



European Commission initiative on Breast Cancer – description of working-group structure regarding:

- 1. Development of the new version of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, and**
- 2. Development of a voluntary European Quality Assurance scheme for Breast Cancer Services underpinned by accreditation and evidence-based guidelines**

1. Introduction

On 2 December 2003, the Council adopted **Recommendation (2003/878/EC) on cancer screening**. The Recommendation acknowledges the significant burden of cancer in the EU population and the evidence relating to the effectiveness of breast, cervical and colorectal cancer screening in reducing the burden of disease. Recognizing that the overall benefits should outweigh any harm that may result from screening, the Council recommended population-based screening for breast, cervical and colorectal cancers on the basis of the available evidence, subject to implementation of appropriate quality-assurance systems. The WHO endorsed these recommendations in 2011 for its 53 Member States in the European Region.

The preparation of **European guidelines on best practice** was identified as the most important means for ensuring the development of high quality cancer-screening programmes at national/regional level. Via the development of the European set of guidelines for breast-cancer screening and diagnosis, this action has been successfully implemented in the case of breast cancer.

In 2006, the European Commission oversaw the production of the *4th edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*¹, in cooperation with: the International Agency for Research on Cancer (IARC), the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services; the European Breast Cancer Network; and the European Society of Mastology. The purpose of these guidelines was to promote best practices identified via a consensus-based approach from regional and national breast-cancer screening programmes over the last 20 years. As such, they provide a valuable resource for health professionals and advocates throughout the EU involved in breast-cancer screening programmes based on mammography, the physical and technical guidelines set the quality control requirements for mammography equipment and its

¹ http://ec.europa.eu/health/archive/ph_projects/2002/cancer/fp_cancer_2002_ext_guid_01.pdf

proper functioning as well as for radiology, radiography, pathology, surgery (when applied for diagnosis) and training. Finally, a certification protocol in the EU guidelines establishes the minimum requirements for certification of diagnostic and screening units. A set of supplements to the guidelines was published by the Commission in 2013.

In 2008, the **Council Conclusions on reducing the burden of cancer**² invited the European Commission to explore the potential for developing a European pilot accreditation scheme for breast-cancer screening and follow-up, also based on the European Quality Assurance guidelines.

The Commission Communication on Action against Cancer: European Partnership³ sets out the intention of the Commission to develop a voluntary **European pilot accreditation scheme for breast cancer screening and follow-up, building on the European guidelines for quality assurance in breast cancer screening and diagnosis** as the most longstanding and developed guidelines in the area.

2. Tasks to be performed

In December 2012, the European Commission assigned this particular action to the Joint Research Centre (JRC). This decision was taken partly in view of the legal constraints imposed by the EU's Financial Regulation⁴, preventing the continual renewal of grants for a specific service. It was also taken with regard to the JRC's independence of national, private and commercial interests as well as its long-term experience in coordinating networks of national experts, stakeholders and Member State representatives.

The following tasks were defined in the action:

1. To develop a new version of the European Guidelines for Breast Cancer Screening and Diagnosis based on new knowledge and evidence;
2. To develop a voluntary European Quality Assurance (QA) scheme for Breast Cancer Services based on the EU legislative framework on accreditation, as defined in the Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance⁵.

With regard to guidelines covering stages other than screening and diagnosis (i.e. treatment, rehabilitation, follow-up and surveillance, pain management, psychological support and palliative care – which are essential for a patient-centred concept of quality), a web platform for breast cancer guidelines is envisaged to host existing evidence-based, high-quality guidelines.

² http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSCO-cancer.pdf

⁴ Regulation (EU, EURATOM) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002

⁵ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance

The development of a new version of the breast cancer screening guidelines and the web platform are functional pre-conditions for the development and piloting of the European Quality Assurance scheme for Breast Cancer Services. This design is essential for ensuring that: (i) the scheme's requirements are linked to guidelines recommendations, and (ii) the updating and maintenance of guidelines and scheme are sustainably planned and implemented. As a consequence, both activities are best performed in a linked initiative.

3. Structure to perform the tasks

a) The policy responsibility

The policy leadership as regards the implementation of the EU public health policy on cancer remains with DG SANCO.

Member States and relevant stakeholders will be consulted by DG SANCO for the implementation of the EU Cancer Policy through the **European Union Group of Experts on Cancer Control** created by Commission Decision, and will replace the Advisory Committee on Cancer Prevention created by Commission Decision 96/496/EC of 30 July 1996.

The EU Group of Experts on Cancer Control should guarantee the full compatibility and coordination of the **European Commission initiative on breast cancer with the overall EU policy on cancer**. Their opinions and recommendations will be taken into account.

b) The technical responsibilities

Responsibility for the technical aspects of the work lies with the JRC, which will ensure synchronisation of the two main tasks (as described under section 2). For each task, working group will be set up.

The working groups will be established following a Call for Expression of Interest organised by DG SANCO. The selection process will be based on specific qualification criteria and will adhere to the principles of transparency implemented as a rule in the establishment of scientific and consultative groups in the European Union. These principles strictly safeguard against any potential conflict of interest. Owing to the inter-dependence of the work of the two tasks, close coordination and collaboration between the two working groups is essential for the success of the initiative. Both working groups will establish, under guidance of the JRC, their internal rules on meetings and procedures for adoption of texts. In addition, any necessary outsourcing – e.g. external peer review or literature review – will be established by the JRC according to the usual tendering procedures of the European Commission.

The two following working groups, under the technical coordination of the JRC, will therefore be created:

i) Guidelines Development Group

The Guidelines Development Group will define the scope of the guidelines, evaluate the evidence, and develop the draft recommendations for the new version of the European Guidelines for Breast Cancer Screening and Diagnosis.

DG SANCO will organise a **Call for Expression of Interest to appoint the members** of this Guidelines Development Group following the necessary criteria of scientific knowledge and active experience in the field. The criteria will guarantee that all profiles involved in the breast-cancer screening and diagnosis healthcare processes are covered.

Additionally to the experts from the associated clinical domains, the group will also comprise patients' representatives and experts in guidelines' development methodology. Concerning the latter, the specific guidelines' methodology to be used will need to be consistent with the technique agreed for grading evidence from the subcontracted systematic literature review.

The group will also advise on the architecture of the web-based platform for guidelines concerning aspects other than screening and diagnosis. It may create a subgroup to assist it in work related to the platform, via a further call of expression of interest (see section 4).

ii) Quality Assurance Scheme Development Group

DG SANCO will organise a **Call for Expression of Interest to appoint the members** of this Quality Assurance Scheme Development Group following the necessary criteria of scientific knowledge and active experience in the field. The criteria will guarantee that all profiles involved in the quality assurance process are covered.

The Quality Assurance Scheme Development Group will agree on the general quality requirements and make use of the evidence provided by the guidelines for the quality requirements specific for breast-cancer care. The European co-operation for Accreditation (EA) will be the main partner for this task. EA will provide the draft scheme design according to Regulation (EC) No 765/2008 and will also coordinate the piloting of the voluntary European Quality Assurance scheme for Breast Cancer Services.

The group will also comprise: Conformity Assessment and Certification/Inspection Bodies which are active in the field; experts in existing schemes; and experts in the area of quality assurance in breast-cancer healthcare.

The definition of the QA scheme specific criteria is critically dependent on the timely availability of the new guidelines' draft recommendations and the selection of guidelines for the other stages of care.

c) Input of Member States and stakeholders

In order to ensure appropriate technical input from Member States (as well as interested EFTA and Candidate Countries), the JRC has asked Member States for the nomination of national contacts to follow the process. This group of national contacts will act as a technical group in the framework of the EU Group of Experts on Cancer Control, without prejudice to the political oversight role of this EU Group of Experts.

Additionally the JRC may invite other relevant stakeholders (patient's organisations, professional societies, industry, etc.) to register their interest to be associated to the process –

in particular concerning the foreseen open consultation stages inviting input from experts and stakeholders not directly involved in the working groups.

The role of these actors is to express their opinion and suggestions on activities performed by the different Groups, but they do not have a right of veto in the development of the guidelines process.

Whilst the EU Group of Experts on Cancer Control will ensure alignment of this initiative, the overall coordinator and driver to ensure that deadlines are met, actions implemented, etc. will be the European Commission (DG SANCO and JRC).

4. Policy responsibility and endorsement of Guidelines and QA scheme

