17 November 2014

Subject: European Patients' Forum recommendations for the Council on in vitro diagnostic medical devices

In vitro diagnostic medical devices provide important information on medical conditions that may assist healthcare professionals and patients in delivering correct diagnosis, in monitoring the progression of an illness or impact of a prescribed treatment, and for screening. They are particularly important to the patient community as obtaining timely diagnosis is essential in many chronic and long term conditions.

While they usually do not pose direct risks to patients, ensuring the quality of these devices as well as education of healthcare professionals and information to patients is essential because healthcare decisions are taken based on the data these devices provide.

For aspects that are common with the Regulation on Medical devices (e.g. the governance, the reform of notified bodies) we refer you to our position on medical devices. However, there are some specific issues related to information to patients, patient safety and quality of care as well as genetic testing which we would like to address specifically in this letter.

The amendments mentioned below refer to the position of the European Parliament available here: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2013-427

Better information to patients on vitro diagnostic medical devices

The European Patients 'Forum strongly welcomes provisions proposed by the European Commission and the European Parliament to strengthen the quality of information provided to patients on in vitro diagnostics. The European Parliament's position is also a step forward in terms of transparency.

We strongly support changes to Annex I, Section 17, proposed by the European Commission to add further information requirements for self-testing and near-patient testing devices[1]. We also welcome the proposal from the European Parliament that instructions for use should be reviewed by healthcare professionals and patients (Amendment 212), as it is currently the case for medicinal products' information leaflets.

We strongly welcome Amendments 14, 15, 16, 18 and 100 that provide for access for the public to parts of the Eudamed database and making available to users evidence on clinical validity, a regular overview of vigilance, and post-market information.

We also welcome Amendments 17 and 102 that provide for a summary of safety and performance reports to be made available to the public for higher-risk devices (Class C and D). We believe,

[1] devices that are not use in a laboratory environment

however, that the Commission should involve users (Patients, consumers, healthcare professionals) in the drawing up of the format to ensure it corresponds to their needs.

We strongly support of Amendment 74 that prohibits misleading information on in vitro diagnostics medical devices.

Further to this, EPF had called for the development of guidelines for professionals on how to communicate results of diagnostic tests with the input of patients' associations. We believe these guidelines are strongly needed to ensure that outcomes of tests are communicated appropriately to the patients, and that patients receive adequate support and information about the diagnosis.

Adequate in house exemptions for health institutions

Under the current legislative framework, devices which are manufactured by healthcare establishments and only used on their own patients are exempt from the requirements of the Medical Devices Directives (it is called the in house exemption). While this exemption is maintained in the proposal for a Regulation, the European Parliament report clarifies the definition of health institutions to ensure it excludes commercial laboratories (Amendment 52). It clarifies that health institutions have to comply with standards for quality management system requirements particular to medical laboratories. EPF welcomes these new rules that in our view will ensure better quality of in-house in vitro diagnostics. Experience from patient organisations indicates that currently the quality of lab tests can vary.

Regulators need, however, to ensure that appropriate exemptions are in place to ensure that health institutions can continue to design tests for rare genetic diseases and to reach out to specific communities. We welcome Amendments 7 and 69 that aim to ensure flexibility to address patients' specific needs in risk categories A, B and C of devices.

As regards Amendment 70 that put in place stricter rules for exemptions for Class D devices, we welcome this provision as a principle, but there has to be enough flexibility to ensure patients have access to the test they need. For instance, patients should be appropriately informed to give their consent when the test is not CE Marked.

Devices subject to a medical prescription

The report of the European Parliament seeks to make some in vitro diagnostic devices available only after a medical prescription – this would apply to all class D devices, and class C when they are genetic tests or companion diagnostics. EPF welcomes this provision as it ensures patients will get appropriate medical advices before and after taking the test.

Genetic Testing

The European Parliament made it clear that genetic tests are within the scope of this Regulation, which EPF supports as we believe it is possible to set standards at EU level for the clinical validity of the tests and to ensure patients are provided with clear high quality information. We support the first part of Amendment 33: "Clear rules on the application of DNA tests are important. It is however advisable to regulate only on some basic elements and leave room for the Member States for more specific regulation in this area".

Definition of genetic testing

According to the European Parliament's position, a device for genetic testing should be defined as "an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development". (Amendment 49)

EPF calls for the modification of this definition which is incorrect as it does not encompass for example mutation caused by cancer. It should be clear that the purpose of an vitro diagnostic medical device is to examine DNA and RNA to identify a genetic characteristic of a person. ?

Rules for genetic testing

The European Parliament position states that a device may only be used for the purpose of a genetic test if the instruction is given by persons admitted to the medical profession after a personal consultation. (Amendment 271).

We call for amending the wording "person admitted to the medical profession". It does not take into account the development of new skills in certain healthcare professions, such as nurses and pharmacists, clinical genetic scientists, and genetic counsellors.

Genetic Counselling

The European Parliament also makes genetic counselling mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed (Amendment 271).

The counselling has to include medical, ethical, social, psychological and legal aspects. It needs to be carried out by physicians qualified in genetic counselling. The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or their family members. It is not obligatory where the patient has already been diagnosed, and for companion diagnostics (Amendment 34).

The European Patients' Forum does not support these measures: Genetic conditions should not be treated as one condition, as there are different risk brackets, there will be some instances where counselling is not necessary. Guidelines for when genetic counselling is necessary should be drafted by health care professionals' societies. As cultural differences could dictate whether counselling is necessary, the member states should be allowed to decide on how to apply the guidelines.

Consent for genetic testing

According to the European Parliament's position, genetic tests can only be used after the person concerned has given free and informed consent to it.

EPF supports the provision on free and informed consent. We believe informed consent is essential, and should ensure patients know what the test will do and any risks associated.

However we do not support that the patient should have to provide consent in writing, as many different valid types of consent exists across Europe.

Clinical performance studies

We believe that the revision of the in vitro diagnostics Regulation provides a crucial opportunity to improve the rules as regards the conduct of clinical investigations and the collection of clinical data.

We welcome the reference to the World Medical Association's Declaration of Helsinki, including its article 15 which states clearly that an ethical assessment needs to be carried out before a clinical study begins (Amendment 22).

The European Parliament report also stated that rules for subjects unable to be give consent have to be in line with the rules for clinical trials (Amendment 5). EPF supports the new definition of "ethics committee" introduced by MEPs which includes at least one patient or patient representative (Amendment 57). The scope of patient involvement was not clearly defined in the European Commission's proposal. However, EPF believes that qualifiers in the European Parliament's position ("well-experienced and knowledgeable") could in practice lead to ethics committees excluding patients on the pretext that they cannot find suitably knowledgeable representatives, therefore we call on the Council to remove these qualifiers.

We support the drawing up of guidelines for patient involvement in ethics committees (Amendment 167).

EPF strongly supports the rules to improve transparency on clinical investigations and their results. We believe this is essential to ensure trust and confidence in the safety and quality of devices, and to empower patients and healthcare professionals to make informed decisions. We support that a layperson summary of results of clinical performance studies must be made available to the public (Amendments 23, 175). But we believe that core elements of the summary need to be defined by the Commission with the participation of key stakeholders including patients and consumers, healthcare professionals and researchers to ensure these groups have access to the quality information they need, in an adequate format. We welcome the provision for the voluntary sharing of raw data, but we believe the Commission needs to consult with stakeholders when drawing up the guideline to ensure data are shared appropriately, with consideration for the privacy of study participants, and in a user friendly way.

Vigilance

Though the risk with in vitro diagnostic devices is different from the risks posed by other medical devices, EPF believes taking the same approach in this Regulation as in the medical devices Regulation is relevant. While the risk is indirect, consequence of a wrong result can be important for the patients.

Therefore we strongly support the additional vigilance measures the European Parliament introduced, including:

- A regular overview of vigilance information for the public (Amendment 16, 261)
- Provisions to ensure that Member States take appropriate measures, including targeted information campaigns, to encourage users to report (Amendments 27, 180)

- Replacement of the wording serious incidents by “incidents” in various instances in the vigilance chapter of the Regulation (Amendments 180, 181). We welcome this as the definition for serious incidents is very narrow and would only encompass incidents that have provoked death, permanent disability, or had life-threatening consequences. In our view it is important to collect information on all incidents to ensure patient safety and to better prevent incidents with medical devices.

Discrimination and Stigma

EPF believes it is important to ensure the testing is done respecting the confidentiality for the patient. We also call on the EU institutions to fight the discrimination and stigma related with the diagnosis of some chronic or long term conditions in the EU.

Conclusions

We thank you for your attention and for taking the patients’ perspective into account in your work on in vitro diagnostic medical devices. The European Patients’ Forum is committed to working closely with the European Institutions and stakeholders to ensure that in vitro diagnostic devices are safe and of high quality.

The **European Patients’ Forum (EPF)** was founded in 2003 to ensure that the patients’ community drives policies and programmes that affect patients’ lives to bring changes empowering them to be equal citizens in the EU.

EPF currently represents 64 members, which are national coalitions of patients organisations and disease-specific patient organisations working at European level. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases throughout Europe.

EPF’s vision for the future is that all patients with chronic and/or lifelong conditions in the EU have access to high quality, patient-centred equitable health and social care.

The EPF strategic goals focus on areas such as health literacy, healthcare design and delivery, patient involvement, patient empowerment, sustainable patients’ organisations and non-discrimination.

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This position statement arises from the EPF 2014 Work Programme, which has received funding from the European Union, in the framework of the Health Programme.