Chapter 7 Conclusions and recommendations of the working group

7.1 Main conclusions of the working group

At the start of the project, the working group was assigned the following three tasks:

- to create an overview of the many different types of test sold on the open market;
- to assess whether the legislation in this area is sufficient;
- to give recommendations on how devices for self-testing can best be used to improve public health, quality of life and the economy in Denmark.

The main conclusions from the work undertaken on these three tasks is set out below.

7.1.1 Overview

The self-test category covers a broad spectrum of products that may be subdivided in many different ways. However, the working group considers that where the task involves assessing the potential and possible consequences of self-testing, it is best to look into who is using the products, and for what purpose.

This report therefore examines self-tests in relation to the following factors:

1. whether the person is healthy or (diagnosed as) sick;
2. whether the testing is undertaken in cooperation with the health service as part of the monitoring procedure, or on the initiative of individuals with a view to diagnosing a condition or illness.

The working group has examined self-tests within these three main areas:

a. the use of tests on healthy subjects on the health service's initiative;
b. the use of tests on sick subjects on the health service's initiative;
c. the use of tests by healthy persons on their own initiative.

The working group found that the greatest potential and challenges lie in the areas (b) and (c), and these two areas therefore form the main focus of the report.

7.1.2 Legislation

Self-tests are governed by the EU Directive on in-vitro diagnostic medical devices. This Directive is complex and does not give a clear picture for the purposes of manufacturers, stakeholders and administrators. In the working group's view, there is a need for the legislation to be simplified and for a new and more flexible risk classification system that can handle new products, without all EU countries first having to approve the classification of each individual product on a certain list of annexes, as is the case with the current listing system.

Medical devices for self-testing differ from other medical devices in that they are to be used by persons who do not necessarily have a background as a healthcare professional or other experience of using the device. For this reason, stringent requirements should be placed on self-tests, including their testing, quality, information and marketing.

The working group considers that the legislation should be made more stringent as regards manufacturers' tests and checks on self-tests, before they are placed on the market, and their obligation to provide information on products and their use.

7.1.3 Assessment

We are pleased to see the health service actively cooperating to promote the use of self-tests by chronically sick patients in cases where self-testing can help to improve possibilities for treatment and quality of life for the chronically sick. However, this is subject to a number of

conditions being in place concerning product quality and the health service's infrastructure, as set out in recommendation 7.3.

The working group is more concerned about the use of self-tests by healthy persons on their own initiative. Some self-tests are relatively unproblematic – this is particularly true of tests that do not concern illnesses, e.g. pregnancy tests, ovulation tests and pulse watches. Tests undertaken with a view to later diagnosis of illnesses are more problematic, among other things, on account of the risk of false positive and false negative results, overdiagnosis and overtreatment, interpretative complexities and because there may be ethical issues associated with testing. The working group regards these problems as being of such significance that there ought to be more information and more debate generated within society on self-testing and its possible consequences.

There are tests that lie in the grey area between medical and other devices, e.g. alcohol and drug tests. These tests gauge a person's condition, but are not covered by the Directive on in-vitro diagnostic medical devices, given that alcohol and drugs are not regarded as medicines. The working group believes that it is worth considering whether the rules on such products should not be made more stringent, so that the products would in future come under the same rules as in-vitro diagnostic medical devices.

7.2 General recommendations of the working group

The five general recommendations below concern the tightening-up of requirements on testing, labelling and information on medical devices for self-testing.

All recommendations are addressed to Danish parliamentarians. Recommendation 4 is also addressed to regional and local politicians.

Recommendation 1: Set up a European body to test and label medical devices for self-testing

At present, there is no impartial, common European body that conducts practical tests on the quality of analysis and user-friendliness of medical devices for self-testing. We recommend that such a body be set up to test all self-tests sold in EU countries, in order to guarantee their quality.

Once the body has tested the products, they should be labelled according to a simple system (e.g. colour-coded with green for satisfactory, yellow for less satisfactory and red for unsatisfactory – along the lines of the evaluation system used by the SKUP [*Skandinavisk Utprøvning af laboratorieudstyr til Primærsektoren* – Scandinavian evaluation of laboratory equipment for primary health care], see Annex 1). The results of the testing and labelling should be made accessible to EU citizens on the body's website.

The procedures for testing and labelling the products should be based on the rules in force and include the conditions set out in the recommendations below.

A European body could be modelled on the SKUP and the European Medicines Agency (EMA). A brief description of both bodies is included in Annex 1.

The body could be funded by the EU – possibly jointly by the EU and manufacturers. Should different authorised bodies be set up in the EU, it is important to ensure that they operate under the same conditions and that they are subject to the same checks by impartial bodies under the European Commission, as these bodies would be competing with one another.

Until such a body is set up, it should be ensured that the products are tested elsewhere. In Denmark, SKUP could, for instance, provide help with testing.

Recommendation 2: Stringent rules for the testing and approval of medical devices for self-testing

As self-tests are characterised as being for the use of lay persons, i.e. people who do not have professional backgrounds qualifying them for the use of medical devices, manufacturers

should ensure that users can understand the information and are able to use the device.

We recommend that the rules in force on the testing of medical devices for self-testing be made more stringent in connection with:

Selection of test populations and testing of products on end-users

The manufacturer should test medical devices for self-testing on a population corresponding to the group that will probably later be using the test. When reporting to the approved body, the manufacturer should describe the population that has undergone testing.

Today, where there are no requirements on the test population, tests may be carried out on the groups of persons that are statistically most likely to obtain a 'result' from the test. This renders the test's positive predictive value much higher than it would be if it was tested on an ordinary group of people, or in other words: the actual number of persons obtaining a false positive (false alarm) would be underestimated. Testing end-users makes it possible to calculate the real predictive values for the test.

The requirement for testing relevant sections of the population is also established in the testing of medical devices, where international rules and the authorities' approval practices in the field of pharmaceuticals – including, among others, ICH E8[1] – ensures that the group of trial subjects resembles the intended patient population. This is the current 'gold standard'.

In order to ensure that the test is user-friendly and meets users' needs, not only does the manufacturer have to test its product among end-users in order to find the most accurate predictive values and to ensure that the product lives up to the technical requirements, but the products should also be tested by the end-users to cover the risks of misuse and its possible consequences. The manufacturer should also investigate whether there is any risk of inappropriate or misinterpretation of the test results.

Testing of the information material/package leaflet

The manufacturer should ensure that the information material accompanying the test can be understood by non-specialists. This should also be done by testing the material on end-users, in the same way as package leaflets for medicinal preparations are tested.

Recommendation 3: Stringent requirements for the manufacturer's obligation to provide information

In addition to the rules in force for the approval of medical devices for self-testing, the following requirements should be imposed on manufacturers:

- manufacturers should state how the users can themselves check that the device is operating correctly;
- manufacturers should state whether use of the product necessitates training of healthcare professionals;
- manufacturers should state whether the product may be used by healthy citizens for risk assessment (population survey), by persons in a risk group for early disease detection (high-risk screening) or for monitoring an illness;
- manufacturers should provide information in the product's package leaflet, in language comprehensible to the non-specialist, on the following:
  - what that test may be used for, and in what instances it should not be used;
  - how the test should be used in practice, and how the result of the test should be interpreted and dealt with;
  - the test's predictive values in the population(s) in which the test is recommended for use;
  - the possibility and probability of false positive and false negative responses,

[1] ICH Harmonized Tripartite Guideline – General Considerations for Clinical Trials E8 - adopted by the regulatory bodies of the European Union, Japan and USA, 1997: www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E8/Step4/E8_Guideline.pdf.

including the possible implications of obtaining a false positive – both in respect of the test itself, but also in respect of a possible subsequent testing programme;

- possible intentional positive and possible unintentional negative implications of the test and recommended subsequent tests.

If figures are included in the information, these should be given in absolute values, and the same names should be used, so that benefits, drawbacks and risks may be compared. Percentages should, for example, be written in standard figures.

- Manufacturers should be bound to provide the abovementioned information on the website mentioned in Recommendation 4 under 'availability of impartial advice and information'.

Recommendation 4: Provide citizens with information on self-testing and access to knowledge on each individual testing product

Public authorities should ensure that citizens obtain the most satisfactory, research-based, comprehensible information on medical devices for self-testing in general, and on the possible implications of using such devices. This information may also be useful if citizens are considering using non-approved tests. This information is set out below under 'obligatory information'.

In addition, citizens should be given the option of seeking impartial information themselves, both on testing in general and on the individual testing products. This information is set out below under 'availability of impartial advice and information'.

- Obligatory information
  - Public authorities should inform citizens of the general conditions regarding self-testing, including the relationship between being sick and healthy, on the usability/non-usability of testing (predictive values) and the possibility of obtaining a false positive and a false negative. In addition, information should be given on the possible intentional beneficial effects of testing, possible unintentional harmful effects, and the subsequent recommended tests in order that the information may be compared. Any social, economic and societal consequences of self-testing should also be included in the information, including any implications regarding insurance, as knowledge of health factors can have an impact on obtaining life or accident insurance (see also Recommendation 7.5, where applicable).
    - The obligatory information may be provided by municipalities and be included in educational material for schools and/or be made available via the municipal health service, e.g. in health centres.
    - Obligatory information may also be disseminated via campaigns and printed material on the advantages and disadvantages of self-testing, including testing via screening, on the initiative of the National Board of Health [*Sundhedsstyrelsen*].
- Availability of impartial advice and information
  - Citizens should be given the possibility of seeking impartial advice and information via a website set up at national level (this could be included on the *Sundhed.dk* website, or be made accessible from the Danish Medicines Agency's website [*Lægemiddelstyrelsen*]), where citizens could seek general information, information on the benefits and drawbacks of public screening and information on individual self-testing products. This applies to information on the test's quality (predictive values, sensitivity and specificity), on the practical use of the test and on how the result of the test should be interpreted and dealt with. Product information should be supplied by the manufacturer and the impartial body that has tested the products. Inspiration for the product database may be found in the *Hjælpemiddelcentralen*'s [Medical supplies centre] database and on the website *Medicin.dk*.

- A link to a 'hotline' may be included on the website in order to enable citizens to obtain answers to any questions they may have.

Recommendation 5: Setting aside funds for research into the use of self-tests

Research-based knowledge on the use of self-tests is very thin on the ground. For this reason, funds should be set aside for research into self-testing among both chronically sick and healthy patients. Some important areas to be clarified are:

- the spread and scope of self-testing; how many people are testing themselves, how often, and using what type of test?
- the reasons for using self-tests; what is the aim of testing and what are the test results used for?
- the social and human consequences of self-testing; does self-testing, for instance, improve quality of life and give greater security, or draw attention to disease, thereby generating insecurity?
- the economic implications of self-testing; does self-testing contribute to or burden the economy? Does self-testing lead to more or fewer visits to the doctor, greater or reduced pressure on health professionals?
- citizens' use of information; are citizens able to use and act on the information they obtain from package leaflets, e.g. on a test's predictive values, sensitivity and specificity? Or is there a need for better or different information?

7.3 The working group's recommendations for the use of self-tests by chronically sick patients on the health service's initiative

The working group believes that there would be significant potential for saving staff and patient time if the health service widened the possibilities for self-testing chronically sick patients. However, this has not yet been proven.

If the health service wishes to widen the possibilities for such patients, there are nevertheless a number of conditions that should first obtain. This applies firstly to the evidence that self-testing within the field in question may benefit both citizens and society and, secondly, to a number of conditions concerning the products' quality and the health service's infrastructure. In addition to this, a number of individual assessments need to be carried out on each individual patient.

A series of recommendations are set out below on what should be in place before the health service introduces more self-testing. The recommendations are divided up into general and individual conditions, although in some cases these may overlap.

- Self-testing may be implemented once the following general conditions obtain:
  - where a cost-effectiveness analysis has shown the likelihood that the test would be a sound investment in relation to the expected improvement in treatment quality or quality as experienced by the patient;
  - where the necessary health-service infrastructure has been established. This may involve technical, clinical or training support systems etc. A technical support system may, for example, involve a 'public safety answering point' which, on the basis of reports from a given type of monitoring ensures that action is taken where required on the discrepancies in the reported values. A technical support system could include a hotline, where patients could ring in and obtain instructions on how to act in certain situations. A clinical support system may comprise a decision support system to instruct healthcare professionals on how to act in certain situations, and a training support system may include training programmes for both patients and healthcare professionals;
  - where the risks and possible negative implications of self-testing have been assessed;
  - where it has been clarified who is to pay for the device; there is no entitlement

to reimbursement for 'aids', and the rules today vary between municipalities;

- where the measurements on self-testing devices correspond to 'official hospital measurements' with 'large devices and the best people to operate them';
- where a clear division of responsibilities has been established between patients and the public health service in respect of who is to follow up on the test results;
- where the responsibility for any technical checks and maintenance of the device has been clarified;
- where an accounting method that covers the doctor's/hospital's costs in setting up the necessary device and tele-consultations has been established, and thereby supports the 'relocation' of health services to the patient's own domain.
- where other conventional monitoring possibilities have been secured for patients who do not wish, or are not in a position, to carry out self-monitoring.

- Self-testing may be implemented once the following general conditions, linked to the individual patient, are met:
  - where the decision on self-testing is based on an expert assessment of the individual patient and their situation, including
    - whether the patient is willing and able to undertake self-testing;
    - whether it generates a positive change for the patient, e.g. increases the patient's degree of self-determination (empowerment/autonomy) and quality of life;
    - whether it enhances the quality of treatment (e.g. day-to-day regulation of medicine);
    - whether it decreases the number of clinic or hospital visits and thus saves the patient's time;
    - whether self-testing is to be undertaken in keeping with the situation and wishes of the other residents in the patient's home;
  - where clear guidelines have been established for the device, and the citizen has been informed of how long he/she has access to it and can carry out self-monitoring, including where it has been assessed and agreed what will happen when the citizen no longer can or wishes to operate the device.

7.4 The working group's recommendations for the use of self-tests by healthy persons on the health service's initiative

We recommend that the health service promotes self-testing of healthy citizens only where this is undertaken within certain defined frameworks. If healthy persons are to be performing self-tests on the health service's initiative, this should be undertaken within the following frameworks, which should also apply to public screening:

- citizens should be informed of:
  - the benefits and drawbacks of testing, including any physical, psychological, social and societal implications of positive and negative test results;
  - the predictive values of the test – this should be in language readily comprehensible to persons outside the health sector;
  - the risk of both overtreatment, and of complications and possible mortality resulting from it;
  - the right to say no to the test;
- it should be assessed whether the citizens understand the complexity of testing/ screening and its possible consequences, before they take the test; this may, for example, be established in a pilot experiment;
- the right of citizens to say no must be respected, without this implying that these citizens are irresponsible, and without any repercussions on subsequent

care provision;

- citizens should be given the option of entering into a dialogue on the test with healthcare professionals;
- in addition, the working group generally endorses the guidelines produced by the Danish Council of Ethics [*Det Etiske Råd*] in 1999 on screening.

7.5 The working group's recommendations for the use of self-tests by healthy persons on their own initiative

Although we consider that it is in essence a good thing that technology is coming up with new options for self-testing, we cannot recommend that citizens test themselves with a view to diagnosing diseases or identifying risk factors for disease, including detecting the risks of disease on the basis of genetic characteristics, as such risk assessments require specialised knowledge of health issues.

With the apparent continued increase in the supply of tests, testing for disease and genetic characteristics, we would point out that there is a greater need for citizens to be given information on this type of test. Possible ways of providing information are described under the general recommendations.

The list below sets out a number of factors that we believe citizens should be aware of, should they wish to test themselves for risk factors, disease or genetic characteristics:

- that test results may provide a false positive (false alarm) or a false negative (false sense of security);
- that there will always be five percent of persons falling outside the normal area, without this meaning that these persons are sick;
- that there can be many factors that affect the results of a test; for example, how the test is used, and how it has been transported and stored; if the test person has eaten, drunk or undertaken physical exercise just before the test was taken, this may also affect its results;
- that abnormal or atypical conditions are not necessarily constant, and that the body is constantly 'repairing' itself; that symptoms are not always a sign of ill-health – there are cases where the best treatment is no treatment, but merely observation; many illnesses and ailments thus remedy themselves;
- that a genetic test can only show a disposition and can rarely predict how an illness will develop, as environmental effects are usually more decisive than genetic tendencies (environment = diet, exercise; smoking; alcohol and narcotics, physical environment, psychological and social aspects, work and private sphere etc.).