Commission of the Bishops' Conferences
of the European Community

COMECE

OPINION ON THE REGULATION OF MEDICAL DEVICES

AND OF IN VITRO DIAGNOSTIC MEDICAL DEVICES IN PARTICULAR

(Translated from French)

Commission of the Bishops' Conferences of the European Community

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Opinion on
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EXECUTIVE SUMMARY

The European Union is currently promoting the revision of the legislative framework that governs medical devices and *in vitro* diagnostic medical devices. As these devices are designed to help the treatment of persons and to improve their health, the COMECE Secretariat welcomes the aims of this revision: developing the independence and quality of the assessment of such devices before they are put on sale, improving their clinical assessment for as long as they are being used, and strengthening measures governing market monitoring and vigilance. As the voting date by the competent committee at the European Parliament approaches, the COMECE Bioethics Reflection Group is publishing their current Opinion which stresses the following key points:

1. The complexity of the data on the subject of genetics, the risks of being mistaken on the significance of the results, the serious nature of what they may potentially reveal in terms of disease or predisposition to a disease and consequently their potential emotional impact require correct information which enables the giving of free and informed consent. A medical doctor can best provide both the interpretation of the results and the appropriate support. This is particularly true as concerns prenatal diagnostic tests given the huge emotional burden generated by the revelation to parents that a foetal anomaly exists.

2. As the usefulness of genetic tests related to polygenic diseases is open to doubt, and they can raise anxiety or unjustified precautions, it would be adviseable that they should be refused certification, or at least that their commercialisation without a doctor's prescription should be prohibited on the grounds that they lack clinical validity.

3. Insofar as devices referred to above are only made available on a doctor's prescription, all publicity about them should be kept within the circle of health care professionals and advertising targeted at the general public should be banned altogether.

4. Subsidiarity plays a key role in this context. Member States are entitled "*to restrict or ban the martketing of a device when it may compromise the health and safety of a patient, user or third person*". The idea of safety shall not be reduced to its physical dimension only, since it is necessary to include also the psychological and social aspects, such as stigmatisation, all kinds of exclusion, discrimination in the context of professional work, creditworthiness for banking and insurance. Otherwise, a device may deviate from its intended medical purposes and be put to use for highly

dubious ones.

5. Predictive tests for genetic diseases should not be carried out for the purposes of selection of human beings according to their genetic characteristics but only "*for health purposes or for medical research*" (according to the wording of the Convention on Human Rights and Biomedicine).

6. The most vulnerable people should be specifically protected. It would be ethically unacceptable to conduct a predictive test for genetic disease on a child or on a person temporarily incapable of giving consent, if the test is not necessary for the treatment of the child during the period when he is under age, or of the adult during the period of his incapacity.

7. Despite of giving recognition to a certain number of ethical references, the instruments of the present revision – and this is to be regretted – make no explicit mention of the fact that "*national regulations relating to ethics continue to apply*" (as laid down in the Directive of 1998 on *in vitro* diagnostic medical devices currently in force), as well as make no explicit reference to the Convention on Human Rights and Biomedicine (as, again, was the case in the Directive of 1998).

8. While *in vitro* diagnostic medical devices are used on people of any age, even at the embryonic or foetal stage, it is legitimate to wonder why in the current revision a distinction is made between the individual and the foetus and the qualification as human being is denied to those at the foetal stage, given that EU law protects human life from the moment of conception. It appears that the possibility that a Member State might confer a level of protection to the human embryo, *in vivo* and *in vitro,* higher than that which is provided for in this revision, is being excluded in infringement of the subsidiarity principle. All this reveals the highly problematic – both legal and ethical – questions posed by practices such as antenatal diagnosis and pre-implantation genetic diagnosis.

9. The rule of taking into account major risks for third persons – and in consequence, for classification of an *in vitro* diagnostic medical device into Class D – must be applied as well when the devices are intended for "*detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring*"; or when they are intended for "*screening for congenital disorders in the foetus*", or even from now on, given biomedical innovations in the field of antenatal diagnosis, for the screening of congenital disorders at the embryo stage.

10. Given the proliferation of medical devices and of *in vitro* diagnostic medical

devices, it cannot be ruled out that some of them, in addition to safety and performance requirements which always have to be taken into account, do raise specific ethical issues that are serious in relation to respecting the dignity of the human beings at different stages of their life. This is true, for example, for every device that would include the use of human tissue, cells and substances of human origin, and this is especially true for human embryonic stem cells. The responsible certification bodies should in every case be required to check the compatibility of such medical devices with EU legislation, the EU Charter of Fundamental Rights and any internationally agreed standards.

In view of the important ethical values at stake, the COMECE Secretariat will continue to monitor this issue.

1. INTRODUCTION

In the European Union (EU), there is a legislative framework that currently governs medical devices[1], especially *in vitro* diagnostic medical devices (IVDMD).[2] The former cover a very wide range of products from adhesive bandages and contact lenses to breast implants, hip replacements and cardiac pacemakers. The latter devices comprise products that may be used for screening for and prevention of diseases, for diagnostic, for monitoring of prescribed treatments and for assessment of medical interventions.

But "*substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directives, i.e. the safety of the medical devices and their free movement within the internal market. Moreover, regulatory gaps or uncertainties exist with regard to certain products*"[3], and also the discovery of fraudulent practices[4] which provide evidence of the inadequacy of the checks currently being carried out on the manufacture of these different products.

1 Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMD) and Directive 93/42/EEC on medical devices (MD).

2 Directive 98/79/EC of the European Parliament and of the Council.

3 Proposal of the European Parliament and of the Council for a Regulation on Medical Devices, modifying Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/20109, of 26 September 2012. Explanatory Memorandum 1. Context of the Proposal. This text will from now on be referred to as the MD Proposal.

4 Cf. MEMO/12/710 of the European Commission,
http://europa.eu/rapid/press-release_MEMO-12-710_en.htm:
"*Recent events such as the scandal about fraudulent silicone breast implants and the problems occurring with certain metal-on-metal hip joint replacements have brought the above mentioned issues to the attention of the public at large.*"

2. OBJECTIVES OF THE CURRENT REVISION

This has prompted the European Union's decision to instigate a revision which "*aims to overcome these flaws and gaps and to further strengthen patient safety. A robust, transparent and sustainable regulatory framework should be put in place that is 'fit for purpose'. This framework should be supportive of innovation and the competitiveness of the medical device industry and should allow rapid and cost-efficient market access for innovative medical devices, to the benefit of patients and healthcare professionals.*"[5] These are the officially declared aims of the dual proposals for establishing a renewed regulation covering medical devices[6], and *in vitro* diagnostic medical devices in particular.[7]

There are three main goals of this thorough revision of the regulatory rules: first, guaranteeing a better quality of medical devices for the safety of patients (and to restore confidence that had been compromised by some serious cases of fraud); second, encouraging innovation and competitiveness of the medical devices industry, and, third, ensuring free circulation of these devices within the EU. Emphasis is placed on these medical devices as goods, on their design, their manufacture and their circulation.

5 *MD Proposal,* Explanatory Memorandum, 1. Context of the Proposal.

6 *MD Proposal,* op.cit. note 3.

7 Proposal of the European Parliament and the Council for a Regulation on *In Vitro* Diagnostic Medical Devices (IVDMD), dated 26 September 2012. This text will from here on be referred to as the *IVDMD Proposal.*

3. ACCESS TO THE TESTS: SHOULD THIS BE DIRECT OR THROUGH A DOCTOR?

The objectives quoted above fall within the competence of the EU and are completely legitimate. But the goods thus designed, manufactured and put on sale are still linked to the safety of human beings. Respect for human beings requires a permanent concern for the quality and a heightened level of safety of medical devices, and indeed it can be seen that this concern is omnipresent in the two Proposals for Regulation. But human health also depends upon a great many other factors which also have to be taken into account. More fundamentally, it is a matter of always taking care to ensure that the dignity and fundamental rights of people are respected, especially their right to be correctly informed in a way that enables them to give their consent that is free and informed. However, one neither has recourse to a genetic test nor receives the results of an *in vitro* diagnosis in the same spirit as placing an order or reading the instruction manual for a household electrical appliance.

The principle of free movement of goods should not therefore put up barriers to prevent the Member States from taking any necessary measures to ensure that information is conveyed to patients under the best possible conditions. However, Direct-to-Consumer Genetic Testing has sparked off intensive debate in Europe[8], especially in the European Parliament[9]. Given the complexity of the data on the subject of genetics, the risks of being mistaken on the significance of the results, the serious nature of what they may potentially reveal in terms of disease or predisposition to a disease (for a number of genetic diseases, in cases of absence of appropriate treatment), and the emotional impact linked to the image of the predictive power of genetics, there is absolutely no evidence that adequate information and appropriate support could be contributed by the manufacturers or retailers of these tests.[10]

Member States may decide, on the contrary, that it is indispensible to have a medical prescription with a doctor to provide both the interpretation of the results

8 Cf. European Academies Science Advisory Council (EASAC), Federation of European Academies of Medicine (FEAM), Direct-to-consumer genetic testing for health-related purposes in the European Union, July 2012.
http://www.easac.eu/fileadmin/Reports/EASAC_Genetic_Testing_Web_complete.pdf

9 Cf. European Parliament, Science and Technology Options Assessment (STOA), Direct to Consumer Genetic Testing, I POL/ A/ STOA/ 2007-11.

10 Cf. STOA, Direct to Consumer Genetic Testing, Conclusions – Policy Options.

and the appropriate support.[11] The European Convention on Human Rights and Biomedicine, which is now in force even though it has not yet been ratified by all EU Member States, states that a genetic test may not go ahead unless it is "*only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling*"[12]. There are many arguments that plead in favour of such measures[13], at least as far as genetic tests with high 'predictive' value[14] are concerned. The same is true for other tests whose results could give rise to a very strong feeling of anxiety, as used to be the case when testing for positive HIV/ AIDS in the days before the discovery of truly effective triple antiretroviral therapies. A fortiori, given the huge emotional burden generated by the revelation to parents that a foetal anomaly exists, prenatal diagnostic tests should only be carried out if there is also some medical monitoring[15]. Moreover, in as far as these different devices are only made available on a doctor's prescription, all publicity about them should be kept within the circle of healthcare professionals.

11 This is what is provided for in Article 1 (6) of the IVDMD Proposal: "*This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.*"

12 Council of Europe, Convention on Human Rights and Biomedicine, Article 12.

13 Cf. EASAC-FEAM, Direct-to-consumer genetic testing…: "*Based on the discussion of the Working Group, it seems to EASAC-FEAM that all kinds of genetic testing require an appropriate and relevant level of professional advice*".

14 Cf. STOA, Direct to Consumer Genetic Testing, Conclusions – Policy Options. See also the Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (referred to from here on as the 'Additional Protocol') whose Article 7 is worded as follows:

"*1. A genetic test for health purposes may only be performed under individualised medical supervision.*"

2. Exceptions to the general rule referred to in paragraph 1 may be allowed by a Party, subject to appropriate measures being provided, taking into account the way the test will be carried out, to give effect to the other provisions of this Protocol. However, such an exception may not be made with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices."

15 Cf. EASAC-FEAM, Direct-to-consumer genetic testing…, 4.1.2.: Excluding prenatal testing. "*Because of significant potential consequences for the mother and foetus, such testing requires the highest quality information, appropriate genetic counselling and closest medical supervision.*"

4. FREE MOVEMENT OF MEDICAL DEVICES, ETHICAL REQUIREMENTS AND MEMBER STATES' RESPONSIBILITIES

Other genetic tests that are likely to be used widely due to the fact that they are related to widespread polygenic diseases are – and shall doubtless be in the future – made available "*directly to the consumer*" by biotech companies, even though their usefulness is open to doubt and they can raise anxiety or unjustified precautions[16]. It would be particularly adviseable that they should be refused certification, or at least that their commercialisation without a doctor's prescription should be prohibited within the European Union or within the Member States, on the grounds that they lack clinical validity[17]. Member States would be very wise, with regard to such tests, to ban all advertising that targeted the general public. These issues should be examined throroughly within the Medical Device Coordinating Group (MDCG) as part of their twofold mandate: first, to draw up guidelines for security and performance for the manufacturers and notified bodies, and second, to assist the competent authorities of the Member States "*in their coordination activities in the fields of clinical performance studies, vigilance and market surveillance*."[18]

Article 20 of the IVDMD Proposal states that "*Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation*." The concept of free movement should therefore be defined in such a way that no obstacle would be placed in the way of Member States exercisising their responsibilities in the

16 Cf. COMECE Reflection Group on Bioethics '*Ethical and Cultural Aspects of Genetic Testing*' in *Science & ethics*, COMECE, 2008, p. 41: "*To make such tests available for general use could be of interest to biotechnology companies. Yet, their usefulness to the population is very limited because confronting a person with the potential risk of developing a particular illness can create great anxiety for that person and have detrimental effects, even when the risk is small. This imposes great responsibility on the medical staff and the health authorities. Respect for the person and concern for the common good can require resisting industrial and commercial interests*."

17 Cf. STOA, Direct to Consumer Genetic Testing, Conclusions – Policy Options. "*It seems crucial in this respect [mandatory pre-market approval] to include clinical validity (and utility) as criteria for the evaluating gene tests*."

18 According to Article 77 of the *IVDMD Proposal*, the principal tasks of the MDCG are given as: "(…) (c) *to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding […..] application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies ; and (d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical performance studies, vigilance and market surveillance*."

sensitive domain of *in vitro* diagnostic medical devices, and particularly regarding genetic tests.

As a rule, one can make the point that everything to do with the three main objectives for reviewing the regulations has been developed very thoroughly, and that in both Proposals very little space is given to the consideration of human values and factors. The prerogative of the Member States to enact laws requiring a medical prescription for certain tests has only been mentioned in passing[19]. Of course, as was recalled in the impact assessment of the current review, "*a central pillar of the regulatory system is the right of Member States to restrict or ban the martketing of a device when it may compromise the health and safety of a patient, user or third person or when the CE marking has been illegally affixed to a product.*"[20] This definition is to be found in both Proposals[21], and partially amends Article 20, yet there is a risk that the idea of safety will be reduced here to its physical dimension only, while it is necessary to include also the psychological and social aspects.

Both Proposals give explicit recognition to a certain number of ethical references. "*This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamenal Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.*"[22] However it is to be regretted that the Regulations proposed are presented as providing a satisfactory response to all ethical questions; this did not happen with the 1998 Directive which, with regard to the practice of *in vitro* diagnostic tests, inevitably involving samples taken from the human body, made reference to the Convention on Human Rights and Biomedicine, clearly stating that "*national regulations relating to ethics continue to apply*".[23]

19 Cf. note 11.

20 European Commission, *Summary of the impact assessment on the revision of the framework regulation applicable to medical devices*, Brussels, 26 September 2012.

21 "*Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it may take any necesssary and justified provisional measures.*" (Article 72 of the IVDMD Proposal). Cf. Article 7 of the MD Proposal.

22 *MD Proposal*, Recital 63; IVDMD Proposal, Recital 59.

23 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 concerning *in vitro* diagnostic medical devices, Recital 33. See also Article 1 (4).

In conformity with the EU Charter of Fundamental Rights, both Proposals provide for guarantees for the protection of personal data. Regarding medical research, they require that every clinical performance study of the devices being examined should be conducted with due respect paid to human dignity, to the right of physical and mental integrity, and in accordance with the principle of free and informed consent.[24] But why limit these last reminders to areas connected with medical research? At every stage, from the tested prototype and manufacture of medical devices to their utilisation for the benefit of patients, attention should be paid to protecting the confidentiality of the personal data collected, and also to fair access to the devices for which "*clinical validity*" has been tried and tested, and also to adequate information, to appropriate counselling and to obtaining consent.

Given the proliferation of medical devices and of *in vitro* diagnostic medical devices, it cannot be ruled out that some of them, in addition to safety and performance requirements which always have to be taken into account, do raise specific ethical issues that are serious in relation to respecting the dignity of human beings at different stages of their life. This is true, for example, for every device that would include the use of human tissue, cells and substances of human origin, and this is especially true for human embryonic stem cells. The responsible certification bodies should in every case be required to check the compatibility of such medical devices with EU legislation, the EU Charter of Fundamental Rights and any internationally agreed standards.

Practically no mention is made of these ethical requirements in either of the two Proposals. While they have been drafted in a way to avoid, in the name of the subsidiarity principle, the intervention of the European Union in domains belonging to the Member States, it is essential to put this explicitly in writing and to recognise very clearly in these domains what are the responsibilities of the Member States. But, as they are currently worded, both Proposals tend to present national laws as obstacles to the free circulation of medical devices.

24 *MD Proposal* and *IVDMD Proposal*, Explanatory Memorandum, 3.11, Fundamental rights. Recital 43 of the *IVDMD Proposal* also makes reference to the ethical principles of the World Medical Association's Declaration of Helsinki.

5. PARTICULAR ISSUES

i. Classification of *in vitro* diagnostic medical devices and genetic testing on human foetuses and embryos

"*Devices shall be divided into class A, B, C and D, taking into account their intended purpose and inherent risks.*"[25] Annex VII lists the various purposes of *in vitro* diagnostic medical devices and the classes to which they are allocated. Class D, the category requiring the strictest controls, includes in particular those devices designed to detect the presence of transmissible agents endangering not only the infected person but also third persons (as in cases of blood transfusion, or human tissue and organ transplants). The same rule of taking into account major risks for third persons – and in consequence, for classification into Class D – must be applied when the devices are intended for "*detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring*"[26] or when they are intended for "*screening for congenital disorders in the foetus*"[27], or even from now on, given biomedical innovations in the field of antenatal diagnosis, for the screening of congenital disorders at the embryo stage.

It is impossible not to see the clumsiness, dithering and fuzziness in the wording concerning prenatal life. Mention is made, in the passage quoted above, of the "*significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring*" It is legitimate to wonder why the text should make this distinction between the individual and the foetus and deny the qualification as human being to those at the foetal stage. Similar remarks can be made about other passages. It cannot be denied, moreover, that in EU law[28] human life is protected from the moment of conception. But the Proposal appears to exclude the possibility that a Member State might confer a level of protection of the human embryo, in vivo and in vitro, higher than that which is provided for in the text. This would therefore be an infringement of the subsidiarity principle. All this reveals the highly problematic – both legal

25 *IVDMD Proposal* , Article 39, *Classification of in vitro diagnostic medical devices.*

26 *Ibid*., Annex VII, 2.3. (c).

27 *Ibid*., Annex VII, 2.3. (j).

28 Cf. Judgment of the European Court of Justice (Grand Chamber) of 18 October 2011 in the case *Oliver Brüstle vs. Greenpeace* eV (in particular, see the wide definition of 'embryo' that was adopted in that judgement).

and ethical – questions posed by practices such as antenatal diagnosis and pre-implantation genetic diagnosis.

ii. Protection of persons incapable of giving valid consent

It is generally recognised that an individual, even if he has asked for a diagnostic test, has "*the right to know and the right not to know*" and may therefore refuse to allow anyone to inform him of the results of the test[29]. It does happen that some people who have taken the step of seeking to find out their risk of developing a very serious genetic disease do hold back at the last minute from coming to receive their diagnosis.[30] It would then be ethically unacceptable to conduct a predictive test for genetic disease on a child or on a person temporarily incapable of giving consent, if the test is not necessary for the treatment of the child during the period when he is under age[31], or of the adult during the period of his incapacity.

iii. Social risks

The two Proposals take into account the physical risks entailed either by a mistaken diagnosis or by dangerously unsafe or defective devices. But *in vitro* diagnosis can also expose the persons using them to serious risks of a social nature, such as stigmatisation, all kinds of exclusion, discrimination in the context of professional work[32], creditworthiness for banking and insurance. It is therefore vital to observe the rule of protection of confidentiality of data gathered by *in vitro* diagnosis. This confidentiality must be protected from every organisation and every person who

29 Cf. Convention on Human Rights and Biomedicine, Article 10 (2): "*The wish of individuals not to be so informed shall be observed*." Some exceptions to this rule are recognised: in cases of risk of transmission of a particularly serious infectious disease, or when the results of a genetics test carried out on one individual could be relevant to the health of other members of the same family (See also *Additional Protocol*, Article 18.)

30 This behaviour has been especially studied in the context of Huntingdon's disease.

31 Cf. COMECE Reflection Group on Bioethics: '*Ethical and Cultural Aspects of Genetic Testing*' in *Science and Ethics*, COMECE, 2008, page 41: "*This same respect for the liberty of the other person also requires that minors are not submitted to such tests, except where there is a strong case in the interests of their own health*." The Additional Protocol provides, as a derogation and under certain conditions, that "*the law may allow a genetic test to be carried out, for the benefit of family members, on a person who does not have the capacity to consent*". But still this is only if the specified conditions are met.

32 Cf. COMECE Reflection Group on Bioethics 'Comments on Opinion No. 18 of the European Group on Ethics (EGE) concerning Ethical Aspects of Genetic Testing in the Workplace, in Science & Ethics, COMECE, 2008, p. 43-44.

might have an interest in finding out about another person's state of health. Here the limitation of the objectives for which predictive tests for genetic diseases may be carried out acquires its full meaning: not for the purposes of selection of human beings according to their genetic characteristics but only "*for health purposes or for medical research*" according to the wording of the Convention on Human Rights and Biomedicine[33].

33 Convention on Human Rights and Biomedicine, Article 12. See also Article 3 of the European Union's Charter of Fundamental Rights, which specifies "*the prohibition of eugenic practices, in particular those aiming at the selection of persons*."

6. CONCLUSION

Further to all these observations, it seems that the protection of users of medical devices, particularly *in vitro* diagnostic medical devices, needs rules designed to obtain a high level of quality of these devices, in a manner that guarantees the safety of patients and restores confidence that has been partially eroded in recent times. To this end, the two Proposals legitimately seek to develop the independence and quality of the assessment of such devices before they are put on sale, to improve their clinical assessment for as long as they are being used, and to strengthen measures governing market monitoring and vigilance. Another objective, which is not unconnected with those already described, is to encourage the free circulation of these goods throughout the European Union and to develop this sector in such a way that it will become an essential vector of economic growth in Europe[34].

These objectives lie fully within the competences of the European Union. They cannot disguise the fact that medical devices, particularly *in vitro* diagnostic medical devices, are linked to the health of human beings and that their use may have widely different consequences. Although designed to help in the treatment of persons and to improve their health, they are also capable of having extremely harmful effects when they are not well understood, not properly used or because there is a lack of support provided to patients who discover that they are suffering from a particularly serious disease. Moreover, such devices may be used on people of any age, even at the embryonic or foetal stage, thus causing great anxiety to the parents who find themselves confronted by extremely serious ethical questions. Furthermore, they may deviate from their intended medical purposes and be put to use for highly dubious purposes.

The use of these devices, especially *in vitro* diagnostic devices, therefore raises (for some of them) highly sensitive ethical and legal issues. These are scarcely mentioned in the two Proposals, and do not necessarily fall within the competences of the European Union. This reveals the need for a deepened ethical reflection and for national laws guaranteeing the respect of the dignity of all human beings and of their fundamental rights, and also the protection of the most vulnerable. While the EU is certainly right to concern itself with rules for the production and commercialisation of these devices, no Member State should feel itself excused from ensuring that their use should comply with the overarching principles and generally accepted values in the territory for which it is responsible and, more widely, in the European Union.

34 Cf. European Commission, Communication from the Commission to the European Parliament, the Council […] COM(2012)540 final, *Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals*.

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