

Expertenfachgruppe ‚Herstellung steriler Arzneimittel‘ - EFG 3
German Expert Group on Sterile Manufacturing

ANNEX 1 – REVISION

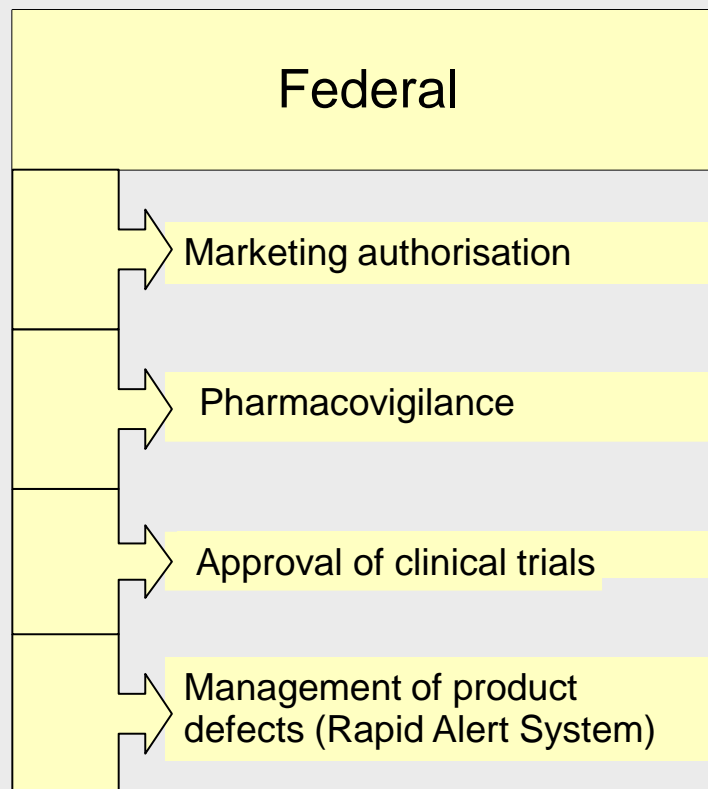
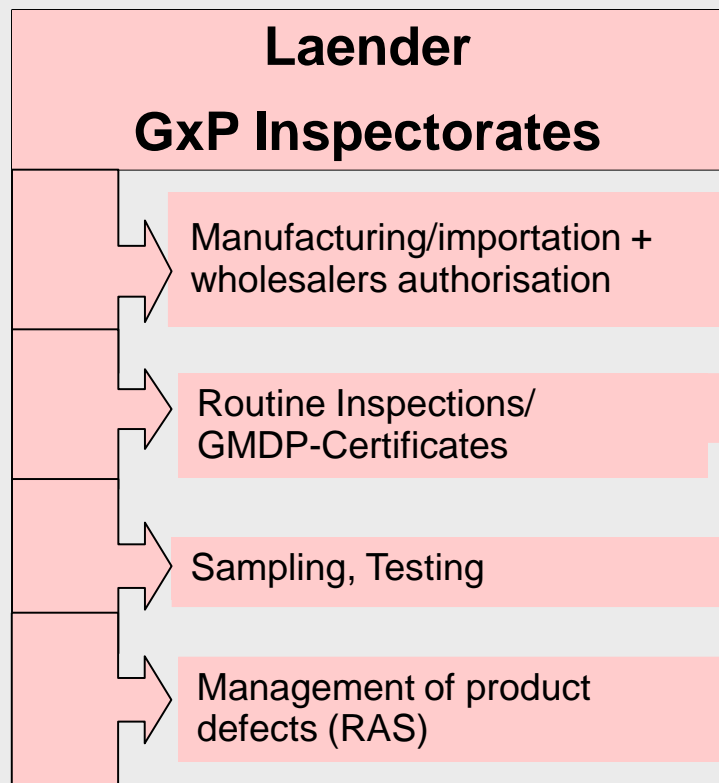
Proposals

Short Introduction

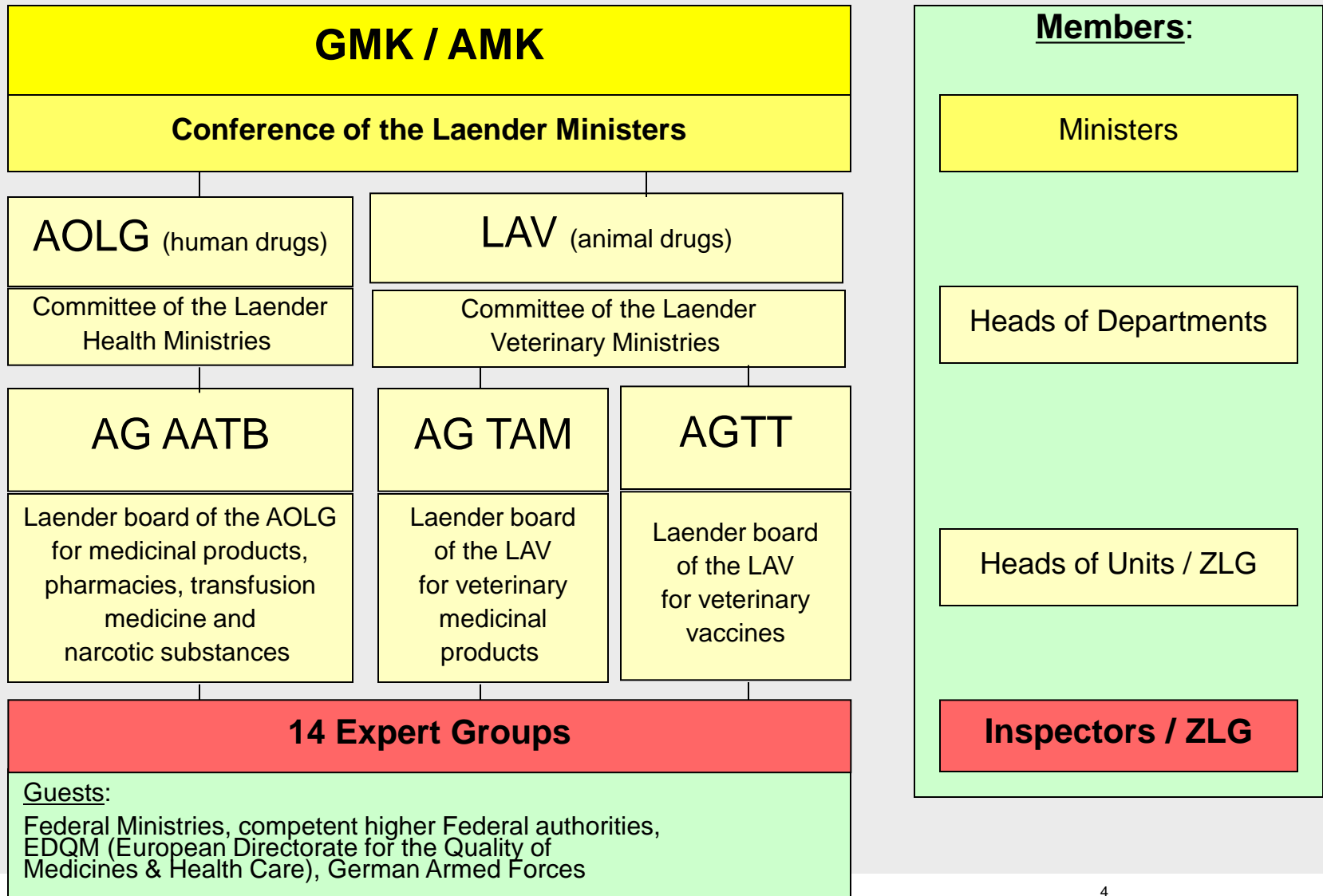
ZLG – LAENDER

e.g. Schleswig-Holstein

German Drug-Law



Laender Boards / Committees



GERMAN PROPOSALS

- **Isolator Technologies**
- **RABS Technologies**
- **Closed Systems**

- **Small Scale Aseptic Manufacturing Sites**
 - **Aseptic Manufacturing using LAF-Cabinets**

- **Personnel Training**
 - especially training in aseptic procedures

- **Microbial Monitoring**

- **Aseptic process validation for very small batches or individually prepared products like ATMP**

Thank you

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