Proposals for Coordination of HTA across Europe: implications for rare disease

European network for Health Technology Assessment
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Program

• Moderator
  – Short introduction

• Rapporteur
  – Julia Chamova, director ISPOR, former EUnetHTA

• Speakers
  – Karolina Hanslik, Health Policy Officer, DG Sante, EC
  – Valentina Strammiello, Program Officer, EPF

• Panellist
  – Trevor Leighton, VP Pricing & Reimbursement, Shire Pharmaceuticals, UK
  – Francis Pang, Head, Global Market Access, Amicus Therapeutics UK Limited, UK
  – Andrea Granados, Senior Director Global HTA Strategy, Sanofi
HTA in the life cycle of technologies

- Presenting and discussing requirements studies in ED*
- Additional data collection
- Comparative or full HTA / REA

Time line of innovation

- Collecting evidence in development
- Preparing submission files for EMA and HTA
- Rapid REA
- Assessment for market authorization
- HTA
- Technology Producers
- Regulators

*Early dialogue
Reasons for European collaboration

• HTA is an important tool for making choices on healthcare allocation (for instance on pharma)
• Expertise is mostly available in countries with a longstanding HTA experience
• Collaboration seems therefore necessary
  – Support the development of national activities and build on European processes and products
  – Decrease duplication on HTA assessments and increase efficiency of national HTA processes
  – But collaboration is on an assessment level (technical) and appraisal and reimbursement is a national remit
EUnetHTA JA3

Aims to build a sustainable model for the scientific and technical cooperation on Health Technology Assessment (HTA) in Europe

80 partners consisting of national, regional and non-for-profit agencies that produce or contribute to HTA

Project Coordinator:
Dutch National Health Care Institute (ZIN)
Summary of select activities in JA3

WP4 Joint Production
- To produce 43 rapid REA on other technologies and 37 on pharmaceutical
- To provide a system for topic selection and prioritization

WP5 Evidence Generation
- To conduct Early Dialogues (joint HTA or parallel/joint with regulators)
- To link additional data collection to on-going activities

WP6 Quality Management
- To provide quality management for EUnetHTA joint products
- To further develop methodologies and tools for joint work if necessary

WP7 National implementation and impact
- To facilitate the uptake of joint products at the national/local level
- To measure the impact of joint work in collaboration with other work packages
Implications for rare diseases

WP4 Joint Production
- To perform REAs on orphan drugs
- Organise input patients in these REA's both in scoping and consultation
- May increase timeliness of HTA production

WP5 Evidence Generation
- To organise input of patients in EDs of rare diseases
- To be involved in pilots on patient registries on rare diseases

WP6 Quality Management
- To involve patients in the development of methodologies and tools for joint work especially for rare diseases

WP7 National implementation and impact
- To study to which extent these activities improve the access to orphan drugs in a sustainable fashion