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COMMISSION OF THE EUROPEAN COMMUNITIES

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**REPORT FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN
PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND
THE COMMITTEE OF THE REGIONS**

**Implementation of
the Council Recommendation of 2 December 2003 on cancer screening
(2003/878/EC)**

1. PREFACE

1.1. Introduction

On 2 December 2003 the Health Ministers of the European Union unanimously adopted a Recommendation on cancer screening¹. The Recommendation on cancer screening of the Council of the European Union acknowledges both the significance of the burden of cancer in the European population and the evidence for effectiveness of breast, cervical and colorectal cancer screening in reducing the burden of disease.

The Council Recommendation spells out fundamental principles of best practice in early detection of cancer and invites Member States to take common action to implement national cancer screening programmes with a population-based approach and with appropriate quality assurance at all levels, taking into account European Quality Assurance Guidelines for Cancer Screening, where they exist. Updated and expanded EU guidelines for breast² and cervical³ cancer screening have recently been published by the Commission; comprehensive European guidelines for quality assurance of colorectal cancer screening are currently in preparation.

The development of new guidelines on cancer screening as a means to foster good health in an ageing Europe, has also been highlighted in the EU Health Strategy⁴. Implementation of the Recommendation has also been supported by the European Parliament through resolutions adopted in 2003⁵, 2006⁶ and 2008⁷.

The Recommendation invites the European Commission to report on the implementation of cancer screening programmes, to consider the extent to which the proposed measures are working effectively, and to consider the need for further action. This is the first such report.

1.2. Basis of the report

In preparing this report, the Commission invited Member States to reply to a written survey in the second half of 2007. 22 of the 27 Member States (82%) returned the questionnaire as of May 2008 (Austria, Belgium, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom).

¹ Council Recommendation of 2 December 2003 on Cancer Screening (2003/878/EC); OJ L327/34-38.

² EU guidelines for quality assurance in breast cancer screening and diagnosis – 4th edition: Luxembourg: Office for Official Publications of the European Communities; ISBN: 92-79-01258-4, catalogue number: ND-73-06-954-EN-C © European Communities, 2006.

³ EU guidelines for quality assurance in cervical screening – 2nd edition: Luxembourg: Office for Official Publications of the European Communities; ISBN 978-92-79-07698-5, catalogue number: ND-70-07-117-EN-C © European Communities, 2008.

⁴ Together for Health: A Strategic Approach for the EU 2008-2013, COM(2007) 630 final of 23.10.2007.

⁵ European Parliament resolution of 05 June 2003 on breast cancer in the European Union (P5_TA(2003)0270); OJ C 68 E, 18.3.2004, p. 611.

⁶ European Parliament resolution of 25 October 2006 on breast cancer in the enlarged European Union (P6_TA(2006)0449 B6-0528/2006); OJ C 313 E, 20.12.2006, p.273.

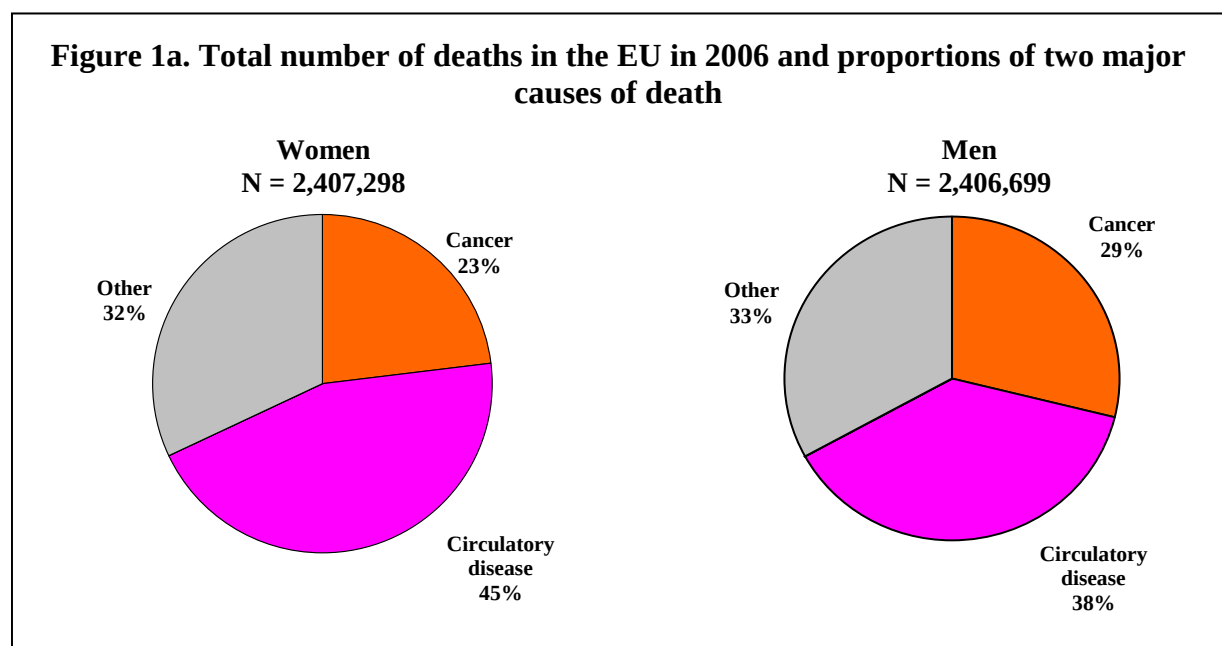
⁷ European Parliament resolution of 10 April 2008 on combating cancer in the enlarged European Union (P6_TA(2008)0121).

This survey was supplemented by information obtained in two ongoing European projects supported by the EU Public Health programme (2003-2008⁸) dealing with monitoring, evaluation and quality assurance of cancer screening: the European Cancer Network (ECN); and the European Network for Information on Cancer (EUNICE).

Population statistics were obtained from the European Statistical System, or from national sources if more recent data was available. Preliminary findings were also discussed with health ministers at the informal health council under the Slovenian Presidency in April 2008, following which several Member States provided further information. This has enabled reporting on programme implementation status for 27 of the 27 Member States. The detailed findings collated and analysed by the European Cancer Network have also been published separately (ECN Report⁹).

1.3. The relative burden of cancer as part of the overall burden of disease

After circulatory disease, cancer is the second most common cause of death in the European Union in 2006, accounting for two out of ten deaths in women, which amounts to a total number of 554,000 women, and three out of ten deaths in men, which amounts to 698,000 men (Figure 1a). Due to the ageing population this number is expected to rise further every year, if no preventive action is taken by the EC and the Member States.



Source: EUROSTAT 2006

As regards cancer cases, every year, 3.2 million Europeans are diagnosed with cancer, most of whom are suffering from breast, colorectal or lung cancers. But the

⁸ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008): OJ L271/1-11 of 09.10.2002.

⁹ First report on the implementation of the Council Recommendation on Cancer Screening by the European Cancer Network and the European Network for Information on Cancer: Luxembourg (http://ec.europa.eu/health/ph_determinants/genetics/documents/cancer_screening.pdf).

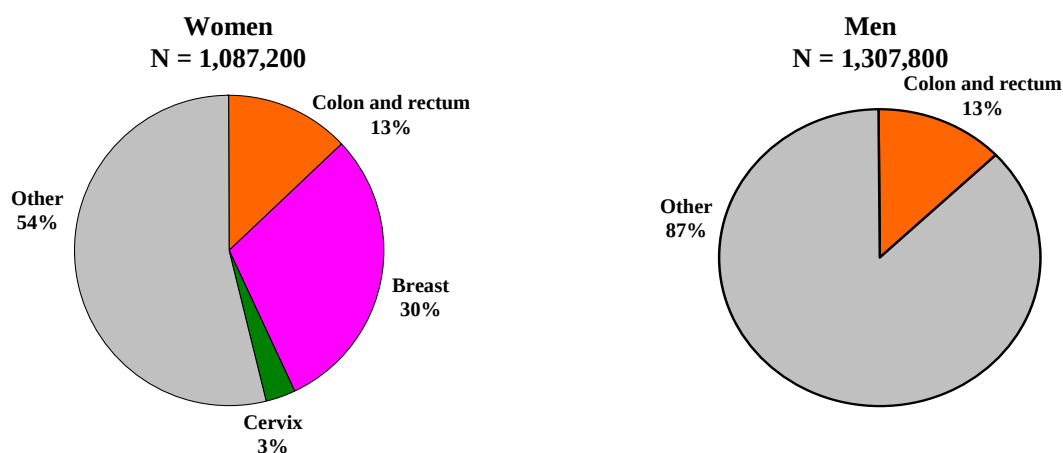
burden of cancer is far from being equally distributed across the European Union (for details see 1.5 below)¹⁰.

As illustrated by national differences in cancer mortality, there is considerable scope to reduce deaths from cancer across the Community by sharing information and exchange of best practice in cancer prevention and control on an EU level. EU cooperation can thus provide significant added value, as developed under "Europe against Cancer" since 1987 for the area of screening for cancer in particular.

1.4. Specific burden of breast, cervical and colorectal cancer

Breast, cervical and colorectal cancer are a major cause of suffering and death in the Member States of the European Union¹⁰. According to estimates of incidence and mortality by the International Agency for Research on Cancer (IARC), there were 331,000 new cases and 90,000 deaths due to breast cancer, and 36,500 new cases and 15,000 deaths due to cervical cancer¹¹ among women in the EU in 2006. At the same time new cases of colorectal cancer were estimated at 140,000 in women and 170,000 in men. Colorectal cancer deaths were estimated at 68,000 for women and 78,000 for men in the EU. Together, these cancers account for almost one out of two (47%) new cases and one out of three (32%) cancer deaths in women in the EU. In men, colorectal cancer currently accounts for one out of eight (13%) new cases and one out of nine (11%) cancer deaths (Figures 1b and 1c).

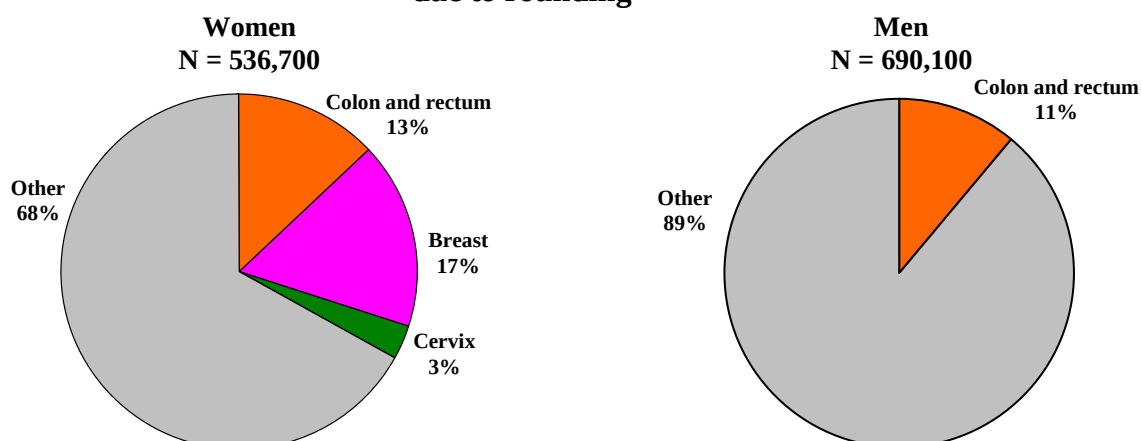
Figure 1b. Total number of cancer cases in the EU in 2006 and proportion of breast, cervical and colorectal cancer^{9,10}



¹⁰ Ferlay J, Autier P, Boniol M, Heanue M, Colombet M, Boyle P (2007) Estimates of the cancer incidence and mortality in Europe in 2006. Ann Oncol 18: 581-592.

¹¹ IARC mortality estimates for cervical cancer include a proportion of deaths attributed to "unspecified uterine cancer".

Figure 1c. Total number of cancer deaths in the EU in 2006 and proportion of deaths due to breast, cervical and colorectal cancer. Percentages for women do not add up due to rounding^{9,10}



1.5. Diversity of cancer rates in the EU27¹⁰

Incidence and mortality rates of these cancers vary widely across the EU, reflecting a major health burden in various Member States.

According to IARC estimates the highest incidence rate of breast cancer is 137.8¹² for Belgium, with a mortality rate of 33.5, while the highest mortality rate is 34.5 for Denmark, with an incidence rate of 122.6. The lowest estimated incidence rate for breast cancer is 61.2 for Romania with a mortality rate of 23.9 and the lowest mortality rate is 19.2 for Spain with an incidence rate of 93.6.

The burden of disease is particularly unevenly distributed in the case of cervical cancer. For cervical cancer IARC estimates the highest incidence rate as 24.5 for Romania with the highest mortality rate of 17.0. The lowest incidence rate is 4.9 for Finland and at the same time Finland enjoys the lowest mortality rate of 1.6. The proportion of cancer cases and deaths attributed to this cancer is markedly elevated in all but one of the Member States which acceded to the EU in 2004 and 2007.

For colorectal cancer the highest incidence rate is 106.0 for Hungary, which in addition suffers from the highest mortality rate of 54.4. The lowest incidence rate for colorectal cancer is 31.0 for Greece, which at the same time enjoys the lowest mortality rate of 15.5.

2. RESULTS

2.1. Overview of results

The maps below show the current coverage of population-based screening programmes across the EU.

¹² Reflecting standard practice, incidence and mortality rates given in this Report are per 100,000 of the population.

Distribution of Breast Cancer Screening Programmes Based on Mammography in the EU in 2007

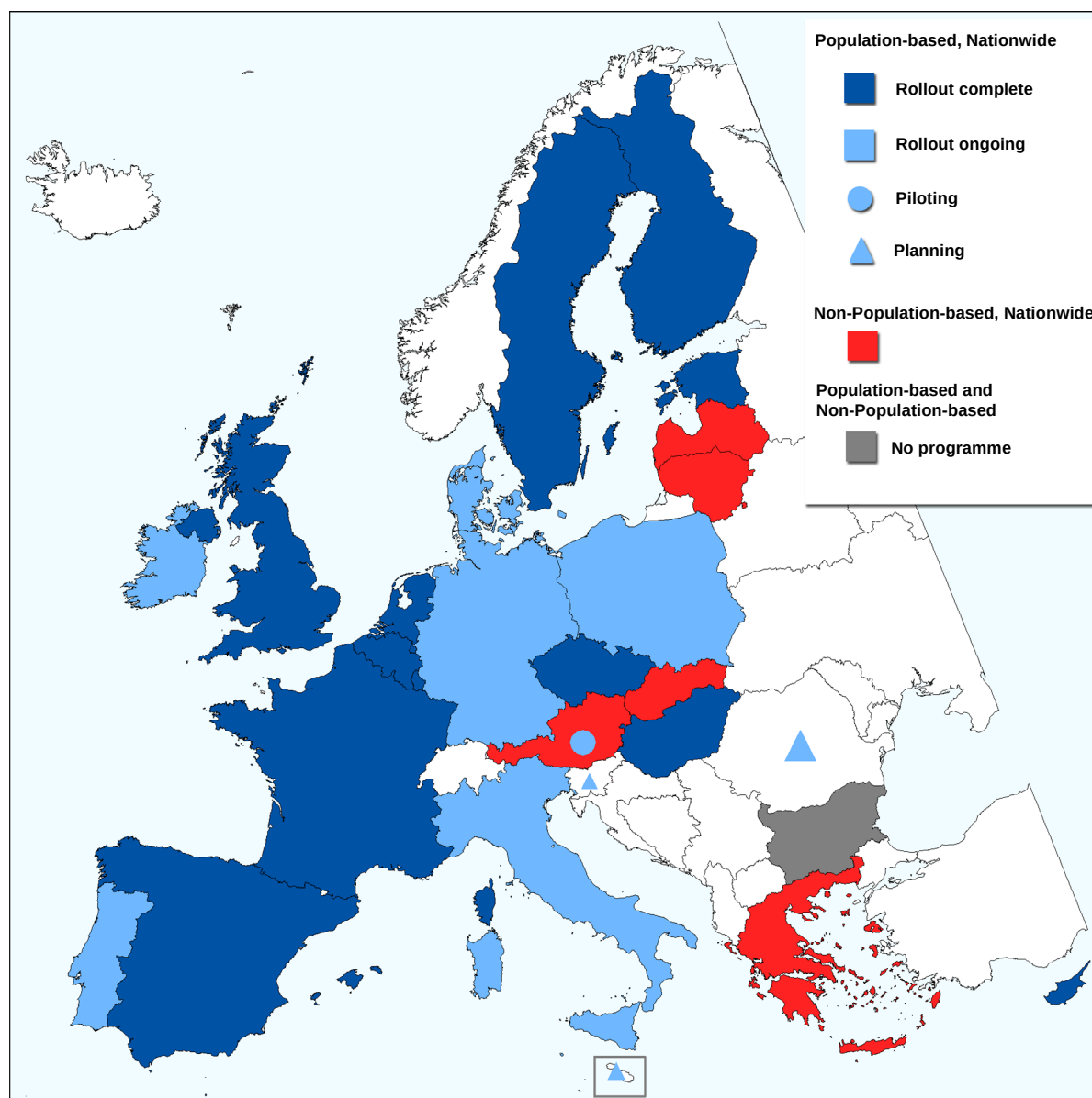


Figure 2. Breast screening programmes in the European Union in 2007, by programme type (population-based; non-population-based; no programme) and country implementation status (population-based: nationwide or regional, rollout complete or ongoing, piloting and/or planning; non-population-based: nationwide or regional). Programmes shown use screening test (mammography) recommended by the Council of the European Union in 2003¹.

Source: ECN⁹

Distribution of Cervical Screening Programmes based on Cervical Cytology in the EU in 2007

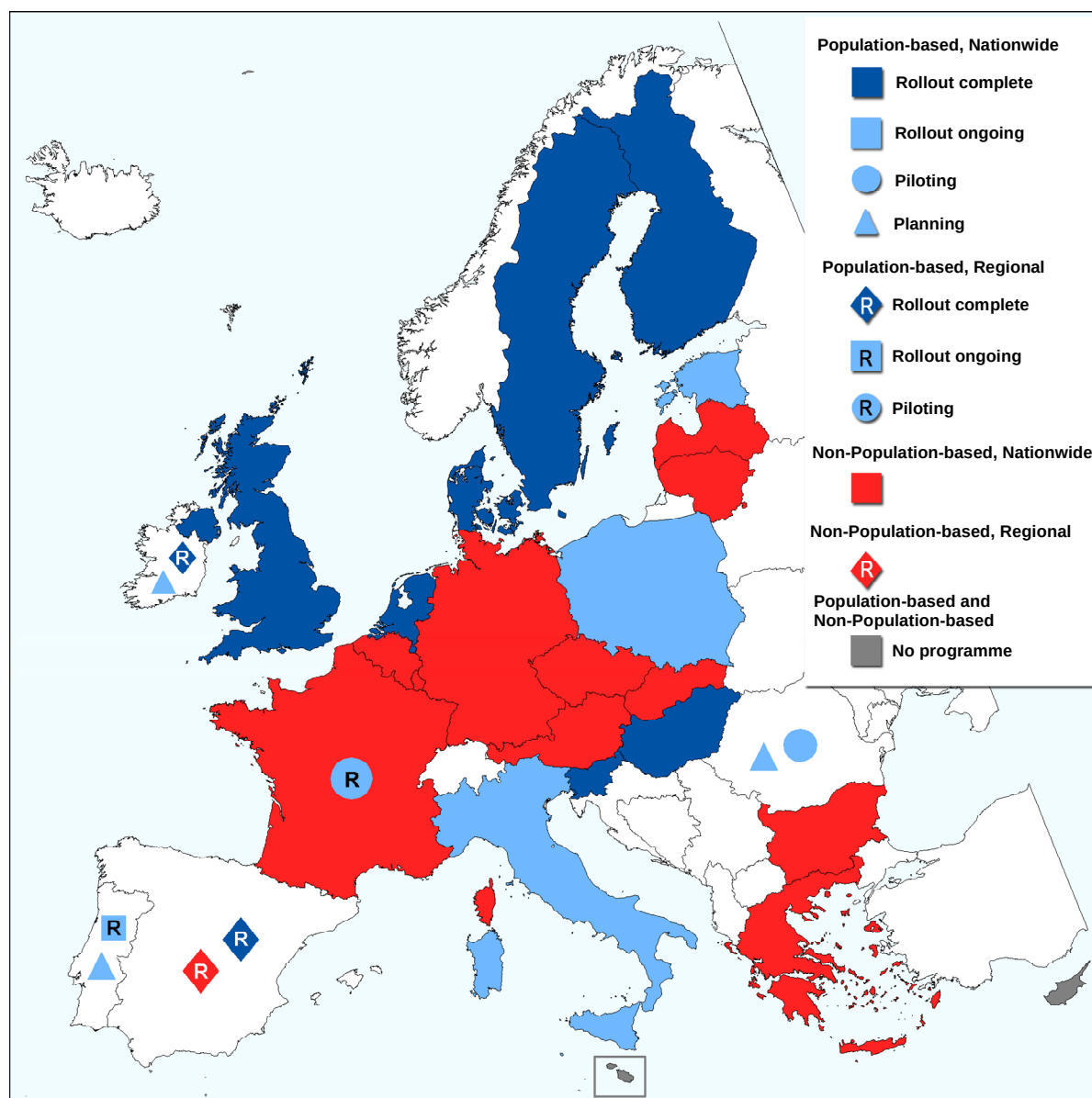


Figure 3. Cervical cancer screening programmes in the European Union in 2007, by programme type (population-based; non-population-based; no programme) and country implementation status (population-based: nationwide or regional, rollout complete or ongoing, piloting and/or planning; non-population-based: nationwide or regional). Programmes shown use screening test (PAP smear) recommended by the Council of the European Union in 2003¹.

Source: ECN⁹

Distribution of Colorectal Cancer Screening Programmes based on the Faecal occult Blood Test in the EU in 2007

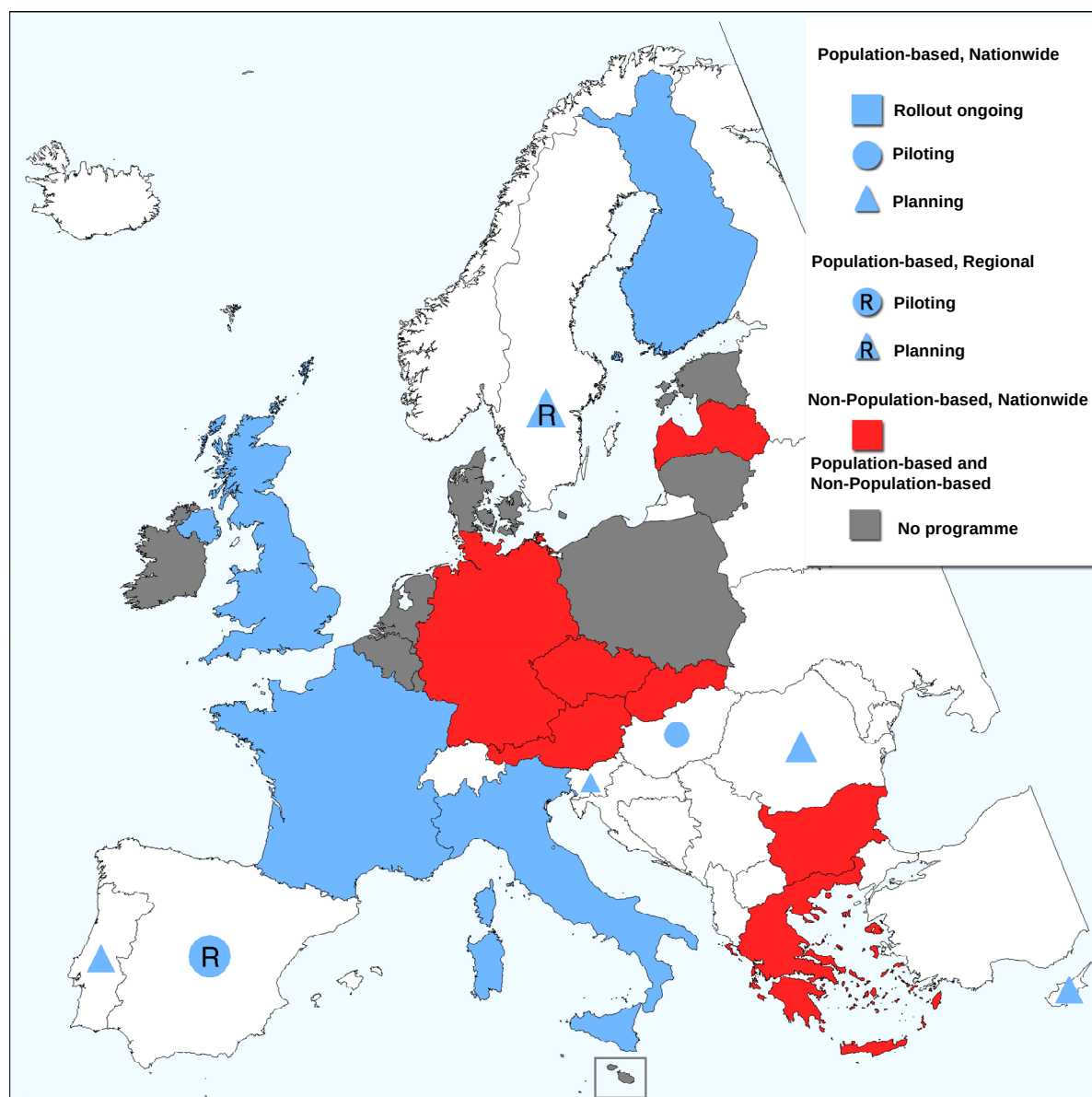


Figure 4. Colorectal cancer screening programmes based on FOBT (faecal occult blood test) in the European Union in 2007, by programme type (population-based; non-population-based; no programme) and country implementation status (population-based: nationwide or regional, rollout complete or ongoing, piloting and/or planning; non-population-based: nationwide or regional). Programmes shown use screening test recommended by the Council of the European Union in 2003¹.

Source: ECN⁹

As the three maps above indicate, although much progress has been made, more is still required:

- For breast cancer, only 22 Member States are running or establishing population-based screening programmes;
- For cervical cancer, only 15 Member States;
- For colorectal cancer, only 12 Member States.

The current annual volume of screening examinations in the EU is considerable; however, this volume is less than one-half of the minimum annual number of examinations that would be expected if the screening tests specified in the Council Recommendation on cancer screening were available to all EU citizens of appropriate age (approximately 125 million examinations per year). Furthermore, less than one-half of the current volume of examinations (41%) is performed in population-based programmes which provide the organisational framework for implementing comprehensive quality assurance as required by the Council Recommendation.

2.2. Implementation of the Council Recommendation by the Member States

2.2.1. Implementation of cancer screening programmes

Section one of the Council Recommendation comprises a set of safeguards, technical, ethical and legal standards to be followed when implementing screening programmes in the Member States. It covers a set of eight recommendations ensuring a strict evidence base for implementing screening programmes, the recognition of EU guidelines on best practice, the observation of ethical standards in informing on benefits and risks and to be able to adequately follow-up any screen-detected lesion, and last but not least the necessary level of data protection. Most of these eight recommendations, dealing specifically with establishing screening programmes, are reported to be followed by at least two out of three of the Member States (67%).

2.2.2. Registration and management of screening data

Section two comprises a set of four recommendations ensuring the proper functioning of any quality assured screening programme requesting an electronic call/recall system and the collection, management and evaluation of all data from screening tests.

These points are reported to be followed by a very large proportion of the responding Member States. Eighteen out of 22 (82%) use centralized data systems and call/recall systems for running programmes and for inviting all targeted persons, respectively. Twenty out of 22 (91%) Member States report that data is collected, managed and evaluated not just on screening results, but also on assessment of persons with positive screening results and on diagnosis. The same high conformity is reported for data handling in full accordance with European data protection legislation, particularly as it applies to personal health data, prior to implementing cancer screening programmes.

2.2.3. Monitoring

Section three comprises three recommendations aiming to establish the necessary basis for quality insurance by regular monitoring of screening programmes.

Although a majority of the Member States indicate that they comply with two of the three specific items in this section dealing with monitoring screening programmes,

compliance was substantially lower than for most items in all other sections (except section six).

With regard to item 3 (a) in the Council Recommendation, only 55% of the responding Member States report that the process and outcome of organised screening is monitored regularly by an independent peer review and 59% indicate that the results are reported quickly to the general public and to screening staff. The lower proportions of responding Member States performing such monitoring reflect the limited applicability of the respective questions in the EU survey to Member States in which population-based cancer screening programmes have not been initiated. The comparatively very low proportion of Member States which report that national cancer registries monitor screening programmes (45%) will have to be further explored.

2.2.4. *Training*

Section four contains one recommendation highlighting the importance of training for all health professionals involved in screening programmes.

Very high compliance is reported for section four of the Council Recommendation dealing with training. Twenty out of 22 Member States (91%) report that screening programme personnel is adequately trained at all levels to ensure that they are able to deliver high quality screening.

2.2.5. *Compliance*

Section five comprises two recommendations seeking high compliance for the population including special action to insure equal access for particular vulnerable social economic population groups.

A high proportion of the Member States indicate that they adhere to these recommendations. Twenty out of 22 Member States (91%) report that a high level of compliance is sought from the eligible population when organised screening is offered. Eighteen out of 22 Member States (82%) report that action is taken to ensure equal access to screening, taking due account of the possible need to target particular socio-economic groups.

2.2.6. *Introduction of novel screening tests*

Section six comprises a set of five recommendations how to deal with and implement new screening methods for two distinct situations: Novel screening tests and variations or improvements of the recommended screening tests listed in the annex of the Council Recommendation on cancer screening.

Approximately 11 out of the 22 Member States (50%) report adherence to the respective items in section six of the Council Recommendation dealing with introduction of novel screening tests taking into account international research results.

3. **CONCLUSIONS**

Four years after the Council of Ministers of the European Union adopted a Recommendation on Cancer Screening, most Member States have acted on the Recommendation and intend to undertake further action where implementation is not yet complete. Thus, the formulation of joint priorities and principles of health policy at the European level has been followed up by actions at the level of the Member States to implement the shared policies and priorities.

Nevertheless, and despite these substantial efforts, overall the EU is still only around half-way towards implementing the Recommendation. Slightly less than half the population who should be covered by screening according to the Recommendation actually are; and less than half of those examinations are performed as part of screening programmes meeting the stipulations of the Recommendation.

This illustrates the need for greater efforts within Member States, supported by collaboration between Member States and professional, organisational and scientific support for Member States seeking to implement or improve population-based screening programmes. Substantial added value may be expected from such support and from additional efforts to improve and maintain high quality of screening programmes.

Work continues to help support the implementation of the Recommendation. For example, development and piloting of EU-wide accreditation/certification schemes¹³ for screening services based on EU guidelines for quality assurance of cancer screening would enable programmes to focus efforts on achieving the EU standards. This, in turn, would enable Member States to reap the potential of population-based screening to lower the burden of cancer in the population.

Even though the current volume of activities is still far from the level which can be expected in the future, the current expenditure in human and financial resources is already considerable. A sustained effort is therefore necessary at Community level and within Member States in identifying appropriate and effective measures to assure the quality, effectiveness and cost-effectiveness of current and future screening activities, taking into account scientific developments. Regular, systematic investigation, monitoring, evaluation and EU-wide status reporting on implementation of cancer screening programmes will continue to support exchange of information on successful developments and to identify weak points requiring improvement.

Cancer continues to represent one of the greatest burdens of ill-health within the European Union. The Recommendation on cancer screening represents a shared EU-wide commitment to taking practical steps to minimise that burden in practice, to the benefit of individual citizens and their families as well as to society as a whole. As this Report shows, putting in place these screening measures is a challenging task, and more work is needed to fully implement the Recommendation.

This effort only addresses one aspect of action against cancer. Actions to better monitor and prevent cancer at Community and Member States' level can help to reduce the number of cases arising at all; application of best-practice treatment can help to ensure better outcomes for people with cancer, as can European cooperation on cancer research for the future. The Commission will also consider whether and what further support can be provided to Member States to address other specific issues related to cancer challenges for the future.

In 2009 the Commission intends to launch a partnership for action against cancer. This partnership intends to put in place EU-wide commitments on concrete action to prevent and control cancer and thus contribute to reducing inequalities in tackling cancer. It will aim to support the Member States by providing a framework for

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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 relating to the marketing of products and repealing Regulation (EEC) No 339/93: OJ L218/30-47 of 13.08.2008.

identifying and sharing information, capacity and expertise in cancer prevention and control, and by engaging relevant stakeholders across the European Union in a collective effort to reduce the burden of ill health that cancer represents.