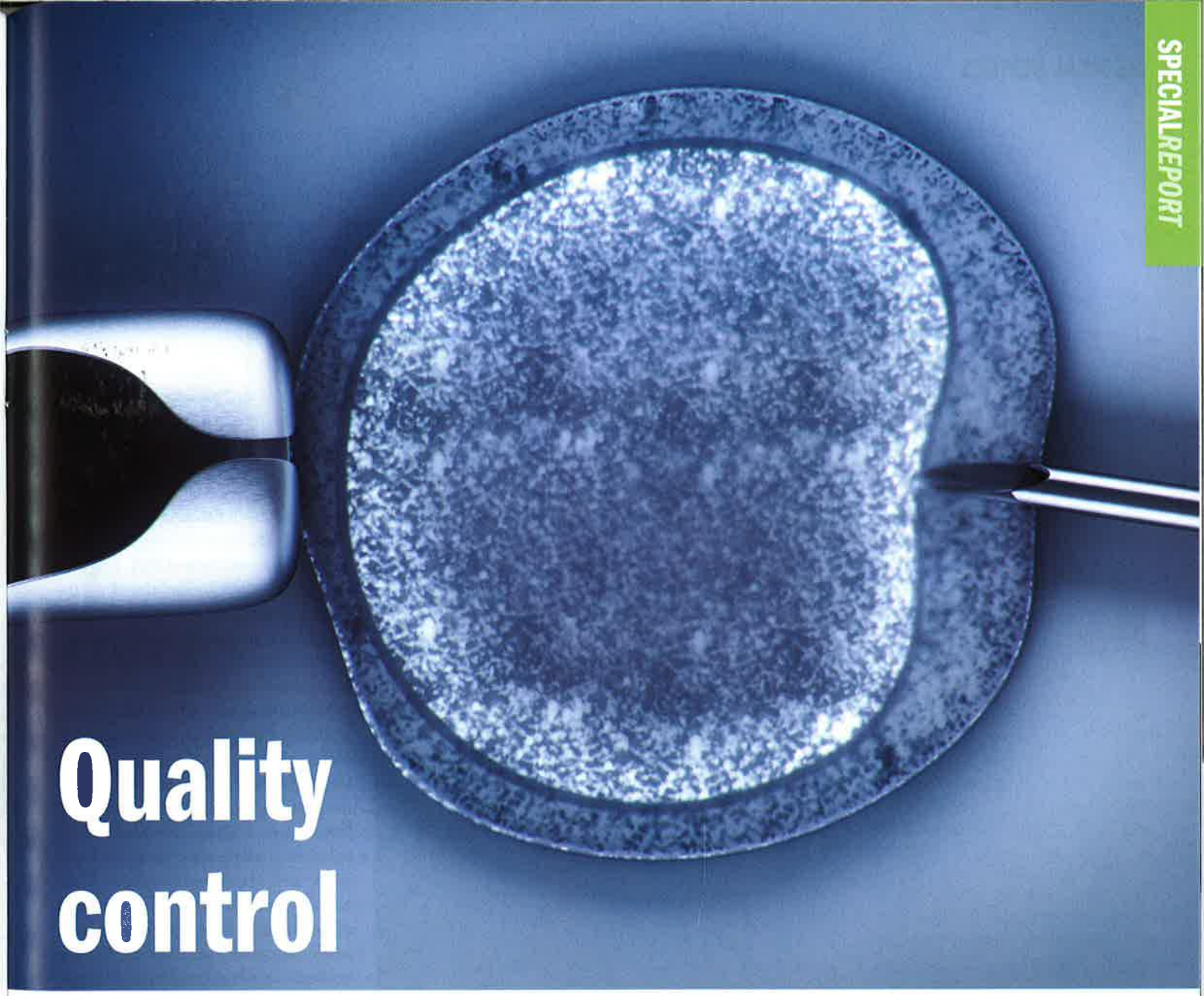


# Quality control

The EU's medical devices directive currently fails to ensure that low quality products do not reach the European marketplace, warns **Peter Liese**

In vitro diagnostics (IVD) medical devices are intended for diagnostic use outside the human body, which applies to blood-sugar measuring, HIV tests and DNA tests, for example. Without a proper diagnostic, no proper treatment or prevention of disease is possible. That is why we should not look upon IVD medical devices as the "little sister", but as the "parents" of medical devices and perhaps the parents of all therapies.

At present, the current directive on in vitro medical devices doesn't ensure that low quality IVD medical devices are not placed on the European market. In the past, for example, there have been cases where a low quality HIV test was placed on the European market with a CE-label – a mark declaring that the product meets the requirements of all relevant EU directives. A scientific institute had already determined before the notified bodies approved the CE-label that these tests find many more false negative results than other available HIV tests. This means that the tests found that there was no virus when in fact the patient had been infected. However, this product was available for years on the EU market. If a blood transfusion is performed on the basis of a false negative result for HIV, this is a life-threatening risk for the recipient of the blood transfusion. Also, those infected with HIV that receive a false negative test may put their partners at risk. In a way, bad performing HIV tests are more threatening for people's health than low quality breast implants or hip implants. Similar cases have been reported with hepatitis C, which is still a life threatening disease →

Peter Liese is parliament's rapporteur on medical devices and in vitro diagnostic medical devices

by the creation of a transparent and sustainable regulatory framework. I support this proposal in general, but, from my point of view, medical devices regulation needs to be improved if it is to ensure the safety of patients.

> *"Medical devices regulation needs to be improved if it is to ensure the safety of patients"*

One important group of diagnostics being affected by the revision is the one of DNA tests. The commission's proposal mainly regulates how DNA diagnostics and other IVDs are placed on the market. However, I propose regulation for at least minimum standards on the application of those tests. For instance, DNA tests should be accompanied by appropriate counselling provided by qualified staff, as the consequences of such tests can be significant for the involved persons. Experts and many international organisations, like the Council of Europe, organisation for economic cooperation and development and the European society for human genetics have time and time again articulated their position that, in many cases, the framework in which a product is applied is even more important than the quality of the product. It is very important to respect the principle of informed consent, especially in DNA testing. This has also been requested by the European parliament several times. As a result, I introduced respective wording in the draft report. Of course there is consensus that it should not be the intention of the European Union to limit the access of patients to DNA tests, but appropriate genetic counselling should be offered in any case to provide information on the consequences before a test is performed. To respect the principle of subsidiarity it should be left to the member states to regulate the details, and national legislators should have the option to go further than the regulation requires. One can even argue that it is mandatory to include informed consent in the proposal because it is a crucial element of the charter of fundamental rights, which is legally binding for the European Union.

and cannot be treated properly. It has been reported that an expert for DNA tests has sent the same sample to four different laboratories and received four different results. These are the reasons why we must improve our system.

The commission's plans for a revised regulation of the parliament and of the council on in vitro diagnostic medical services are therefore supposed to overcome divergences in the interpretation and application of the present rules across member states. Patient safety is meant to be increased





# Safety first

Pan-European legislation is needed in order to prevent a repeat of the PIP breast implant scandal, argues **Nora Berra**

There will be few who cannot recall the Poly Implant Prothèse (PIP) implant scandal which erupted in France in 2010 whenever new legislation to encompass medical devices comes up for discussion. What this unprecedented healthcare drama, which touched the lives of thousands of women all over the world, actually succeeded in doing was to bring a host of failings in the current system to light.

It was with this in mind that the European commission adopted an ambitious regulatory proposal covering the entire lifespan of medical devices. In a unique market, where products are able to circulate freely, only transversal legislation, directly applicable in all EU countries, can provide us with the assurance that all European citizens will be afforded the highest level of safety. The introduction of a European regulation to take the place of the current directive is a move in this direction.

Insofar as this text defines the requirements imposed upon both economic operators and certification authorities, the compliance checks required prior to both marketing and the statutory marketing procedure and the measures to ensure a level of vigilance and surveillance appropriate to the risks which such products could present, the opinion of the committee on internal market and consumer protection makes perfect sense.

In order to avoid any disparity of interpretation and secure the same level of safety across the EU, the committee must ensure that a given product has the same definition and satisfies the same quality and safety requirements in all member states. What I wanted to do in my report, therefore, was put forward a certain number of specifications and clarifications concerning the scope of this regulation, so that we may be sure that it does, indeed, cover all products with characteristics similar to what defines medical devices. In the case of devices referred to as 'borderline', it was also important to ensure that a legislative context, as well as a framework, could be found which was suited to their purpose and the risk which they presented.

The strengthening of the relevant legislation will also, inevitably, require a greater degree of rigour on the part of cer-

> *"In a unique market, where products are able to circulate freely, only transversal legislation, directly applicable in all EU countries, can provide us with the assurance that all European citizens will be afforded the highest level of safety"*


tification authorities. Where private law bodies certify private companies, we must limit any relationships of proximity which could be established and take steps to avoid any conflicts of interest. Only the independence and standard of evaluation of devices before they are marketed can safeguard public confidence, which is vital for the economy of healthcare sectors.

In the case of the most innovative at risk devices, the conformity investigation conducted by such bodies, in terms of expertise and probity, which frequently varies from one to another, cannot suffice to identify every inherent risk. In the absence of guidelines to encompass the clinical evaluation of these devices, a third, pan-European authority, with indisputable collegiate expertise, should undertake a prior, systematic and independent evaluation of their performance and all the risks involved in their use.

Given that, in the case of a number of these products, a full risk assessment cannot be undertaken in advance, a centralised auditing system should also make it possible to identify, at an early stage, those requiring special post-marketing monitoring. For, if pre-marketing checks of medical devices are to be tightened, the same should be the case with their post-marketing monitoring plan, supervisory mechanisms and monitoring measures. Indeed, once in circulation, several parameters could call the established performance level of a device into question.

The multiplication of undesirable secondary effects, the use made of a device by the patient or the healthcare professional, unsuitable reutilisation or reprocessing, the arrival of more advanced devices, could lead manufacturers or authorities to review the specifications of a product or its utilisation requirements, and, even, in some cases, to withdraw it. Post-marketing monitoring is, therefore, essential.

Strengthening this aspect of the process will require true device traceability and the creation of a large database which could be used to cross-check all reports. Its efficacy would depend upon a proper exchange of data among all players within the system together with the prompt, appropriate processing of that data.

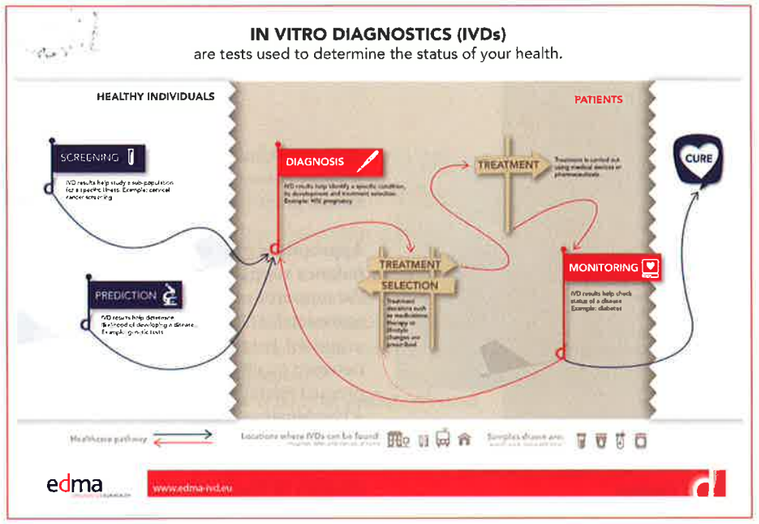
This new regulation will give the European Union a truly appropriate tool to prevent the occurrence of any new scandals. The European parliament must play its part in ensuring that the regulation addresses every public concern. ★

*"Only the independence and standard of evaluation of devices before they are marketed can safeguard public confidence, which is vital for the economy of healthcare sectors"*

Nora Berra is parliament's internal market and consumer protection rapporteur on in vitro diagnostic medical devices



# European Regulation:
## Understanding the Specificities of In Vitro Diagnostics




Regulating medical technology has always been a balancing act. On one hand ensuring that safeguards are in place to guarantee the availability of safe and effective devices while on the other hand ensuring innovative technologies reach those who need them rapidly. Failing to reach this balance point can have a detrimental impact on patients.

Parliament is considering not one but two new regulations which will guide the future legal framework of medical technology for the coming decades. One is the regulation on medical devices, which covers the majority of medical technology and the other is the in vitro diagnostics (IVDs) regulation, which covers only those devices used to analyse samples taken from the human body. This ranges from blood samples analysed in a clinical laboratory, rapid urine tests performed at the point of care to self-testing devices used by patients with chronic diseases such as self-monitoring of blood glucose levels by patients with diabetes.

The first question that arises when discussing these proposals is the need for having two different laws, especially knowing that the text is actually very similar, if not identical. Essentially the answer to the question lies in the balance point and the core nature of IVDs.

IVDs by their very nature do not interact with a patient, ever. Any sampling device such as a needle or a lancet that may be used to obtain a sample for analysis is a medical device, not an IVD. This means that the direct risk to a patient from an IVD is negligible. However, IVDs provide critical information for patients and health professionals to diagnose, monitor and manage their medical conditions. The quality of information IVDs provide and their indirect risk is no less important and therefore addressed in a different way.

Guaranteeing their safety and effectiveness lies in these key differences:

- **Role of common technical specifications** - The performance criteria set by scientific and clinical experts to ensure the safety of IVDs has been successfully executed for a decade. Moreover, they have effectively controlled the quality and the nature of information generated by IVDs.

- **Concept of reference laboratories** – An informally created concept of reference laboratories within the IVD space enables internationally renowned centres of scientific excellence to assist regulators in establishing their performance and strengthening the safeguards in place for IVDs. These reference laboratories will have a critical role to play in the post-market control phase of IVDs by analysing IVDs that are collected by authorities or notified bodies to ensure that they are indeed performing to a level that guarantees their safety and effectiveness.

Thus understanding and building into the IVD regulation the specificities which set apart in vitro diagnostics from other devices will enable the new regulations to successfully strike the right balance between safeguarding public health and ensuring access to critical diagnostic technologies throughout Europe.

**Serge Bernasconi, CEO,** European Diagnostic Manufacturers Association, EDMA