Round Table discussion
Translating Innovation into access for ATMPs
15th November 2024, Rome

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Main factors affecting development and access to ATMPs in the EU

- Current legislation has sound principles, but there is space for improvement at the interfaces of legislations (CTR – MDR – IVDR – GMO etc.) – *discussions ongoing*
- The demand for flexibility of future legislation needs to be balanced to maintain standards and enable enforcement
- Developing a medicinal product and maintaining a life-cycle requires special skills, organisational structures and a need to switch from a „research mind“
- Funding – There needs to be a clearer emphasis on getting products to the market