EQA contribution and industry expectations

European Diagnostic Manufacturers Association

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Introduction

- EDMA believes that External Quality Assessment Schemes (EQAS) provide an effective and useful monitor of the analytical performance of clinical laboratories
- Together with effective laboratory procedures and internal quality control, EQAS contribute to the maintenance and improvement of the quality of clinical laboratory analysis.

Introduction

- **The results of EQAS depend on many factors that reflect day to day practice in the clinical laboratory :**
  - the reagent
  - the instrument
  - the maintenance
  - the user (skill and training)
  - the characteristics of the sample material supplied

THE IN VITRO DIAGNOSTICS DIRECTIVE 98/79/EC

- The IVD Directive is concerned with the regulation of products and not with the analytical performance of clinical laboratories.

THE IN VITRO DIAGNOSTICS DIRECTIVE 98/79/EC

- Recital 9 excludes materials used in EQAS from the Directive
- Recital 29 mentions that information obtained from EQAS is useful for decision-making on the classification of devices.
- Article 11 section 2 mentions that Member States can require EQAS organisers to report incidents (as defined in section 1) which they may become aware of.

THE IN VITRO DIAGNOSTICS DIRECTIVE 98/79/EC

- Article 14 section 2(a) also mentions that information from EQAS should receive due consideration in assessment of classification of devices.

THE IN VITRO DIAGNOSTICS DIRECTIVE 98/79/EC

- In these references EQAS is clearly not considered to be part of the device vigilance procedure nor post market surveillance.
- However, information from EQAS is of value to manufacturers as one element in post- production review (Annex III section 5).

THE IN VITRO DIAGNOSTICS DIRECTIVE 98/79/EC

- In the IVD Directive the analytical performance evaluation of the product is part of the technical documentation that the manufacturer must prepare before a product is placed on the market.

- External Quality Assessment is not a post-marketing tool, but in some cases it may provide useful post-marketing information.

EQAS: PRESENT SITUATION

The basic principles of these schemes are similar, but there are many national and regional differences:

- in the nature of participation (compulsory or voluntary);
- in the organisation and design of the schemes;
- in the extent to which schemes are run (or funded) by health agencies, scientific societies, individuals or companies;
- in the cost of participation;
- in the criteria against which laboratory results are judged;
- in the follow-up and consequences of unsatisfactory performance of individual laboratories.

EDMA CONCERNS

- some of the differences between national or regional EQAS, especially in assessment criteria, may lead to market segmentation and counter the beneficial effects of the Single European Market for IVD products.
- EQAS may impose, in practice, national or regional technical guidelines blocking the dissemination of new and beneficial technologies

EDMA SUGGESTIONS

EDMA suggests that the possibility of trade barriers arising from EQAS can be minimised by a series of measures

- **Institutions organising EQAS should have a documented and certified Quality System**

EDMA SUGGESTIONS

- A standardization of the practices should include:

- description, preparation and distribution of EQAS materials with high degree of commutability;
- statistical models and data reduction;
- definition criteria to evaluate the performance of participants;
- support or guidance to be provided to unsatisfactory performers.
- scientific advisory panels to be provided to scheme Organisers;

EDMA SUGGESTIONS

- Where necessary (if the EQAS is aimed to evaluate trueness) reference measurement procedures and materials selected by the JCTLM should be used
- Current EQAS should be progressively extended to more analytes.
- Mechanisms should be developed to ensure regular and effective dialogue between Organisers of EQAS and other interested parties including Industry.

- **EDMA suggests that a harmonisation of the basic approach be developed on a European level.**
- **EDMA suggests that European EQAS should be developed for those analytes for which there are not sufficient laboratories at the national level to ensure statistical validity**

CONCLUSIONS

- Laboratories and other clinical testing sites should be strongly encouraged to participate in EQAS.
- Schemes should be based upon support and education.
- Performance criteria should be those of a European wide concept which would facilitate the organisation of schemes on a regional basis. This would harmonise the routine practice of EQAS and permit the operation of schemes even across National boundaries

Thank you !!

Questions?

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