

European Civil
Justice Systems

An Informed Dialogue Supporting Safe Innovation In Medical Technology

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Policy Brief

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The Foundation for Law, Justice and Society

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The Foundation for Law, Justice and Society

European Civil Justice Systems

The CMS/Swiss Re European Civil Justice Systems programme aims to evaluate all options for dispute resolution in a European state, and to propose new frameworks and solutions. It encompasses a comparative examination of civil justice systems, including alternative dispute resolution and regulatory redress systems, aspects of system design, procedure funding and outputs. It aims to analyse the principles and procedures that should, or do apply, and to evaluate effectiveness, in terms of cost, duration, and outcomes in redress and achieving desired behaviour.

The programme also involves research into substantive EU liability law, notably consumer and product liability law, harmonization of laws in the European Union, and in particular the changes taking place in the new Member States of central and Eastern Europe. The programme receives research funding from the Swiss Reinsurance Company Limited, the European Justice Forum, and the international law firm CMS.

This policy brief expresses the views of the two authors. It has, however, been informed by discussions involving the following, but who should not necessarily be taken as agreeing with the views expressed: John Wilkinson (MHRA), Jonathan Mogford (MHRA), Graeme Tunbridge (MHRA), Niall MacAleenan (HPRA), Loraine Nolan (HPRA), Sabina Hoekstra-van den Bosch (Philips), Jonathan Groves (Philips UK), Neil Mesher (Philips UK), Erik Klassen (Medtronic), Zeger Vercooteren (Johnson & Johnson), John Brennan (EUCOMED), Mike Kreuzer (ABHI).

Executive Summary

- This policy brief addresses a series of interrelated questions on how regulatory reform in the European Medical Devices sector should proceed. The following issues are key:
 - How do we ensure patient safety and care?
 - How do we balance safety and innovation?
 - How do we successfully operate a sophisticated but complex multi-actor pan-EU regulatory system, to maximize public confidence in it?

- The European medical technology sector is subject to a comprehensive regulatory system, which conforms to the EU regulatory matrix applied to all engineered products (the New Legislative Framework). The regulatory systems for chemical, biocidal, medicinal, and engineered products are all complex — and different from each other. The combination of complexities and different architectures gives rise to inherent confusion for the public, and for many health-care professionals.

- Extensive debate has arisen on reform of the medical technology regulatory system. Reform is necessary for technological reasons in order to introduce a series of changes, but the debate has been influenced by public and political statements in response to some high-profile failures, involving orthopaedic implants and the PIP breast implant scandal.

- *It is proposed that the key to successful operation of the system for regulatory safety lies in ensuring that every actor, both at institutional and human professional levels (regulator, manufacturer, compliance, marketing, clinical, user) needs to work together in an integrated fashion, since the reliable performance of every function is essential. There needs to be closer cooperation and support between the multiple actors. There should be strategic and ongoing review of the various functions and their performance and integration.*
The question that therefore arises for governments, regulators, industry, health-care professionals, and patients is how these challenges should be addressed.

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Safety and regulation: Public expectation vs regulatory complexity

What do we want from medical technology, and how can we get it? These simple questions demand complex answers, each of which must be examined carefully, particularly given the increasing number of sectoral reforms and resultant conflicts between values, expectations, technology, and practice that are expected over the next few years.

The European medical technology sector is subject to a comprehensive regulatory system, which conforms to the EU regulatory matrix applied to all engineered products — now called the New Legislative Framework.¹ It is not widely understood outside the sector that this matrix differs from the various matrices that apply to chemical, biocidal, and medicinal products. Many health-care professionals and patients wrongly assume that medicines and medical devices are examples of the same generic type, and that the same regulatory approaches are appropriate for both. Rather, the nature of medical devices requires that safety is controlled by an appropriate, distinctive model.

The medical technology sector, and its regulatory system, has suffered from adverse publicity generated from a small number of high-profile failures, notably the PIP breast implant scandal — a rare example of clear fraud by a manufacturer.² Public and political responses to PIP have raised issues over what reforms might be relevant, and diverse answers have been raised.

Discussion is hampered by the inherent complexity of the European regulatory system for medical devices. It involves multiple actors, operating in ‘vertical’ regulatory chains and across ‘horizontal’ national boundaries.

Let us look first at expectations. Healthy individuals and patients wish for ever more scientifically advanced means of staying healthy, diagnosing and treating illness, and providing social care. But the advances in medical technology needed to deliver ever more sophisticated responses to such expectations come at significant cost to the health-care sector. Industry needs to earn enough from products to make a fair return for capital employed and to be able to fund further innovation and development. Patients expect products and procedures to be safe, but — as with pharmaceuticals — there is no absolute guarantee of safety. Regulatory systems are complex and require resources to maximize effectiveness. Risk is inherent in all medical procedures, and especially when medical technology pushes at boundaries of innovation and scientific advancement.

A particular series of challenges arises in relation to medical technology. Firstly, both the scientific aspects and regulatory systems are complex and at times difficult to understand. The public expectation is that products will be absolutely safe, despite the fact that (as noted above) this is impossible to guarantee. When a safety problem occurs, the widespread assumption among the public is that the regulatory system governing medical technology is similar to that for medicines (involving clinical trials and licences granted by public authorities), a misconception that leads to considerable confusion regarding the nature of the more decentralized system for medical devices. This typically results in calls by groups of affected patients, magnified by the media and subsequently taken up by politicians, to reform what they see as an inexplicably lax system in order to bring it more closely into line with the regulation of medicinal products.³

It should be understood that the inherent differences between product types, their risk profiles and economics (specifically, medicines and medical devices) support their being regulated by approaches

and systems that are specifically focused and comprise different elements.⁴ Most medical devices are revised and developed in some way on a constant, regular, iterative basis. It follows that there is little logical necessity — and it may be unethical — in order to achieve acceptable safety, to subject every ‘new’ device to extensive clinical evaluation and scrutiny by a public body — such as devices that are simply improvements on a previous design — as is the case for a fixed biochemical compound that does not evolve and may be used for many years in the same form in which it was developed. If such a system were adopted, the additional costs and delays would disincentivize development of useful products, and many small manufacturers would find it uneconomic to develop and market new products. Health care and people’s state of health would clearly suffer.

Furthermore, unlike the relatively small number of pharmaceutical product categories and new compounds, there are thousands of different types of medical devices, comprising widely differing risk profiles. A rational response to this fact necessarily involves a differentiated regulatory approach between different classes of devices.

An outsider might wonder why one should have any trust in a regulatory system that involves public authorities that do not licence or inspect manufacturers, privatized ‘regulators’ in the form of notified bodies that can have variable standards and be purchased by the manufacturers that they contract with, manufacturers who hold considerable personal regulatory responsibility and who do not undertake clinical trials on every product, and mutual recognition between bodies in different European states. Robust answers can be given to all these points, but such description is outside the scope of this policy brief: the key point is that the system is not readily grasped by a non-expert.

So the core challenge is how to operate a regulatory system that people outside it have great difficulty in understanding and therefore having trust in

Sector-specific challenges

The next few years are likely to see a series of challenges for the regulation of medical technology.

These include:

- increasing restrictions in public funding that challenge the resource capabilities of competent authorities and public funding for core activities such as running databases;
- variations in resources, functionality, and effectiveness among public authorities;
- variations in performance of notified bodies;
- trends towards increased transparency of all data and increased availability of clear evidence on which to base decisions;
- the need for increased efficiency at all levels;
- globalization;
- the arrival of new technologies.

The current revision to the EU medical devices legislation introduces a great number of new regulatory requirements.⁵ While the motivation for these is clear — to improve safety — increased complexity and cost is also introduced. This raises a number of questions concerning the degree of complexity under which the system can effectively operate:

- How much can we expect to achieve for our money?
- At what point have we over-complicated the system?
- Can we expect both large enterprises and especially SMEs to be able to cope?
- How do we achieve both safety and increased efficiency?
- Should there not be ongoing monitoring of the value and cost of regulatory activities and reforms, such that requirements that under-perform can be subject to impact assessment and review?

Most of the forthcoming regulatory changes apply to the post-marketing phase of medical device development, and will rely for their effectiveness on strong oversight by notified bodies and competent authorities.

The need for consensus

These forces and trends give rise to a need for strategic insights and planning in the future

development of the regulation of medical devices. How is the system to work effectively so as to foster public trust in it? All those involved in overseeing the European system need to think hard about what should be changed to improve the system, and *all* actors are needed to contribute positively in fulfilling their roles if the system is to work optimally.

There are signs of a developing consensus on the need for increased and inclusive dialogue on such issues. Such consensus can be seen among all groups involved in European regulation of medical technology: regulators, notified bodies, manufacturers, patients, and experts. This inclusivity is important. Every constituency has an interest in making sure that the system works well.

The latest thinking in regulatory system theory in Europe is based on the idea of the coordination of multiple actors who share relevant information and collaborate so that the system as a whole can function properly. This is far from a binary and authoritarian model in which a powerful regulator exercises authoritarian oversight over a manufacturer which tries to operate independently and withholds information about its activities. There is strong evidence to suggest that good regulatory practice should be based on the sharing of information between all relevant public and private actors in a collaborative, systematic fashion, so as to support regulatory compliance, and that the US approach to impose large fines, based on a theory of deterrence, is far less effective.⁶

European regulatory systems are, by design, significantly decentralized (this is the essence of mutual recognition, incorporating layers of authorities, notified bodies, and private sector actors), and both information and responsibilities must be shared between the actors. A system that is designed to integrate multiple actors in a matrix that has various vertical and horizontal dimensions can only function properly if all components perform the functions expected of them. Thus, individuals within manufacturers and notified bodies have to perform their functions in pre-market design, and all actors have to collect, circulate, and evaluate post-marketing safety information. The emphasis is placed on ensuring compliance rather than on enforcement by deterrence.

It is important to recognize that the European regulatory system is capable of performing extremely well, delivering high levels of safety, innovation, economic growth, and health care. The European approach has many potential advantages over most historical systems and systems in other parts of the world. If it is to deliver these goals, the core requirement is that all actors must work together openly, collaboratively, and effectively. The system can even withstand isolated examples of fraudulent noncompliance if the general level of performance and collaboration is such that unacceptable behaviour can be swiftly identified. Indeed, if the system is working well, signals about safety concerns or noncompliance should be picked up without delay. Furthermore, within this approach, the cohort size of population that exists across Europe is a considerable asset when detecting safety signals or noncompliance which would be far more difficult to establish from smaller sampling pools.

Policy recommendations on concrete goals

The following are the main recommendations for addressing the challenges noted above over the next few years.

1. There should be a wide-ranging, informed *dialogue* on strategic and innovative issues, and the establishment of a *small strategic group* to provide thought leadership on changes, a roadmap for achieving them, and monitoring of their speedy implementation. The group should encompass all stakeholders, including patients and clinicians across the EU.
2. There should be a *review* of means to generate and support *closer cooperation and collaboration between stakeholders*, especially governments, regulators, notified bodies, manufacturers, clinicians, and patients, within a 'collaborative regulation' model. There is a need to *foster a culture* within which every individual and organization recognizes the need to perform their functions well, so that the system as a whole can operate optimally. It should be recognized that everyone involved is important, and as such, needs to have appropriate expertise, motivation, and

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- an ethical approach. This will require common expertise and understanding by all individuals across the vertical and horizontal parts of the regulatory system, for which there is a need for common professional training. It may well require a specific governance structure to achieve this.
3. There should be an *Annual Report* on the functioning and effectiveness of the system as a whole, to provide feedback to competent authorities, notified bodies, manufacturers, clinicians, and patients.
 4. The strategic group should *review the core regulatory functions* to be performed by public authorities, notified bodies, manufacturers, and their relevant officers, standards organizations, industry associations, consultants, and others across the internal market, to ensure maximal expertise, effectiveness, and efficiency. The major parameter would be how to remain efficient while supporting effective regulation, safety, and innovation in medical practice and product development. Special attention should be given to which functions could be performed by others or differently, in relation to: post-marketing surveillance/vigilance (investigation of adverse incidents, compliance, and enforcement); advisory functions; classification issues; designation and oversight of notified bodies; approval of clinical investigations.
 5. A culture of pro-active *communications* should be developed in order to *explain* the regulatory system for medical devices, to the public, clinicians, patients, politicians, and other stakeholders, so as to clarify how and why it works and can be trusted, its benefits and achievements, and the nature of residual risk.
 6. *Measures of effectiveness* of the medical devices regulatory system should be developed, monitored, and actively communicated.
 7. There should also be a review of the public or other bodies that are responsible for *public health* across Europe, to ensure effective collaboration between them and systems that address regulation and practice.
 8. Front-line *clinicians* need to be more directly embedded into the regulatory and behavioural system. What can be regarded as separate worlds of products and clinical practice should be more closely integrated, and a mechanism should be identified and put in place at European level to facilitate open and effective engagement between clinical practitioners, regulators, notified bodies, and industry.
 9. Moves to *coordinate post-marketing* oversight of information should be accelerated. A fully functional centralized European *database* on products (including regulatory, safety, performance, and economic data) should be established swiftly. Until such a system is in place, the planned reforms requiring unique device identifiers will not function. There should be a review of whether this should be administered by public and/or private entities or a public–private partnership model.
 10. There should be a *review of the current investment* in the regulatory system in relation to the level of risk, where the activities and costs should be located, and how public sector (Competent Authority) activity should be funded. The review could assess whether the database could be used to provide equitable funding for the regulatory system.
 11. There should be a collaborative system for *management of notified bodies* to common requirements and a standard approach to their oversight by the responsible authorities.
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12. There should be a coordinated system for identification by competent authorities and notified bodies of independent technical and clinical *experts*. Existing national lists need to be expanded with appropriate governance. Since potential conflicts of interest are to be expected with leading experts, effective management of potential conflicts and full transparency is required to ensure the necessary levels of expertise.
 13. There should be debate and review of the best way to balance the competing demands of increased *transparency* of product compliance data, delayed and risk-managed and -monitored release of new products, and the incentive for investment. Ideas should be investigated as to how this might be achieved, for example, the pharmaceutical system's mechanism of a limited marketing exclusivity period, for perhaps two or three years, could be investigated in the device context, balanced against undesirable impacts such as rushed market entry.
 14. Requirements for and best practice in *clinical evaluation*, and its core role in risk evaluation, should be clarified. There should be increased oversight of practice in clinical evaluation so as to improve consistency.
 15. In order to encourage increased reporting of safety events and to enhance the body of relevant safety information, there should be a '*no blame*' reporting system coupled with a shift to '*no fault*' compensation schemes. Such approaches are viewed as essential in order to deliver safety in the aviation industry, and should be replicated across Europe in relation to clinical practice. There should be reform of the infrastructure necessary to review the breadth of health-care performance data. New reporting technology such as mobile application software (apps) should be supported. There should be harmonization of the approaches to enforcement by national authorities across Member States, since the PIP case has revealed significant differences in policies and sanctions.

Notes

- 1 Regulation (EC) No 765/2008 and Decision No 7687/2008/EC. See http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/new-legislative-framework/index_en.htm and *The 'Blue Guide' on the implementation of EU product rules*, at http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_type=254&lang=en&item_id=7326.
- 2 See <http://www.bbc.co.uk/news/health-16391522> and *Poly Implant Prothèse (PIP) silicone breast implants: Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health* (London: Department of Health, 2012), at <https://www.gov.uk/government/publications/pip-silicone-breast-implants-review-of-the-actions-of-the-mhra-and-department-of-health>; 'Restoring confidence in medical devices. Reporting on the success of the PIP Action Plan, European Commission', June 2014, at http://ec.europa.eu/health/medical-devices/regulatory-framework/pip-action-plan/index_en.htm
- 3 See <http://www.theguardian.com/science/blog/2012/feb/29/hip-implant-fiasco-regulatory-failings>
- 4 See M. Drummond, A. Griffin, and R. Tarricone, 'Economic evaluation for devices and drugs, same or different?', *Value in Health* 12/4 (2009): 402–404, at <http://medtecheurope.org/ehtiresearch/22/116/Economic-evaluation-for-devices-and-drugs-same-or-different>
- 5 See the extensive EU documentation at http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm
- 6 I. Ayres and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford: Oxford University Press, 1992); N. Gunningham and P. Grabosky, *Smart Regulation. Designing Environmental Policy* (Oxford: Oxford University Press, 1998); C. Parker, *The Open Corporation; Effective Self-Regulation and Democracy* (Port Melbourne: Cambridge University Press, 2002); C. Parker and V. L. Nielsen (eds), *Explaining Compliance. Business Responses to Regulation* (Cheltenham: Edward Elgar, 2012); C. Hodges, *Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Compliance and Ethics* (Oxford: Hart Publishing, 2014).



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