

## Health care services:

### Main consumer expectations from CEN Workshop Agreement on quality criteria for health checks

ANEC welcomes the work which has started within CEN/Workshop 68 on the development of a CEN Workshop Agreement on basic quality criteria for health checks, although a European standard would have been more suitable for such public health related subject.

Although not a member of CEN/WS 68, ANEC would like to share with the group its concerns about health checks in general (under point 1) and to express our expectations from the Workshop Agreement (under point 2).

#### 1. Current situation and consumer concerns

Health checks performed on a large population scale in the context of national screening programmes raised several concerns in many member states in the last decade. There have been debates in France and in the UK about alleged failures in for instance breast cancer screening (e.g. screening not identifying cancers or leading to overdiagnosis or overtreatment). This suggests that there must be inadequacies in the process. For this reason, this issue has notably become a national healthcare priority for many governments and raised the question of evidence based medicine. Although falling out of the scope of the future CWA on quality criteria for health checks, national screening programmes raised concerns which can be easily applicable to all health checks, including those provided by private companies for commercial purposes and those involving joint collaboration between the private and state health care services.

It is therefore worrying to see a continuous increase in the number of different checks and screenings offered to consumers by private companies and in the number of these companies themselves. These checks will continue to rise in number considering that more and more consumers perform self-medication or buy medicines over the internet. Health checks and screenings have therefore become a real new market with all the implications which we can expect. There are for instance leaflets spread around in medical centers, advertising campaigns, attractive sales' offers etc. This information is unfortunately barely complete, reliable or transparent and is provided in a way that is not harmonized making it difficult for consumers to make a responsible choice. Unfortunately, in the absence of regulation the information about the service as well as about risk predictions will continue to be provided in different ways without any control.

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Beyond the issue of unreliable or non-transparent information are the health risks associated with the checks. Many of the tests performed are barely accurate or reliable. They can lead to false results making people seek unnecessary treatment or have a false sense of security. These tests can also be provided to people who have not had any symptoms or do not fall within the categories of people for whom the test was intended. The tests performed can also pose health risks alone, such as a radiation risk sometimes aggravated by incorrect installation or maintenance of the devices. The technologies are even sometimes too new making it difficult to ensure that they are used in a safe way as possible side effects associated with the use of the technologies may not yet be known. The qualifications of the personnel providing the service and the installation and maintenance of the appliances may also leave room for improvement.

In this context, ANEC believes that quality and safety criteria for health checks and screenings, whatever the context in which they are provided<sup>1</sup> need to be established and their implementation ought to be controlled.

## **2. Consumer expectations from CEN Workshop Agreement**

Although ANEC is not a member of CEN/WS 68, quality criteria for health checks is a crucial issue for consumers and we will closely monitor the work and react if need be. We believe it important however to share our concerns and expectations with the group at this early stage of the CWA's development so as to ensure that the consumer views are taken into account.

ANEC calls for:

- The quality criteria to reflect the needs of consumers and not those of patients exclusively.  
Although the voice of patients' groups is important, their concerns are not always similar to those of 'average' consumers, who do not suffer from any particular disease or handicap. It is therefore crucial that quality and safety criteria reflect consumer needs and concerns in general and not just specific patients' needs – this is a consumer issue and not just a clinical issue.

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<sup>1</sup> e.g. in the context of national screening programmes or provided directly by private companies or in joint collaboration between the private and state health care services.

- Written contracts to be provided to prospective patients beforehand, giving full details of services offered, risks, costs, complaints procedures.
- Scientific evidence to be made available to guarantee the safety of every technology used in health checks.
- Service providers to be required to state their qualifications and experience to customers before carrying out tests (covering all staff involved in tests and in diagnosis, and follow-up).
- The safety and quality of the tests (including the devices used and the service associated with them) to be ensured.
- A guarantee that the tests performed accurately predict diseases avoiding providing false reassurance or unnecessary warning with the test results.
- Transparency of the information provided to consumers.  
All given information (including contractual terms, the medical terms used, information on health risks incurred when getting the test and on follow up etc) shall be explained to consumers/patients in a language and formulation they can easily understand. The service provider should also be transparent about the real benefit of the health check for each individual and be able to deliver proper evidence in relation to the health check methods applied.
- The principle of 'informed consent' to be respected (i.e. the consent given by the consumer should meet specific minimum standards).
- A guarantee that the tests are not applied to people who have not had any symptoms or do not belong to the target group<sup>2</sup> so as to ensure that only sound and safe health checks are offered and to the right categories of consumers.
- Assurance that results will be provided in written reports that the patient can take to a 3<sup>rd</sup> party clinician (e.g. GP).
- Assurance of follow-up consultation to discuss any monitoring, further tests (by other contractors if the patient so chooses) at inclusive (or otherwise pre-agreed) cost.

END.

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<sup>2</sup> e.g. a test intended for women between 50-70 years old should not be performed on a 18 years old woman