G-BA conference “Drei Jahre frühe Nutzenbewertung” – Contribution from the European Medicines Agency

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Collaboration between regulators and HTA bodies on European level

EMA EUnetHTA Dialogue

- 1st meeting (EMA)
- 2nd meeting (EMA)
- 3rd meeting (CVZ)
- 4th meeting (HAS)
- 5th meeting (DHMA)
- 6th meeting (EMA)
- 7th meeting (IQWIG)

- EPAR Improvement Project
- Parallel Scientific Advice/Early dialogue
- Exchange on Guidelines
- Databases for post-marketing data generation
- Evidence generation of development plan
- Orphan Medicines
- Availability of regulatory data for REA
- Effects table

2010 - Joint Action I
2012 - Joint Action II
2014 - HTA network
Experience with parallel Scientific Advice: 35 ‘tripartite’ advice procedures (ongoing or completed)

- Variety of indications including diabetes, breast cancer, heart failure, Alzheimer’s, asthma, rheumatoid arthritis, NSCLC and melanoma, but also orphan diseases
- EU member states’ HTA/payer organisations: Sweden, UK, France, Netherlands, Spain, Italy, Germany, Belgium, Austria
- Big Pharma (including multiple use) as well as SMEs
- 3 planned meetings under the SEED framework
Examples for the variety of opportunities for exchange and collaboration

“Effects tables” used by regulators and HTA bodies for their respective decision making

Methodological aspects of study design., e.g. ENCePP HTA working group regarding pharmacoepidemiological studies or workshop regarding scientific guideline for PAES

Guideline development (methodological and clinical guidelines)

Presentation of data and provision of assessment reports

New approaches for data generation, e.g. IMI GetReal

Initiatives and efforts in the interest of serving public health