

REGULATING THE USE OF GENETIC TESTS: IS DUTCH LAW AN EXAMPLE FOR OTHER COUNTRIES WITH REGARD TO DTC GENETIC TESTING?

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Introduction

Scientific knowledge of genetics is expanding rapidly, which generates many possibilities for predicting and improving human health and life.¹ Individuals have high expectations about the potential benefits of genetics and are also increasingly eager to learn more about their genetic profile and future health. Commercial companies seek to appease the hunger for genetic information by offering Direct-To-Consumer (DTC) genetic tests, also via internet. These tests are carried out without the involvement of a healthcare provider, fail to provide adequate information and are not foreseen in genetic counselling services.²

After undergoing a DTC genetic test individuals will receive information about the presence of genetic risks and hereditary diseases. The validity of these tests is, however, questionable. The use of DTC genetic tests may thus easily cause unjustified anxiety and spur individuals to undergo unnecessary follow-up tests and medical treatment, at considerable personal and societal expense. Despite these shortcomings, it can be argued from a legal point of view that unrestricted access to DTC genetic tests strengthens the personal autonomy of individuals. It empowers them to take independent responsibility for their health and future,³ and it leaves them the decision of whether they want adequate information and genetic counselling. At the same time, States have the obligation to protect individuals against (potential) health risks, including exposure to misleading information upon the basis of which individuals may make decisions they would otherwise have rejected. This positive obligation is well entrenched in international human rights law.⁴

Several European States are at present considering the introduction of legislation to regulate the supply of and access to DTC genetic tests.⁵ The

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¹ H. Calsbeek, et al., 'Knowledge and Attitudes Towards Genetic Testing: A Two Year Follow-Up Study in Patients with Asthma, Diabetes Mellitus and Cardiovascular Disease', *National Society of Genetic Counsellors* 2007, pp. 493.

² S. Hogarth, G. Javitt & D. Melzer, 'The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues', *Annual Review of Genomics and Human Genetics* 2008, pp. 162-165; C.M. McBride, C.H. Wade & K.A. Kaphingst, 'Consumers' Views of Direct-to-Consumers Genetic Information', *Annu Rev Genom Hum Gen* 2010, pp. 429-432 and GAO, *DIRECT-TO-CONSUMER GENETIC TESTS, Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices*, Washington 2010. The report of the Study is available on internet at: <http://www.gao.gov/products/GAO-10-847T> (22/07/2010).

³ J.L. McGregor, 'Why John Stuart Mill Would Support Restriction on DTC Marketing of Genetic tests', *The American Journal of Bioethics* 2008, pp. 9-10.

⁴ See for instance Article 25 of the UN Universal Declaration on Human Rights (1966) and Article 14 of the UNESCO Universal Declaration on Bioethics and Human Rights (2005).

⁵ V. Brower, 'FDA To regulate Direct-to-consumer Genetic Tests', *Journal of the National Cancer Institute* 2010, p. 1611; The UK Human Genetic Commission, *A Common Framework of Principles for direct-to-consumer genetic testing services*, 2010, at: www.hgc.gov.uk; Report

Netherlands is one of the few countries that already has such legislation in place, in an effort to save the general public from harm resulting from preventive screening tools. The internationally widely praised Wet op het bevolkingsonderzoek (Act on population screening) seeks to offer protection against harmful screening programmes by way of a permit system.

The Netherlands is a Member State of the Council of Europe and the European Union. These organisations influence, in their own specific way, the freedom of Member States to regulate the supply of and access to DTC genetic tests. National measures seeking to protect the public against harm from these tests have to abide by the standards adopted by these organisations.

This paper seeks to examine whether the Wet op het bevolkingsonderzoek can serve as an example for other European countries. It aims to assess the effectiveness of this Act as well as its compliance with European standards. We start by describing the normative questions surrounding the supply of and access to DTC genetic testing by internet in section I. Then, we unravel the international, but particularly European, patchwork of (legal) standards concerning the supply of and access to DTC genetic tests through internet in section II. Section III provides an overview of Dutch legal standards and problems that emerge in practice when seeking to regulate the supply of screening programmes, including DTC genetic tests. Lastly, in section IV we formulate an answer to the above questions, followed by conclusions.

I. DTC Genetic Testing

Genetic screening can be defined as any kind of test being offered to a person or group of individuals with the aim of detecting or ruling out a hereditary disease, a predisposition to such a disease or to determine whether a person carries a genetic variant that may produce a hereditary disease in their offspring.⁶ Individuals can buy a test kit for screening their DNA on the internet without the involvement of a physician or genetic counselling. After visiting the online shop and ordering a genetic test, the individual will receive a test kit from the company. This kit commonly includes a tube for taking a DNA sample, such as saliva or a hair, to be returned to the company. Upon receiving the DNA sample, the company's laboratory starts the analytic process. A few weeks later the individual can download the test results using a simple code.

In this respect it is important to make a distinction between presymptomatic diagnosis and susceptibility genetic tests. Presymptomatic diagnostic genetic tests are mostly aimed at discovering a monogenetic disease, that is to say a gene mutation which, by definition, will almost inevitably lead to the development of disease at some point in later in life.⁷ By contrast, testing for multiple genetic variants is generally associated with low risks of developing common health conditions and traits. A 'positive' test result—meaning that an affected gene has been detected—generally implies a(n enhanced) statistical risk but not a certainty of developing the disease later in life.⁸ The

on the Workshop Legal regulation for genetic testing, ESHG-Conference in Gothenburg, 14 June 2010, at:

<https://www.eshg.org/fileadmin/www.eshg.org/documents/Europe/LegalWS/ReportESHG-LegalWorkshop2010.pdf> (14/06/2010).

⁶ B. Godard, *et al.*, 'Population genetic screening programmes: principles, techniques, practices and policies', *European Journal of Human Genetics* 2003-49, pp. 49-50.

⁷ P. Borry, 'Genetic testing in asymptomatic minors: recommendations of the European Society of Human Genetics', *EJHG* 2009, pp. 1-2.

⁸ McBride, Wade & Kaphingst 2010, *supra* note 2, pp. 430.

results of the latter susceptibility tests do not necessarily accurately establish the risk of developing a disorder, because in most cases not all risk factors are included and additional relevant factors, such as family history and lifestyle, are not taken into account by the test. Furthermore, there are carrier tests that have been developed to determine whether a healthy person or couple carries a relevant mutation for an autosomal recessive disorder.⁹ The majority of DTC genetic tests concern susceptibility tests, sometimes in combination with presymptomatic diagnosis tests or carrier tests.

Against this background it is not a surprise that the interpretation of test results can be challenging for a person, particularly for those with limited knowledge of genetics and medical statistics. It is well known from various studies on genetic counselling that complex information on risk factors is particularly difficult to handle for a layman, regardless of their background or education.¹⁰

I.1 Normative Questions Surrounding Access to DTC Genetic Testing

DTC genetic tests have the potential to empower individuals to take more responsibility for their health and life by providing risk assessment information.¹¹ However, individuals often overestimate the benefits of DTC genetic tests now that these tests are generally offered without adequate information. It is well known that individuals may take important health decisions concerning prevention or prophylactic treatment based on incomplete or misunderstood information about their expected health.¹²

The validity and clinical utility of these tests are questionable and can even have detrimental effects for the individual concerned as well as others due to needless and invasive follow-up tests or unnecessary medical treatment.¹³ Under human rights law, States are bound to protect individuals against such serious risks. Unrestricted access to DTC genetic tests can also interfere with other fundamental human rights and interests of others. Individual genetic health information can, for example, reveal information about family members and could have implications for their health, thus directly impacting on their rights and interests. If follow-up tests and unnecessary medical treatment happen on a large scale, unrestricted access to DTC genetic tests may also indirectly threaten the accessibility of the health care system.

States are then torn between Scylla and Charybdis¹⁴ when confronted with the shortcomings of DTC genetic tests. Should they allow individuals to freely make use of tests of questionable quality for the sake of respecting autonomous decision making, or should health concerns prevail, thus restricting the commercial activities of companies and inhibiting individual use of their products?

⁹ *Idem*.

¹⁰ S. van Dijk, *et al.*, 'Feeling at risk: How woman interpret their familial breast cancer risk', *American Journal of Medical Genetics* 2004, pp. 47-48.

¹¹ C. Marietta & A.L. McGuire, 'Direct-to-Consumer Genetic Testing: Is It the Practice of Medicine', *Pharmaceutical regulations* 2009, pp. 370.

¹² *Ibid*, pp. 371.

¹³ *Ibid*, pp. 370.

¹⁴ In Greek mythology, monster Scylla and whirlpool Charybdis were both dangerous to sailors. They lived on opposite sites of the Strait of Messina. 'Between Scylla and Charybdis' therefore means a situation in which one has to choose between two equally unattractive options.

II. European Standards

DTC genetic testing offered by internet companies is a cross border activity affecting millions of people across the European region. In order to uphold the same standards with respect to autonomy and protection it is important that convergence is sought between the law and policies on screening in different jurisdictions.¹⁵ The main regional organisations in Europe, being the Council of Europe (Council) and the European Union (EU), have developed standards regulating the supply of and access to genetic tests for health purposes. These instruments also, and sometimes specifically, apply to DTC genetic tests. In this section we describe and examine the most important standards adopted within the context of the Council and the EU, relevant for the use of DTC genetic tests.

II.1 European Convention on Human Rights

The Council of Europe's most important legal instrument, the European Convention for the Protection on Human Rights and Fundamental Freedoms (ECHR),¹⁶ is of crucial importance when it comes to regulating the use of DTC genetic tests, even though the Convention does not contain a reference to the right to health or a right to health care. From the European Court of Human Rights' (ECtHR) case law it can, however, be seen that compliance with ECHR established rights also requires contracting States to the ECHR (henceforth: States Parties) to take adequate measures in the area of health promotion and the prevention of health risks. These duties to protect and ensure the enjoyment of Convention rights are known as positive obligations, as opposed to negative obligations that are imposed on States Parties not to interfere with human behaviour and inter-human relations.

The Court's doctrine of positive obligations is essential for health law, notably now that these obligations do not confine themselves to the vertical relations, but extend to horizontal ones. In other words, by imposing positive obligations regulating human conduct with respect to other private parties, the Court acknowledges that States Parties should also uphold respect for human rights in the relations between private parties. By way of example, it can be recalled that the Court has held that States Parties are obliged to formulate adequate legislation to protect the integrity of individuals against violations by others.¹⁷

According to the Court's standing case law, States Parties are bound by the positive obligation to protect their citizens against (potential) health risks.¹⁸ The State has equally emphasised the importance of adequate information, including informing the patient about health risks, as a precondition for informed consent.¹⁹ In a number of cases the Court concluded that the failure to provide adequate information prior to a health intervention results in a violation of an individual's physical integrity, which is protected by Article 8 of the ECHR.²⁰

¹⁵ J.K.M. Gevers, 'Health Screening Services Supplied Directly to the Public', *European Journal of Health Law* 2009-3, pp. 6.

¹⁶ All Council of Europe treaties, incl. those referred to in this paragraph, can be found on <http://conventions.coe.int/> > treaties > full list.

¹⁷ ECtHR 26 March 1985, *X & Y v. Netherlands*, no. 8978/80.

¹⁸ ECtHR 9 June 1998, *L.C.B. v. the UK*, no. 23413/94.

¹⁹ ECtHR 5 October 2006, *Trocellier v. France* (Dec.), no. 75725/01 and ECtHR 2 June 2009, *Codarcea v. Romania*, no. 31675/04.

²⁰ ECtHR 12 July, *Testa v. Croatia*, no. 20877/04.

It can be argued that free access to DTC genetic tests strengthens the individuals' autonomy, as protected by the right to private and family life.²¹ Autonomy, particularly relevant in the field of health care,²² also means that States have to respect the choices of harmful activities from mentally competent individuals.²³ However, autonomous decisions have to be compatible with human dignity, the principle underlying all human rights. This explains why the Court has held that an individual cannot legally consent to practices deemed to be at odds with human dignity, such as being tossed around to entertain others and gain oneself an income (dwarf tossing) or to engage in extremely violent sexual practices.²⁴

It can be maintained that the requirement to obtain the individual's informed consent prior to a health intervention also entails obligations for companies offering DTC genetic tests – or at least a duty for States to ensure that these companies abide by the informed consent requirement.²⁵ From the case law of the ECtHR it follows that an individual can only agree with an interference with his/her private life in the field of health care after he/she has voluntarily and unambiguously consented to this on the basis of prior and adequate information. It can be debated whether there is lawful consent when companies offering DTC genetic tests fail to provide adequate information on such issues as the scientific validity of these tests, their limitations and the benefits as well as the risks.

In conclusion, the obligation to provide adequate information about the health benefits and risks prior to obtaining the consent of an individual is a well-established requirement recognised under the ECHR. States should ensure that this requirement is also upheld in the so-called horizontal relations. From a human rights perspective there are therefore good reasons for States to regulate the supply of and access to DTC genetic tests because of the (potential) health risks to individuals and the deficiencies with respect to adequate information and valid consent.

II. 2 Biomedicine Convention

Particularly relevant with respect to the use of DTC genetic tests is the Council's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Biomedicine Convention). The Convention itself consists of principles, rights, and standards applying to specific fields of biology and medicine. Yet only a certain number of principles, rights and standards have been clarified by the drafters. Other issues, including those on which it is difficult to achieve consensus, have been or will be dealt with in Additional Protocols.

The Protocol concerning Genetic Testing for Health Purposes (the Protocol) deserves special attention. The Protocol, to be read in conjunction with the Biomedicine Convention itself, came into force on 1 December 2009. The Protocol seeks to protect the human dignity and the fundamental rights and freedoms of individuals with regard to genetic testing for health purposes. The Protocol applies to all genetic tests whether they are provided publicly or

²¹ ECtHR 7 February 2002, *Mikulic v. Croatia*, no. 53176/99; ECtHR 29 April 2002, *Pretty v. the UK*, no. 2346/02 and ECtHR 11 July 2002, *Christine Goodwin v. the UK* (GC), no. 28957/95.

²² ECtHR 14 December 2010, *Ternovszky v. Hungary*, no. 67545/09.

²³ ECtHR 20 January 2011, *Haas v. Switzerland*, no. 31332/07.

²⁴ ECtHR 16 October 1996, *Wackenheim v. France*, no. 29961/96; ECtHR 19 February 1997 *Laskey, Jaggard & Brown v. United Kingdom*, no. 21627/93; 21826/93 & 21974/93 and ECtHR 17 February 2005, *K.A. & A.D. t. Belgium*, no. 42758/98 & 45558/99.

²⁵ ECtHR 2 June 2009, *Codarcea v. Romania*, no. 31675/04.

privately. It also covers genetic tests that are carried out for health purposes, such as DTC genetic presymptomatic diagnostic, predictive and carrier tests. Genetic tests carried out on the human embryo or foetus and for research purposes are, however, excluded from its scope.²⁶ The Protocol requires States Parties to take the necessary measures to ensure that genetic tests meet generally accepted criteria of scientific validity and clinical validity. Clinical utility of genetic tests must, according to the Protocol, be an essential criterion for deciding to offer genetic tests to the public.²⁷

The Protocol furthermore stipulates that when a genetic test is considered, the persons concerned shall be provided with prior appropriate information, notably about the purpose and the nature of the test, as well the implications of its results.²⁸ Appropriate genetic counselling should also be provided.²⁹

States that have ratified this instrument need to uphold these standards,³⁰ which are considered to reflect European *minimum standards*. States are explicitly also allowed to grant potential test subjects a higher level of protection.³¹ It follows that the supply of and access to DTC genetic tests in European States, at least in those countries that have ratified the Protocol, should be in conformity with these standards. Failure to guarantee these standards equals a violation of human rights for which States eventually can be held accountable.

II.3 The Internal Market Rules of the European Union

Despite the considerable powers of the EU in various areas of social life, the main responsibility for health policy and provision for health care rests with the Member States.³² It is settled case-law of the European Court of Justice (ECJ) that EU law does not detract from the freedom of Member States to choose their own health security level.³³ Nevertheless, notably in the case of cross border activities, EU law indirectly regulates access to DTC genetic tests. States have the obligation to comply with the rules of European Free Market that prohibit—amongst others—measures that impair free-market competitions. Thus Member States are in principle required to respect the free movement of goods, services and establishment when exercising their power in the field of health.

As for EU law, it is important how to qualify DTC genetic tests. It is settled case-law that the ECJ³⁴ will examine in principle a national measure in relation to one freedom if a restriction relates to several fundamental freedoms. It shall appraise a national measure in relation to two fundamental freedoms if it appears that one of them is not entirely secondary to the other one.³⁵

²⁶ Article 2 Protocol, <http://conventions.coe.int/Treaty/en/Treaties/html/203.htm> (27/11/2008).

²⁷ Article 6 Protocol.

²⁸ Article 8(1) Protocol.

²⁹ Article 8(2) Protocol.

³⁰ By December 2010 5 States had ratified the Protocol.

³¹ Article 22 Protocol.

³² Article 152 TFEU and European Commission, Together for Health: A Strategic Approach for the EU 2008-2013, COM (2007) 630 final.

³³ Case C-372/04, *Watts v. United Kingdom* [2006] ECR I-4325.

³⁴ The Court of Justice of the European Union has the power to interpret the EU treaties, to measure the interpretation of these treaties by EU bodies and institutions, and to judge a limited number of conflicts within the realm of the EU law.

³⁵ Case C-20/03, *Burmanjer et al.* [2005] ECR I-4133; Case C-390/99, *Canal Satélite / Administración General del Estado* [2002] ECR I-607 and Case C-275/92, *Her Majesty's Customs and Excise/ Gerhart Schindler en Jörg Schindler* [1994] ECR I-1039.

In our opinion a DTC genetic test is not a good but rather a service because the test kit with the tube (good) is entirely secondary to the analytic process in the laboratory (service). In connection with this discussion, some authors argue that DTC genetic tests fall within the scope of Directive 98/79/EC on in vitro diagnostic medical devices. This Directive ensures a quality review before 'high risk' self tests (for instance self tests for HIV) are marketed.³⁶ In our opinion DTC genetic tests are not covered by this Directive. In the first place this Directive does not apply to services. In the second place products of general laboratory use are not in vitro diagnostic.³⁷ The tube for taking a DNA sample has no particular diagnostic value and is not produced with special characteristics for testing.

In the absence of harmonisation of DTC genetic tests EU Member States are under certain circumstances allowed to take measures, which restrict the free movement of services and establishment to protect their citizens against (potential) health risks.³⁸ These measures have to be objectively necessary for the purpose, and the result could not be achieved through less restrictive rules. In addition, these measures should not discriminate services or the establishment on grounds of nationality.³⁹ Furthermore when measures derogate the free movement of services or establishment they must pursue its goal in a consistent and systematic way.⁴⁰ Prior administrative authorisation, like permit systems, must be based on objective announce criteria that are stated well in advance.⁴¹

Reference should also be made to Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (E- Commerce Directive). This Directive covers the online services by which DTC genetic tests are offered on internet. In principle this Directive allows a permit system, which is meant to be exclusively for information society services. Information society services are services that are normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.⁴² Member States may take measures to derogate the freedom to provide information society services to protect health under the same conditions as we have described above.

II.3.1 Recommendations and White Paper

In 2004 the European Commission published 25 recommendations on the ethical, legal and social implications of genetic testing.⁴³ A multidisciplinary

³⁶ P. Borry, 'Europe to ban direct-to-consumer genetic tests?', *Nature Biotechnology* 2008-7, pp. 736-737.

³⁷ Article 1(2b) Directive 98/79/EC.

³⁸ Case C-108/09, *Ker Optika* [2010], not published yet.

³⁹ Case C-169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721; Case C-444/05, *Aikaterini Stamatelaki/NPDD Organismos Asfaliseos Eleftheron Epagelmaton* [2007] ECR I-3185 en Case C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509.

⁴⁰ Case C-171/07 and C-172/07, *Apothekerkammer des Saarlandes et al.* [2009] ECR I-4171; Case C-531/106 *Commission v. Italy* [2009] ECR I-4103.

⁴¹ Case C-169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721 and Case C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509.

⁴² Article 1(2) Directive 98/34/EC M1 laying down a procedure for the provision of information in the field of technical standards and regulations and rules on Information Society services.

⁴³ European Commission, *25 Recommendations on the ethical, legal and social implications of genetic testing*, Brussels 2004, at:

http://ec.europa.eu/research/conferences/2004/genetic/pdf/recommendations_en.pdf

expert group was invited by the Commission to discuss the implications of genetic testing. The 25 recommendations are the results of the expert groups work. They seek to be a starting point for the EU and Member States to consider an action plan for genetic testing and the recommendations can be used for implementation by policy-makers.

According to the report underlying these recommendations, genetic testing should only be carried out in specialised laboratories under the supervision of a trained geneticist. The application of genetic testing for non-medical reasons requires careful consideration with regard to its potential consequences for society. The report also requires that genetic testing in Europe has to be based on high quality scientific knowledge. A system for the validation of tests should be established by the EU. In the context, of human healthcare genetic tests should be offered only when there is a sound medical reason for testing. Furthermore the report stipulates that medical relevant genetic testing has always be a free personal choice. Therefore comprehensive information about genetic test should be available. Informed consent, the right to know and not to know, and genetic counselling must be guaranteed and are essential requirements for genetic tests, in particular for highly predictive tests for serious disorders. The report demands test providers to ensure that the information they provide is accurate and in agreement with international quality standards according to the recommendations.

The EU has presented its strategy toward health in a so called White Paper.⁴⁴ This Paper sets out a framework to give direction to EU health policy until 2013. The EU has pinpointed out objectives key areas to develop more specific activities to promote health. Two of these key areas are protection of consumers against health threats and supporting new technologies and considering their implications.

II.4 Preliminary Conclusions

The ECHR, the Biomedicine Convention and the Protocol offer an authoritative framework for the regulation of the use of DTC genetic tests across Europe. Not all States Parties to the ECHR, including the Netherlands, have, however, ratified the Biomedicine Convention, let alone the Protocol. That does not mean that these standards have no meaning for these countries. It can be argued that the adopted norms reflect emerging European standards that can not always be enforced throughout Europe yet. When regulating the use of DTC genetic tests, the obligations enshrined in the ECHR, the Biomedicine Convention and the Protocol therefore have to be taken into account.

The supply of and access to DTC genetic tests is in principle also regulated by the Internal Market Rules of the EU, even though there is discussion with respect to the precise qualification of a DTC genetic test. This body of legislation has to be respected by Member States considering the regulation of the use of DTC genetic testing. The EU has as yet not adopted a directive setting specific normative criteria for access to DTC genetic tests. The EU Commissions recently adopted 25 recommendations on the ethical, legal and social implications of genetic testing that provide normative guidance as it relates to the supply of and access to DTC genetic tests.

(06/05/2004) and at http://ec.europa.eu/research/conferences/2004/genetic/pdf/report_en.pdf (06/052004).

⁴⁴ European Commission, *supra* note 32.

In the absence of more elaborate standards with respect to the supply of and access to DTC genetic tests at the European level, States enjoy a considerable margin of appreciation to regulate the supply of and access to DTC genetic tests in the way they deem most appropriate to find a fair balance between personal autonomy and the need to protect individuals against the disadvantages of these tests.

III. Dutch Legal Standards

In the Netherlands companies and health professionals are in principle free to offer health testing kits to the public. Some forms of screening can, however, only be carried out with a permit issued by the Minister of Health, Welfare and Sports. The criteria to be met by the applicant for these forms of 'high risk screening' are laid down in the Act, 'Wet op het bevolkingsonderzoek' (the Act). This system was introduced to establish and guarantee a fair balance between the right of self-determination of individuals and the need to protect them against (potentially) harmful screenings techniques.⁴⁵

In the Act, population screening is defined as: "a medical examination which is carried out in response to an offer made to the entire population or to a section thereof and to detect diseases of a certain kind or certain risk indicators, either wholly or partly for the benefit of the persons to be examined".⁴⁶ Offering and practicing tests for detecting (risk indicators of) cancer and 'incurable diseases' without a licence is unlawful.⁴⁷ Moreover, performing these screening methods without permission is a punishable offence.⁴⁸

According to the Act, the Dutch Minister of Health, Welfare and Sports grants the licence for screening (risk indicators for) of cancer or (risk indicators for) untreatable diseases, provided that the screening is scientifically sound, in accordance with the professional medical practice standards and maintains proper balance between health risks and benefits.⁴⁹ The Act does not set quality norms for the information to be provided to the (potential) test subjects, consent, the use of samples, and counselling to be provided. Nevertheless, health care workers and companies wishing to perform a population screening programme have to comply with the professional medical practice standards that entail the main rights of the patient as laid down in the Dutch Civil Code.

III.1 Interpretation and Enforcement Problems

The Act came into force in 1996. From the very beginning there was confusion about its scope, and thus uncertainty about the requirements of obtaining a license. Over the last fourteen years the Dutch Health Council, a scientific advisory body that has been allotted the task of advising the Minister on the provision of a license to applicants under the Act, has written seven reports seeking to clarify the realm of the Act.⁵⁰ Despite these helpful contributions certain uncertainties remain that are probably inherent to the

⁴⁵ P.J. van der Maas, *et al.*, *Evaluatie Wet op het bevolkingsonderzoek, Evaluation Act on population screening*, Den Haag: ZorgOnderzoek Nederland 2000, pp. 7.

⁴⁶ Dutch Health Council, *Genetic screening*, Den Haag 1994: GR 1994, pp. 18 and article 1(c) WBO.

⁴⁷ Article 2 Wet op het bevolkingsonderzoek (WBO).

⁴⁸ Article 3(1) jo 13 WBO.

⁴⁹ Article 7 WBO.

⁵⁰ Van der Maas *et al.* 2000, *supra* note 45, pp. 37-33.

use of terms like 'population screening', 'offer' and 'incurable'. There has therefore been a call to revise this Act to enhance its effectiveness.⁵¹

Moreover, the Act has several loopholes. Companies use these for their own benefit, for example in the area DTC genetic screening. Enforcement of the Act is difficult because offering and performing screening for the (risk of) hereditary cancer and incurable diseases without a licence are prohibited, but only practicing without a legal permission is actionable. Dutch companies offer screening programmes directly to the public on internet sites, in newspapers and in magazines. They do this without a licence in their homeland and practice screening across the border. Furthermore the Act does not cover DTC carrier tests whilst these tests can have serious psychological and familial implications. The Act does not regulate the access to these tests because they do not detect the (risk of) hereditary disease of the individual but provides information about the risk of having a child with a genetic condition.

III.2 Preliminary Conclusions

The Dutch Act was not developed for nor does it exclusively regulate the use of DTC genetic tests. Nevertheless the Act does apply to DTC genetic tests due to the fact that these tests fall within the definition of population screening, as laid down in the Act. Therefore, the Act does apply legal quality standards to 'high risk' DTC genetic tests.

DTC genetic testing is classified as population screening because companies offer their genetic services directly to the public. The key word in the definition of the Act is 'offer'. The fact that individuals visit the web shop on their own initiative makes no difference when classifying DTC genetic tests as population screening. This means that in the Netherlands offering and practicing screening for detecting the (risk indicators of) cancer and untreatable diseases without a licence is unlawful⁵² and practicing without permission is a punishable offence.⁵³

IV. Discussion

Can the Dutch Act serve as an example for other European countries, when regulating the use of DTC genetic tests in a way that is consistent with European legal standards? Despite various initiatives there is as yet no comprehensive European legal framework regulating the supply of and access to DTC genetic tests. When studying the different existing instruments and documents adopted by the Council of Europe and the EU, there appears to be a prevailing opinion that the validity and utility of genetic tests are essential preconditions for allowing them to be offered to the public. Moreover, there is widespread (international) support for the idea that genetic tests, including DTC genetic tests, should be offered only under medical supervision.⁵⁴ DTC genetic tests with risks that can have far reaching implications for the person concerned or his or her relatives should not be allowed without appropriate non-directive genetic counselling.

⁵¹ Van der Maas et al. 2000, *supra* note 45.

⁵² Article 2 WBO.

⁵³ Article 3(1) jo 13 WBO.

⁵⁴ ESHG, official response of the EuroGentest network of Excellence in Genetic Testing to the Public consultation on the revision of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, Vienna 2010. This document is available through the internet <https://www.eshg.org/fileadmin/www.eshg.org/documents/ESHG/ESHG-IVD-def.pdf> (2010), pp. 7 (question 11).

Furthermore, there is a common opinion that people should be given the opportunity to make their decision freely and based on adequate information about the limitations of the test and its physical, psychology and social implications, meaning giving informed consent.

The Dutch Act, despite interpretations and enforcement problems, provides a basic level of protection against population screening activities that could potentially threaten the health of individuals. Yet, we doubt whether the Act in its current form can serve as an example for other countries considering regulating the use of DTC genetic tests. On the one hand, the Act appears to be too liberal compared to the European normative criteria in place.⁵⁵ For example, the Act does not regulate access to all genetic tests and only guarantees the European normative criteria for DTC genetic tests aimed at detecting the (risk indicators of) cancer and (risk indicators of) untreatable diseases. On the other hand, the permit system established under the Act effectively prevents individuals from getting access to DTC genetic tests in the Netherlands if they have questionable validity and utility. However, the permit system only applies to the Dutch jurisdiction, seemingly not taking into account that its guarantees can easily be by-passed by offering DTC genetic tests through the internet and performing the tests outside of the Netherlands.

Besides these practical problems and shortcoming it should be noted that the Act is not in accordance with EU law. The definition of population screening and the licence requirements are ambiguous. The permit system of the Act does not meet the rules of the Internal Market because of the absence of objective advance announce criteria. A permit system without foreseeable and accessible licence criteria could be an invitation to arbitrariness. It could be used to avoid sharp ethical discussions or decisions and inhibit scientific knowledge.⁵⁶ Furthermore, the Act conflicts with EU law because of its enforcement problems. It does not pursue its goal consistently and systematically, now that offering and practicing of DTC genetic tests for detecting (risk indicators of) cancer and untreatable diseases without a licence is unlawful⁵⁷ and practicing without permission is punishable. In addition, the Act conflicts with the Protocol⁵⁸ because it seems to be too liberal. Lastly, it could only be used with necessary adjustments as an example for other EU Member States, because it conflicts with the European law due to its interpretation and enforcement problems.⁵⁹

Conclusion

Worldwide there is growing concern about the availability of DTC genetic tests. Individuals can easily access these tests without adequate information and genetic counselling services being provided, let alone safeguards with respect to the validity and utility of the tests. This raises the question of whether making use of these testing methods to obtain information about the presence of genetic risks and hereditary diseases, and thus one's future health, truly reflects an expression of personal autonomy. It was argued here that there are good public health and human rights reasons to protect individuals from subjecting themselves to these tests.

⁵⁵ *Ibid*, pp. 1.

⁵⁶ Dutch Health Council, *Screening between hope and hype* (advies 2008/05), Den Haag: GR 2008.

⁵⁷ Article 2 WBO.

⁵⁸ It should be noted that the Netherlands has not yet ratified the Biomedicine Convention.

⁵⁹ R.E. van Hellemond, A.C. Hendriks & M.H. Breuning, 'Wet op het bevolkingsonderzoek op gespannen voet met EU-recht', *Nederlands Tijdschrift Europees Recht* 2010, pp. 245-251.

The need to regulate the use of DTC genetic tests follows from the standards adopted within the context of the Council of Europe and the EU. Despite the absence of a comprehensive European normative framework, important principles and norms relevant to the use of DTC genetic tests, and thus its supply and access to, have gained recognition on a European level, which implies that the validity and utility of DTC genetic tests are crucial factors when deciding on allowing the marketing of such a test. Furthermore, DTC genetic tests with far reaching implications for individuals should not be allowed without the supervision of a healthcare worker and appropriate non-directive genetic counselling being offered. Moreover, access to DTC genetic tests should be accompanied by rigorous informed consent procedures.

The Dutch Act on population screening is a unique piece of legislation regulating the use of screening programmes and also applying to DTC genetic tests. Yet in its present form, the Act cannot serve as an example for other countries considering the regulation of DTC genetic screening. The Act not only suffers from a number of practical problems and shortcomings, but is also inconsistent with some EU legal standards.

To conclude, a broad consensus exists among professionals in genetics that the implications of DTC genetic tests are far reaching and complex. Such testing should not be left to the free forces of the market, but should be accompanied by adequate information, and informed consent. There is – also in view of these concerns expressed by professionals – not only a need to revise the Dutch Act; it is above all important to elaborate on the emerging body of European legal standards applicable to DTC genetic screening. Offering genetic tests directly to individuals via internet raises complex legal questions that can not merely be answered by individual States. National measures can, moreover, easily be bypassed by making use of cross border constructions. Adequately protecting individuals against questionable testing kits therefore calls for international vigilance and comprehensive measures by the international community, in Europe to start with the Council of Europe and the European Union.