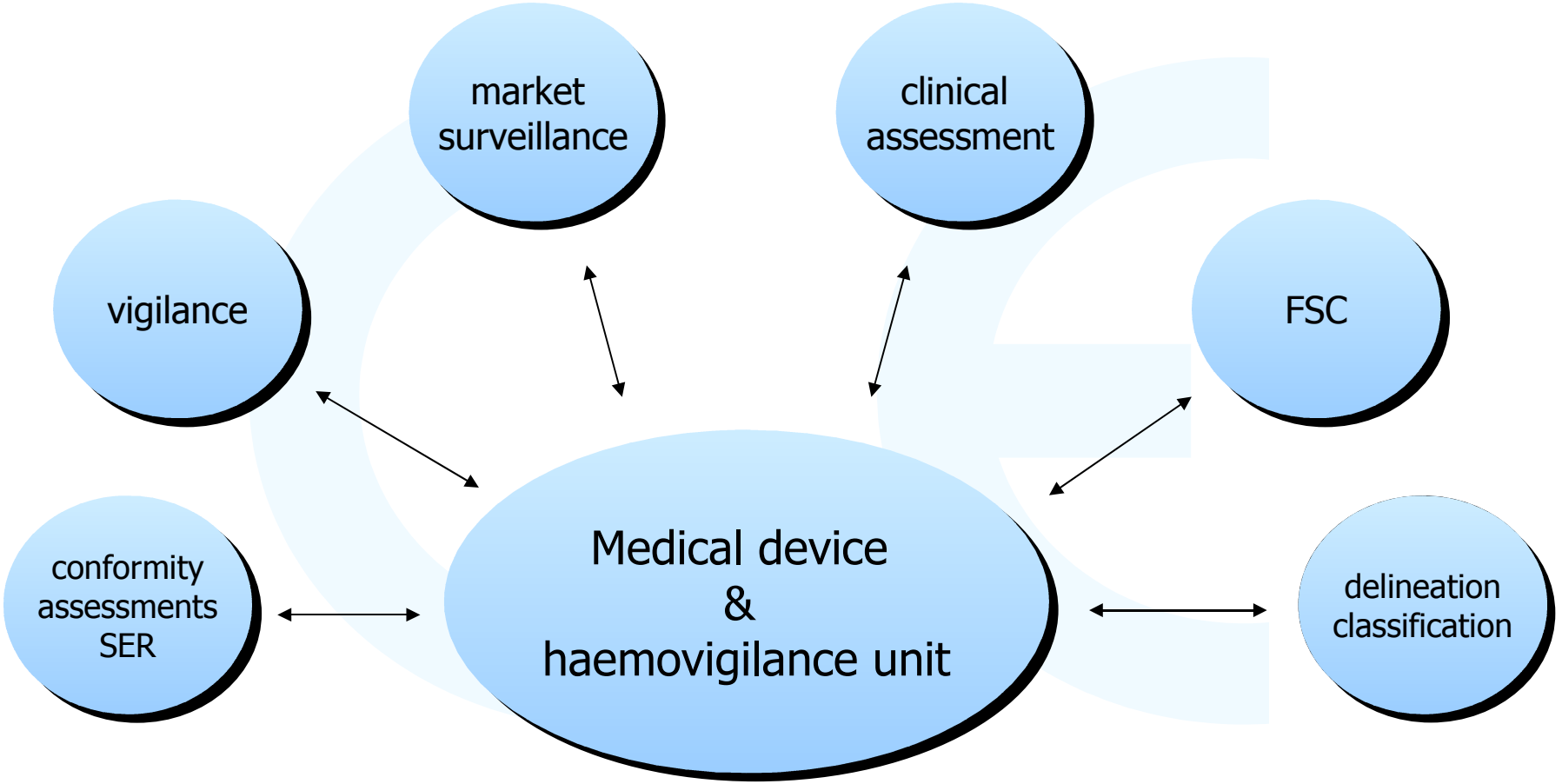


ver 02.11.2006

processes - tasks



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medical devices - 1

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approx. 8.000 different types, approx. 500.000 products

Medical devices, such as bandage, infusion sets, ECG electrodes, contact lenses and their accessories such as cleaning solution

Medical devices for handicapped, such as wheel chairs, crutches

medical devices - 2

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Medical equipment, such as X-ray equipment, ECG, defibrillators, audiometers, rf-surgery tools, endoscopes, catheters, infusion pumps

Implants - active implants, such as pacemakers, neurostimulators, radioactive implants

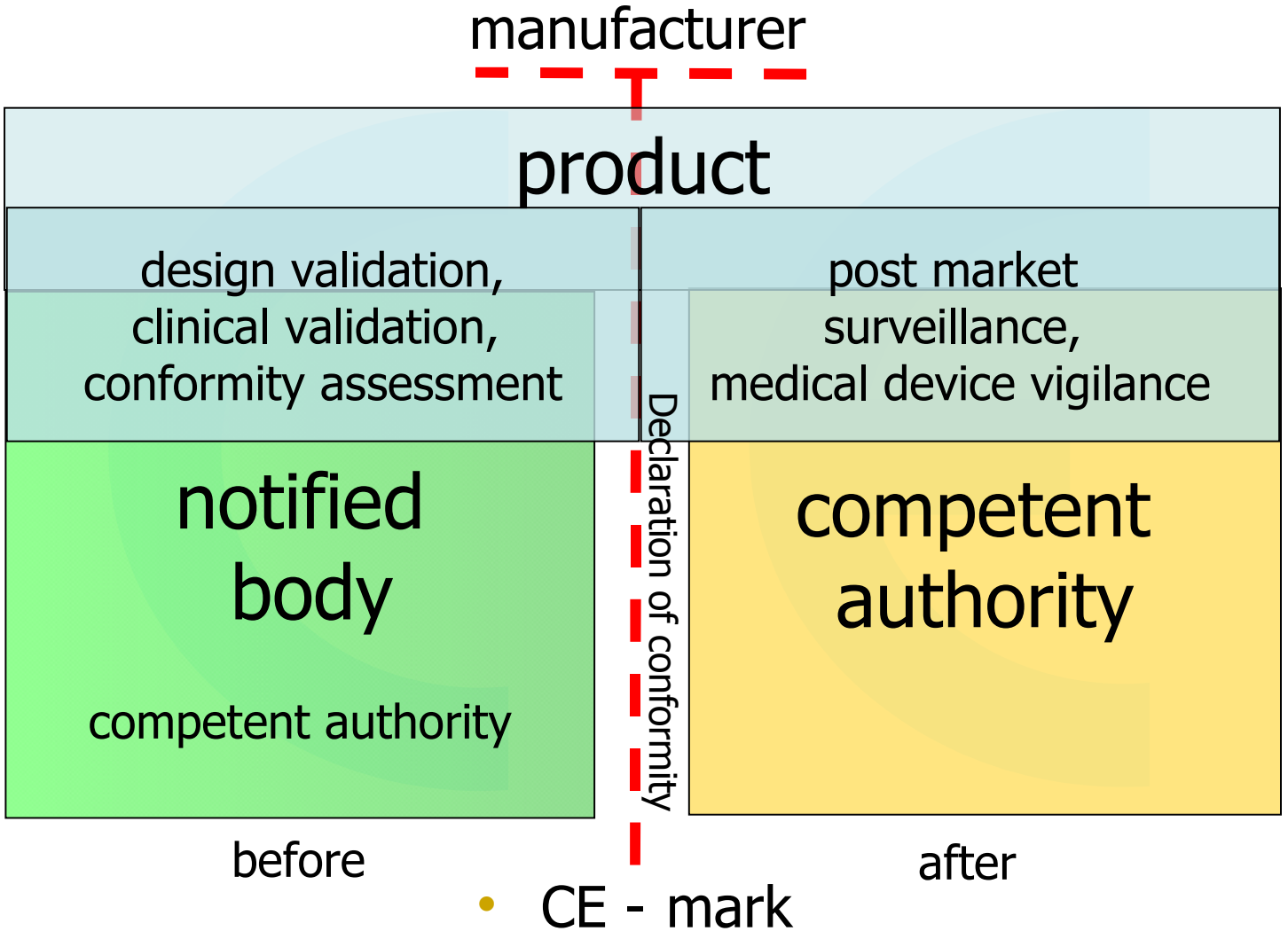
- non active implants, such as joint replacement implants, bone screws, breast implants

In vitro diagnostics, such as HIV, HCV, HBV - tests, pregnancy tests, glucose tests

In vitro diagnostic laboratory equipment, such as fully automated IVD analyzers for blood testing, blood gas analyzers, analyzers for glucose, PCR

Medical software, such as software to control medical devices, medical expert systems

market access for medical devices



manufacturer

The manufacturer (or the authorized European representative) is fully responsible

- the **manufacturer** must perform the **conformity assessment**
- if passed, the manufacturer can issue the declaration of conformity, thus declaring that the product fullfills the essential requirements of all applicable directives
- then the manufacturer can affix the CE-mark on the medical device

requirements

- the **manufacturer** shall implement and maintain a **Post Marketing Surveillance System** (PMS System)!
- the users / medical practitioners / health professionals, and manufacturers as well, shall comply with the **requirements about reporting** (§§ 70ff MPG)
- the federal office for safety in health care registers the reported cases, investigates and assesses them

requirements

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an essential part of the PMS-system is the

vigilance system

definition

- The purpose of the Vigilance system is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.

scope

- Therefore a functioning **medical device vigilance system** protects
  - the patient
  - the health care professionals
  - the medical doctor
  - the manufacturer
  - the distributor

vigilance – reporting

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- **What shall be reported?**

- all serious incidents / events , which happened in Austria
- all potential serious incidents / events, which potentially happened in Austria but have been avoided,
  or incidents, which could have happened in Austria, as those devices are placed on the market in Austria
- all field corrective actions (e.g. recalls), without any exception

vigilance – reporting

- **How to report whom?**

- Reports shall be sent to the Federal office for safety in health care (refer to § 70)
- The form should be used (www.ages.at)
- The reports shall be filed immediately/without delay (according to Austrian law, the outlined schedules in the guideline MEDDEV 2.12 are legally not correct in Austria)

download the forms

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www.ages.at

processing .....

- **the staff of the unit ...**
- collects the reports
- assesses of the report by means of a risk assessment about any likelihood of further occurrences, risk control and reduction measures, for safeguarding the patients and public health
- Contacts the manufacturer (authorized representative) or the Austrian distributor
- investigates ..... (if applicable within the EEC)

vigilance - structure

- The medical device market is an open market within the EEC …
- All European Competent Authorities communicate with each other
- There are several procedures for communication and information exchange implemented („Helsiniki-procedure", MSOG,…)
- Although this is a decentralized organization, in several cases one CA takes the lead and coordinates the European activities

vigilance

- **Therefore – it‘s all about safety and efficacy and the benefit of the patient**
- So let‘s cooperate and work together to resolve issues in the interest of public health

To achieve out goal

safe and efficient medical devices

→ risk – benfit ⌘

→ clinical safety and efficiacy ⌘

- **www.ages.at**
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- http://www13.ages.at/servlet/sls/Tornado/web/ages/content/FF1494909796F444C12570D5002C02C1
- Meldeformular für klinische Prüfungen:
- **F_D02_meldung_studie_mp.doc**
- **F_D04_beiblatt_pruefzentrum_mp.doc**
- **F_D06_beendigung_studie_mp.doc**
- **F_P08_SAE_mp.doc**
- Meldeformular für Vorfälle und Nebenwirkungen außerhalb von klin. Prüfungen:
- **F_D10_VigiMeldeForm_mp.doc**

and that‘s the final slide ....

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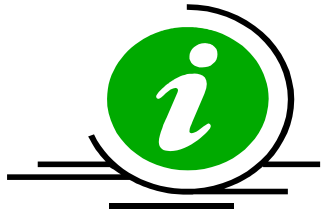

discussion .....