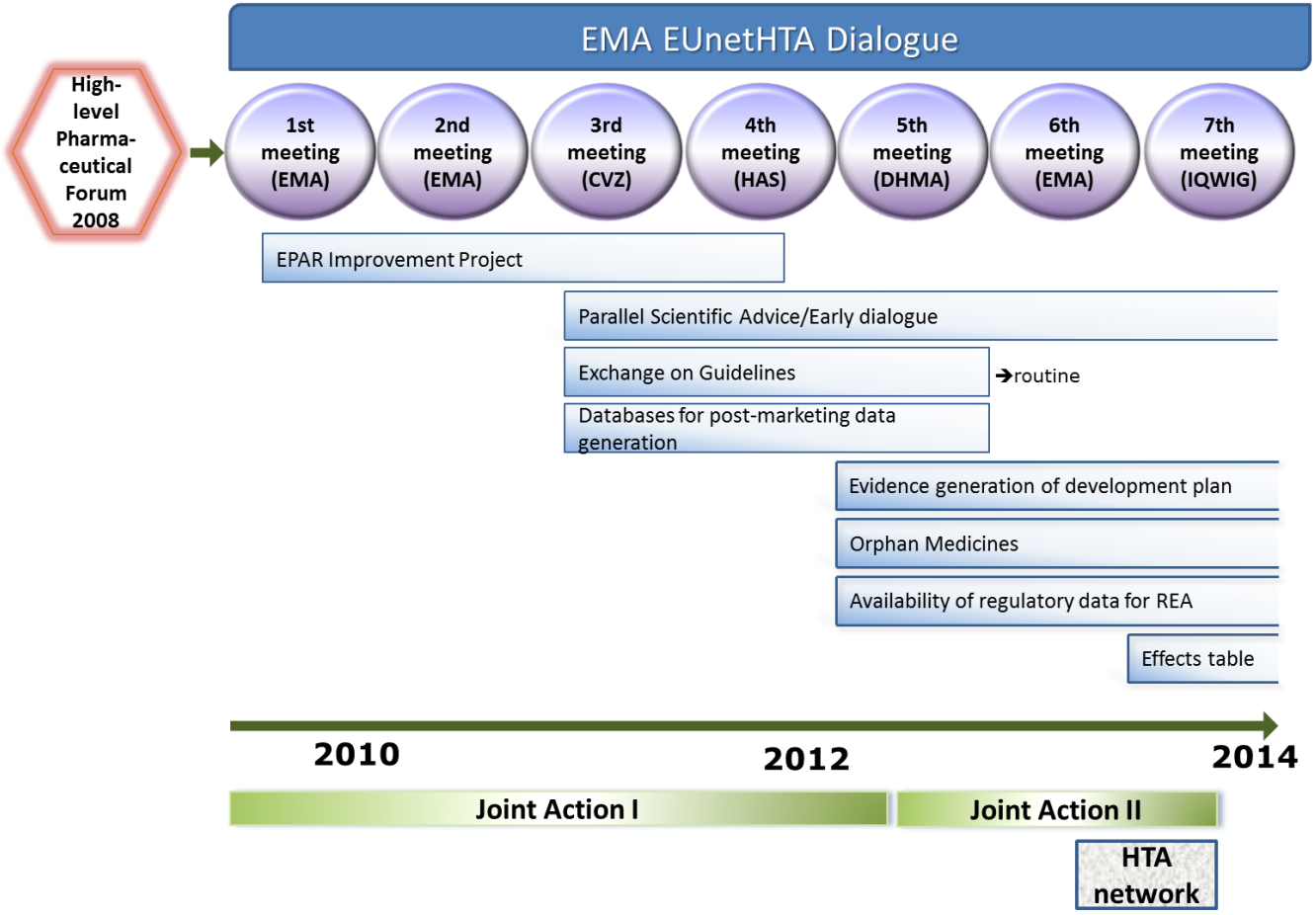
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

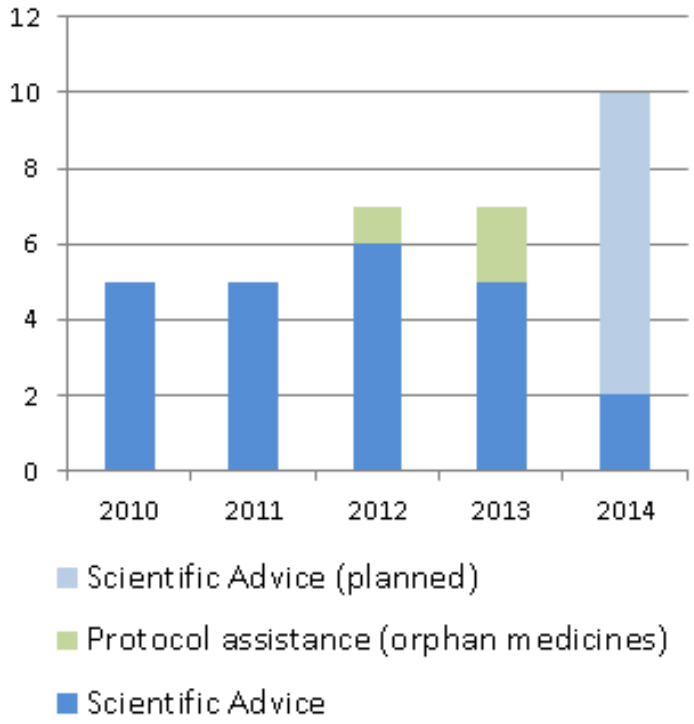
Berlin, 30th April 2014

Presented by: Michael Berntgen
Head of Scientific & Regulatory Management Department

Collaboration between regulators and HTA bodies on European level



Experience with parallel Scientific Advice: 35 'tri-partite' 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