EUCERD
European Union Committee of Experts on Rare Diseases

NEW BORN SCREENING IN EUROPE

OPINION OF THE EUCERD ON POTENTIAL AREAS FOR EUROPEAN COLLABORATION

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NEW BORN SCREENING IN EUROPE – DISCUSSIONS OF THE EUCERD ON POTENTIAL AREAS OF EUROPEAN COLLABORATION

Background

In the Council Recommendation of 8 June 2009 on an action in the field of rare diseases, it is recommended that Member States "**Gather national expertise on rare diseases and support the pooling of that expertise with European counterparts in order to support: the development of European guidelines on diagnostic tests or population screening, while respecting national decisions and competences**".

The European Commission launched a **tender** within the EU Program of Community Action in Public Health (work plan 2009) for an "**Evaluation of population newborn screening practices for rare disorders in Member States of the European Union**".

The tender delivered:

1. A **report on the practices** (RP-NBS) of NBS for rare disorders implemented in all Member States[1];
2. An **expert opinion document**, including a decision-making matrix, on the development of European policies in the field of newborn screening for rare diseases[2];
3. An **executive report** to the European Commission on newborn screening in the European Union[3].

It also led to the **establishment of a European Network of Experts** on Newborn Screening (EUNENBS).

The report shows that:

- **NBS is commonly offered** as a service of the public health system in all EU, Candidate and EFTA Countries and in most Potential Candidate Countries.
- The criteria used refer usually to Wilson & Jungner, together with economic issues and expert reports.
- **National panel of diseases** which are screened **varies** from 2 to 29 disorders with no relation to Gross Domestic Product. All targeted diseases are rare.
- Quality control and **quality assurance** are focused mainly **on laboratory assays** and not on the process.
- **Procedures** and contents of **information** to parents on the disease and the treatment are **controlled loosely**.

The **EC requested the EUCERD** to consider the EU tender report and to issue their **proposals for next steps.**

The content of the tender report was presented and discussed at the EUCERD meeting of 20-21 June 2012. During this meeting an agreement on the general areas for action at EU level was determined which respected the principle of subsidarity and it was decided to prepare a draft proposal for further action for the next meeting.

[1] http://ec.europa.eu/eahc/documents/news/Report_NBS_Current_Practices_20120108_FINAL.pdf
[2] http://ec.europa.eu/eahc/documents/news/Expert_opinion_document_on_NBS_20120108_FINAL.pdf
[3] http://ec.europa.eu/eahc/documents/news/Executive_Report_to_EC_20120108_FINALE.pdf

At the EUCERD meeting held on 15 November 2012, possible areas of European cooperation were proposed, based on aspects where collaboration between MS would have an added value and respect the principle of subsidiarity. Member States representatives asked to be consulted on the prioritisation of the potential points for action, to decide on which should be tackled first. At the EUCERD meeting held on 31 January-1 February 2013 the possible areas of European cooperation were discussed.

The topics identified below respect the principle of subsidiarity and were proposed to the EUCERD for discussion: they include actions to improve the quality and the efficiency of the screening process, while respecting the values of the MS. They are presented in no particular order and do not represent a prioritisation of areas for action.

Topics for potential European collaboration

The topics which have been identified as areas for potential European collaboration are the following (in no particular order):

- Production of Standard Operating Procedures for the organisation and management of a Newborn Screening Process;
- Production of good practice guidelines for the management and follow-up of patients, for each screened disease;
- Adoption of Standard Operating Procedures for the communication with parents;
- Production of information material for prospective parents and the public, and for parents whose child was screened positive but whose diagnosis is not yet confirmed;
- Adoption of Standard Operating Procedures for the training of health professionals involved in the screening process;
- Organisation of European training schemes;
- Networking between laboratories to ease collaboration and resource sharing in order to improve the quality and cost-efficiency of national operations;
- Establishment of shared databases between NBS laboratories and centres of expertise in charge of the follow-up of patients to gain better knowledge of the screened diseases and to assess the benefit of the screening strategy;
- Discussion on the Wilson and Jungner criteria and other criteria to be used when considering any expansion of NBS, as views diverge in many countries on this issue;
- Common assessment of new proposals for NBS, between MS wishing to do so, when new technologies allow for such a consideration, via EUnetHTA;
- Establishment of public health key indicators for the continuous evaluation and monitoring of the screening programs.

Next steps

These points are submitted to the European Member States, to the European Commission and to any third party involved for further consideration.