EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)

Patients' and Consumers' Working Party Meeting
13th September 2011

An agency of the European Union

Aim of this presentation

- **To introduce Enpr-EMA:**
  background, stakeholders, milestones, patients' role

- **To discuss how possible ways to collaborate and cooperate could be initiated and established.**

- **Most importantly to get your feedback** ☺

Introduction and background of Enpr-EMA

Legal basis

European Paediatric Regulation:

"The EMA shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population."

Introduction and background of Enpr-EMA

Mission Statement:

Enpr-EMA will facilitate studies in order to increase availability of medicinal products authorised for use in the paediatric population.

Introduction and background of Enpr-EMA

This will be achieved by:

➢ Fostering high quality ethical research on the safety and effectiveness of medicines for children.

➢ Efficient inter-network and stakeholder collaboration in order to build up the necessary competences at Community level and to avoid unnecessary duplication of studies.

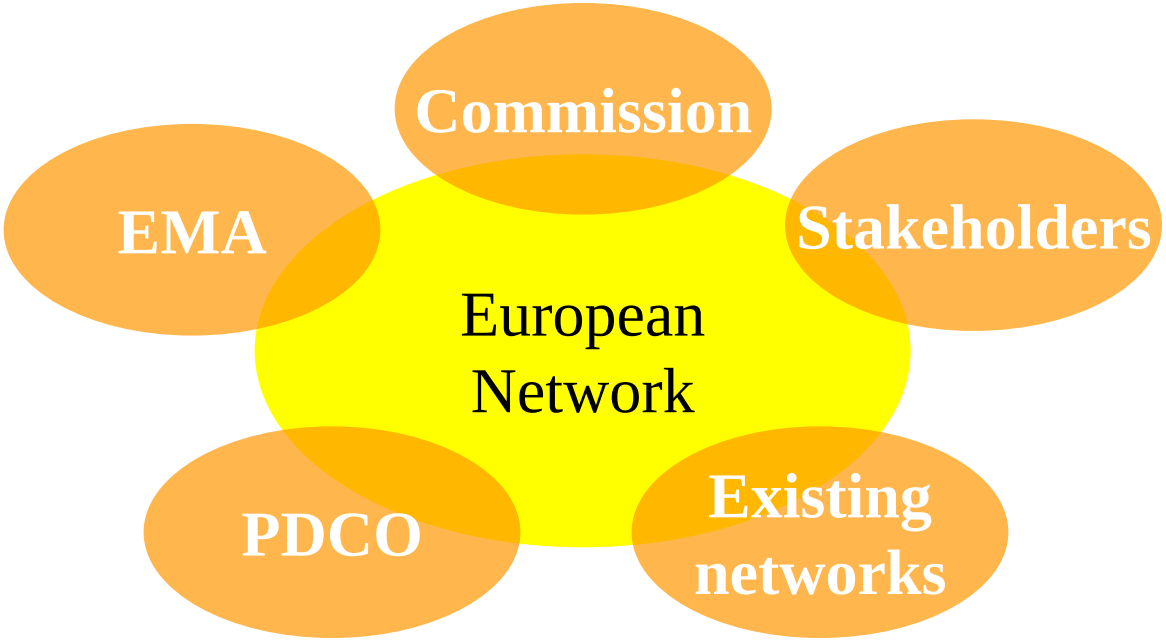
➢ To inform parents, carers, children and young people about clinical trials and encourage their participation.

➢ Raising awareness among health care professionals of the need for clinical trials in all ages of children and supporting their involvement in such studies.

➢ Assisting and collaborating with ethics committees on issues relevant to research and clinical trials in children.

Introduction and background of Enpr-EMA

Organisation and structure



Introduction and background of Enpr-EMA

Stakeholders

- Pharmaceutical Industry
- Patients, parents and patient organisations
- National Competent Authorities
- Ethics Committees
- Medical devices industry
- CRO’s
- Hospital pharmacists
- Laboratories and imaging centres

What has been achieved so far?

- Identification of existing networks
- Implementation strategy adopted by EMA Management Board (01/2008)
- 1st workshop with existing networks (02/2009)
- 2 working groups:

  WG 1: structure and operational model (06/2009)

  WG 2: definition of recognition criteria (Public consultation 02/2010)
- 2nd workshop with existing networks (03/2010)
- Publication of finalised recognition criteria for self-assessment (05/2010)

What has been achieved so far?

- 3-month period for networks to do self-assessment and publish results
- Self-assessment reports screening and clarifications requested
- Publication of list of Networks members of Enpr-EMA (01/2011)
- 3rd workshop with existing networks and industry representatives (03/2011)
- 1st Coordinating Group face to face meeting (06/2011)
  - Mission statement, Mandate, and Conflict of Interest policy agreed
  - Communication strategy: visibility and website (adopted)
- Currently 33 networks:
  - Category 1: 18
  - Category 2: 1
  - Category 3: 14

Enpr-EMA

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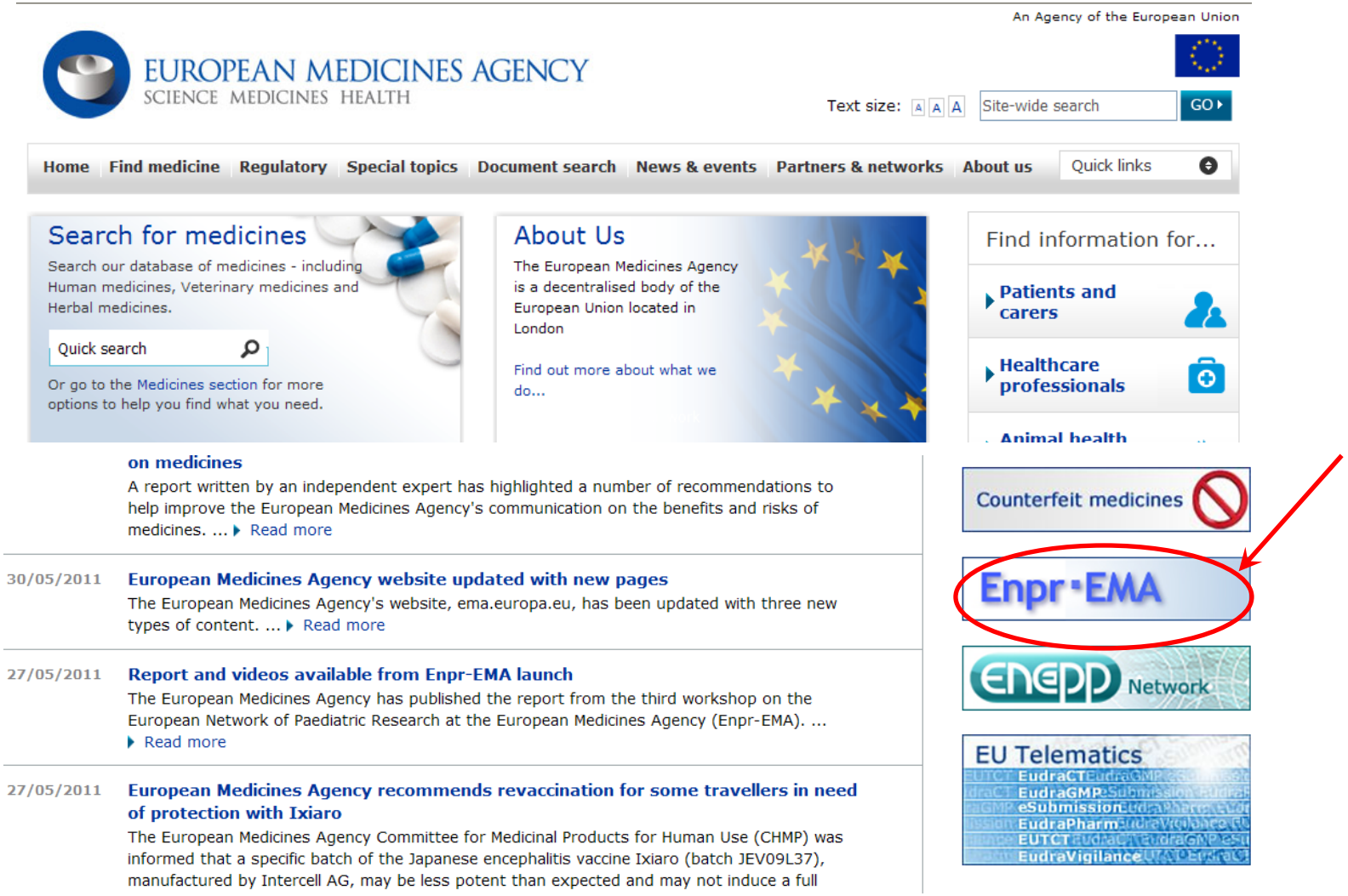
Enpr-EMA information: http://www.ema.europa.eu



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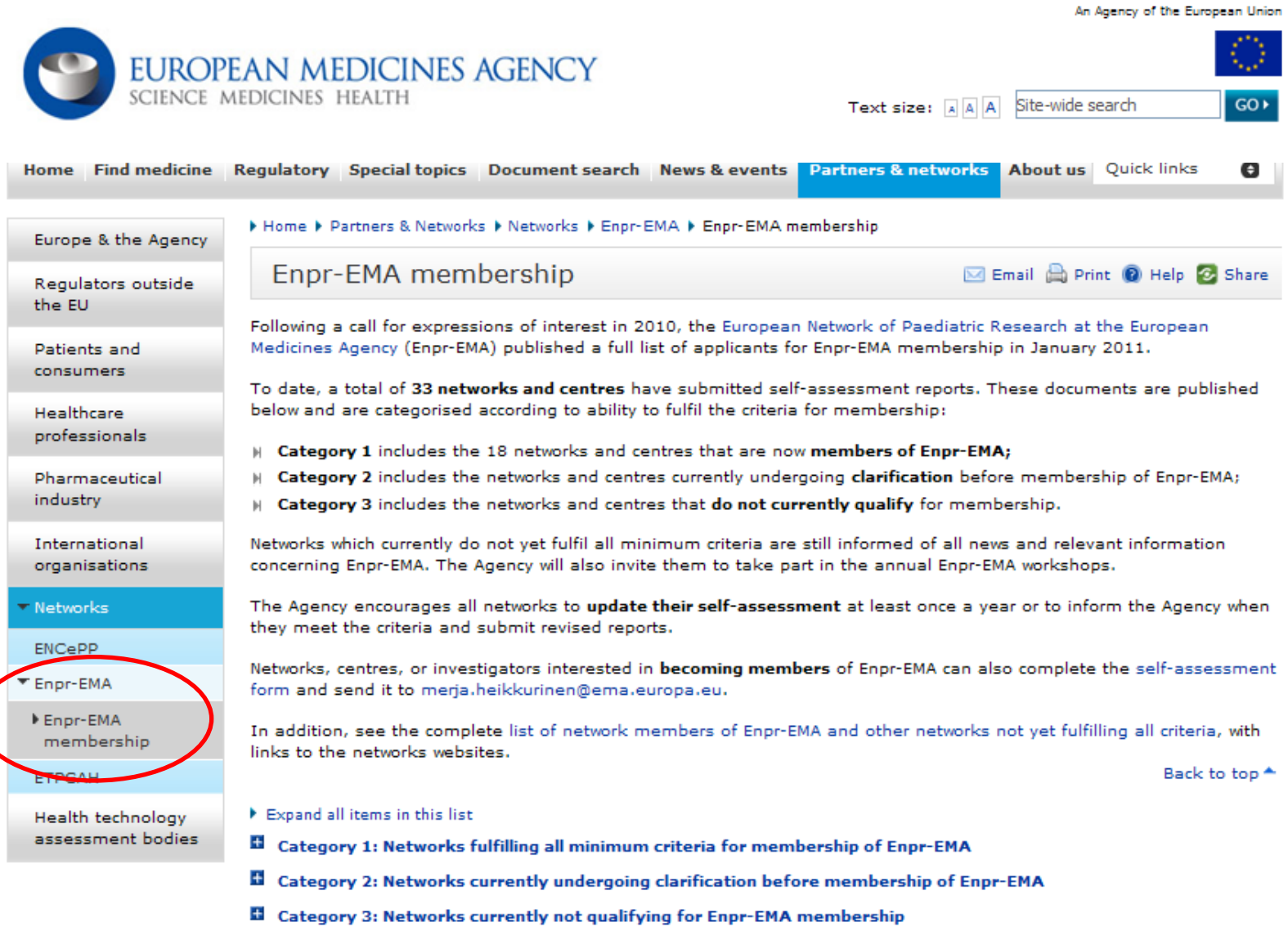

Self-assessment report

Networks should be recognised by quality of paediatric research
Recognition criteria and quality standards for self-assessment elaborated
6 Criterion:

- **Research experience and ability**
- **Efficiency requirements**
- **Scientific competencies and capacity to provide expert advice**
- **Quality management**
- **Training and educational capacity to build competences**
- **Public involvement**

To become member of Enpr-EMA a set of minimum recognition criteria had to be fulfilled

Criterion 6: Public involvement

- 6.1. Involvement of patients, parents or their organisations in the protocol design.
- 6.2. Involvement of patients, parents or their organisations in creating the protocol information package.
- 6.3. Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children.

To become member of Enpr-EMA involvement in at least one of the above items.

Suggestions for collaboration between Enpr-EMA and PCWP

- Our Aim is to increase awareness of the need to participate in paediatric trials, AND increase patient participation in protocol design, protocol information package and prioritisation of needs for clinical trials in children.
- We have a few high level suggestions BUT we need your feedback.
- To link available webpages
  - ➢ On Enpr-EMA webpage to create a section for Patients organisations & link to their own pages?
  - ➢ On patients organisations websites to create a link to Enpr-EMA pages?
- Active collaboration with a PCWP representative? Would you consider nominating a contact person?? Participation in Annual workshop? CG meetings?

Collaboration between Enpr-EMA and PCWP

Thank you for your attention,

Any feed back will be greatly appreciated