





EUROPEAN MEDICINES AGENCY
 SCIENCE MEDICINES HEALTH

**Green Park
 Collaborative Pilot –
 EMA activities**

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An agency of the European Union 



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**EMA collaboration with HTA/Payers
 (EUnetHTA)**

- Improvement of regulatory assessment reports (EPARs)
- Collaboration related to databases for observational studies
- Experience with parallel Scientific Advice to industry

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**Early dialogue between
 industry + regulators +
 HTA's/payers**



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Parallel-joint (!) scientific advice:

- Alignment of regulatory and HTA/payers evidence requirements
- Enable relative efficacy/effectiveness assessment
- Alignment of post-marketing research activities
- Alignment of conditional access to market

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**Early dialogue between
 industry + regulators +
 HTA's/payers**


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Status: Oct 2011: 11 'tri-partite' advice procedures

Companies: Big Pharma (so far)

Therapeutic areas: diabetes (2), breast cancer, heart failure, Alzheimers (2), asthma, rheumatoid arthritis, NSCLC and melanoma, food allergies, infection with multiresist. bacteria

EU member states' HTA/payer organisations: Sweden, UK, France, NL, Italy, Germany

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- Improvement of regulatory assessment reports (EPARs)
- Collaboration related to databases for observational studies
- Experience with parallel Scientific Advice to industry
- Mutual input to scientific guidelines



Mutual input to scientific guidelines

- Methodology and/or therapeutic-area specific guidelines
- Goal: reconcile the regulatory and HTA evidence standards
- In EU just started (small scale)
- Similar to GPC objectives

Thank you!

