Recasting Legislation

Elisabethann Wright of Hogan & Hartson Brussels consider the European Commision's attempts to strengthen the legal framework for regulating medical devices in Europe

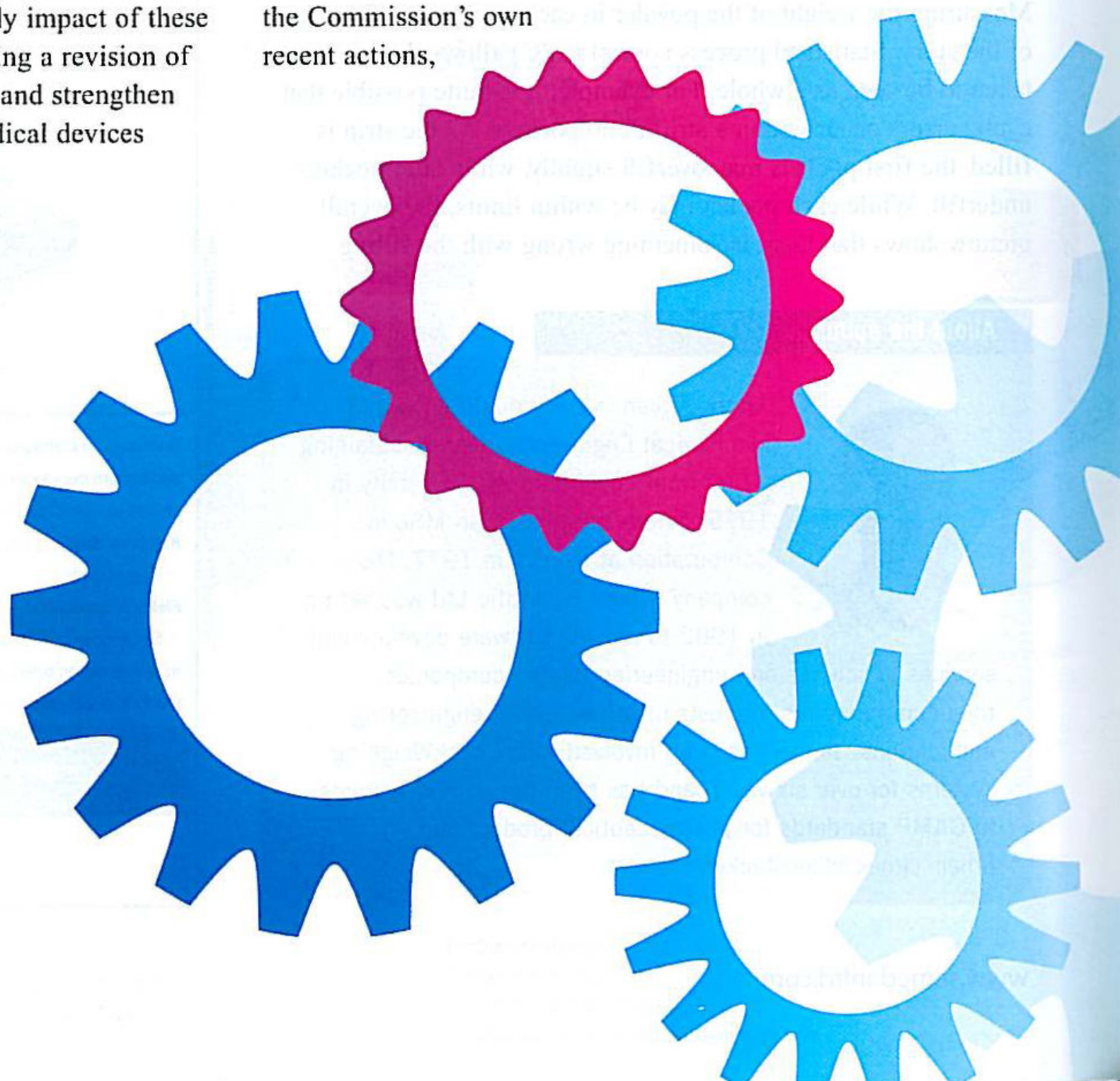
When the European Commission published its public consultation document concerning the recast of the current EU provisions governing medical devices on 7th May 2008, this did not come as a great surprise to the informed public. In its 'Communication to the European Parliament and the Council' in 2005 on Implementing the Community Lisbon programme the Commission had already indicated its intention to recast two of the three basic EU Directives governing medical devices into a simplified regulation. While the subsequent proposal may have been "much awaited" (as the Commission's own press release claimed) it was not in the form of a regulation. Moreover, there was a certain level of disappointment that the proposal, as finally submitted, did not constitute the overhaul of the existing medical device legislation that was hoped for in at least some corners.

No explanation as to the change of legislative approach was provided in either the impact assessment report for the Commission's proposal or in the explanatory memorandum that accompanied the proposal. Moreover, even before the resultant modifications to Directive 90/385/EEC (1) and Directive 93/42/EEC (2) had been adopted, there were already rumblings that it was time for a complete revision of EU medical device law. While the EU member states are still implementing the last set of amendments to the medical devices directives, and manufacturers continue to determine the likely impact of these for their products, the Commission is proposing a revision of this existing framework in order "to improve and strengthen the legal framework for the regulation of medical devices in Europe".

DISPUTED CLAIMS

In its public consultation document, the European Commission states that experience indicates that the current system does not always offer a uniform level of protection of public health in the EU. New and emerging technologies present new challenges to the current framework, highlighting gaps and pointing to a certain scarcity of expertise. However, the medical device industry disputes this. In what is, arguably, a fair historical comment, Eucomed has asked why the need to protect public health has come to the fore now when it was not considered to be such a fundamental priority during the recent revisions of some aspects of EU medical device legislation.

The procedure towards CE marking is already fairly comprehensive. Moreover, while there are undoubtedly areas for concern, such as the appearance of counterfeit devices on the European market, there does not appear to be any marked increase in public health issues related to the CE marking process itself. Added to this are the Commission's own recent actions,



including the very practical and useful guidelines on a medical device vigilance system. Admittedly, the guidelines do not have legal effect. Moreover, there are reports that the competent authorities in a number of EU member states refuse to accept incident reports in the formats laid down in the annex to the guidelines. However, there is a growing set of provisions, both legislative and guidance, to help ensure that medical devices placed on the EU market do not present a threat to public health.

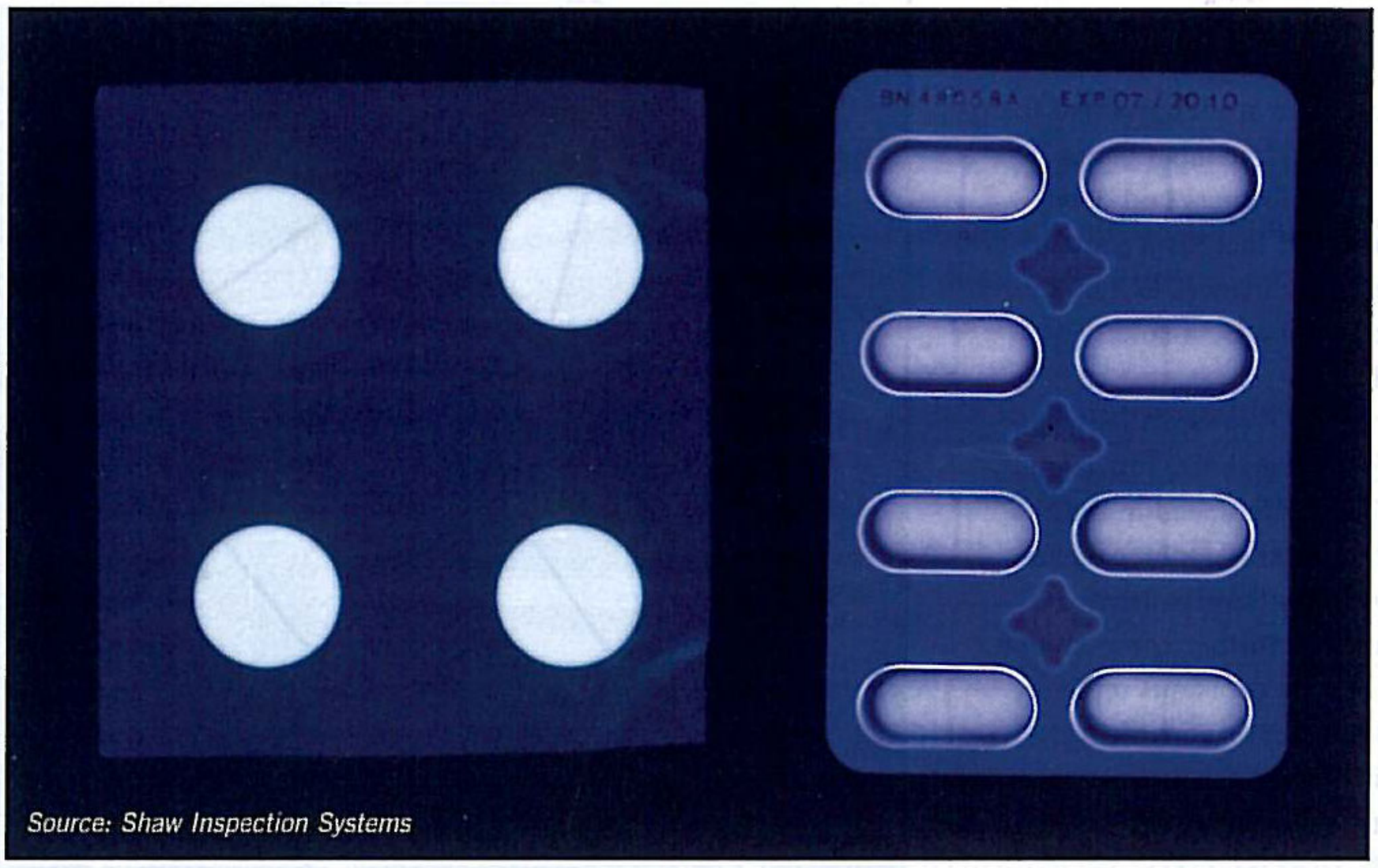
The existence of a number of different legislative provisions governing medical devices is an issue referenced in the public consultation document. The Commission considers that the current legislative framework is too fragmented and difficult to follow. This situation is further compounded by national variation including different decisions on whether a product is a medicinal product or a medical device, differences in the classification of the same type of devices, and different registration requirements.

SINGLE FRAMEWORK

The Commission wishes to recast the existing medical devices legislation, possibly adopting a single regulation governing all types of device. This approach may address concerns regarding the current inconsistencies between the manner in which the national authorities of the EU member states have implemented medical device legislation. Directives are EU legislative acts which require member states to achieve a particular result without dictating the means of achieving that result. Regulations are self-executing and do not require any implementing measures. If the existing legislation were transformed into a single regulation this should result in, at least, a decrease in existing inconsistencies in the content and application of EU legislation between EU member states.

There is, however, an argument to be made for having separate legislative provisions governing differing types of medical device, rather than a single provision governing all types of device. Eucomed considers that, for a highly complex and diversified sector such as the medical device/ technology industry, nine directives are appropriate. The organisation does not oppose the consolidation of the existing legislation. However, this would be on condition that there are no major changes to the current legislative framework.

One of the aspects of existing EU medical device legislation that the Commission considers in the recast document is the role and function of notified bodies which, it considers, is in need of revision. The Commission predicates the proposed modifications on the fact that, since 1993, the number of EU member states increased from 12 to 27, and the number of notified bodies rose to 80.



Source: Shaw Inspection Systems

NOTIFIED BODIES

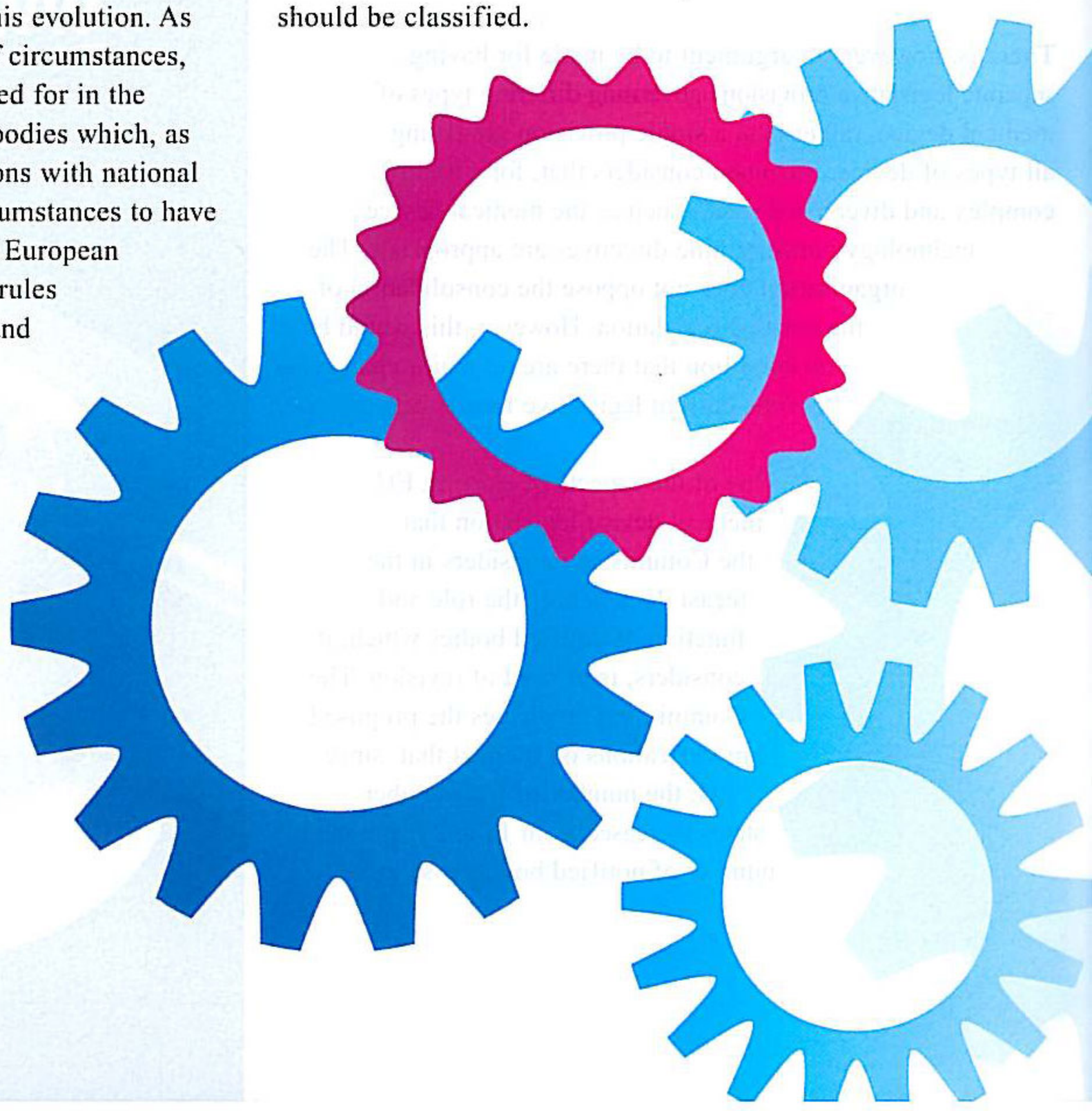
Notified bodies play an important, and generally useful, role in the CE marking of medical devices in the EU. The proposal by the Commission that the role of the notified bodies be revisited has provoked a debate as to whether notified bodies should be replaced with either national authorities in EU member states or a single supra-national body. Indeed, the Commission proposes the creation of a new committee in the European Medicines Agency (EMEA) to complement the existing CE marking process for medical devices, including the role of notified bodies.

While the number of EU member states and notified bodies has increased, so has the variety and, in many instances, the complexity of medical devices. However, legislation and guidelines have not always kept pace with this evolution. As a result, notified bodies have, in a variety of circumstances, reportedly taken on roles that are not provided for in the existing EU legislation. Replacing notified bodies which, as a general rule, are largely private organisations with national authorities would seem unlikely in such circumstances to have any great impact as compared to the current European process. Nevertheless, increasingly detailed rules aimed at achieving uniformity of approach and obligations would arguably be beneficial.

PROTECTING PUBLIC HEALTH

One of the arguments put forward by the Commission in its Public Consultation document for the involvement of the EMEA in the evaluation of medical devices – through the creation of a specific medical device component of EMEA – is the fact that the organisation has over 10 years of experience in the protection and promotion of public health, through the evaluation and supervision of medicines for human and veterinary use in Europe. The Commission continues that the EMEA already works with member states' national authorities, many of which have dual responsibility for both medicinal products and medical devices. There can be no disputing the level of expertise available in the EMEA. However, this is, as the Commission acknowledges, in the area of human and veterinary medicinal products. It can be expected, particularly given the means by which EU legislation currently functions in the CE marking of medical devices, that such expertise can easily be transferred to what many may argue to be an entirely different type of product.

The most recent revisions to the medical device legislation, combined with the adoption of the Advanced Therapies Regulation (3), were intended to ensure clarity concerning the classification of all types of currently available medical device. However, as the Commission's Public Consultation document mentions, there are some medical devices that are still not regulated at EU level. These are "products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action". Prior to the adoption of the Advanced Therapies Regulation there was debate as to how such products should be classified.



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It appears, from the variety of options presented in the Public Consultation document, that this will continue to be a subject of debate.

QUASI-MEDICAL SERVICES

In its public consultation document, the Commission proposes that some implantable or invasive products that are not currently regulated at the EU level should be considered "quasi-medical devices". The need to create a new category of "quasi-medical devices" to cover products that the Commission itself acknowledges are not covered by the current detailed definition of what constitutes a medical device can be expected to give rise to debate. Creating a category of products that fall, to some extent, within the term 'medical device', yet are outside the definition of these devices as provided for in existing EU legislation, may well lead to confusion. Perhaps a more simple solution is to create a new term and new criteria for determining which products fall within this classification.

References

1. Council Directive 90/385/EEC of 20th June 1990 on the approximation of the laws of the member states relating to active implantable medical devices
2. Council Directive 93/42/EEC of 14th June 1993 concerning medical devices
3. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13th November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

About the authors

Elisabethann Wright has been practicing European law for more than 20 years. Her practice focuses largely on EU regulation of medical devices and pharmaceutical products. She has extensive experience in litigation before the European Court. Having successfully challenged decisions of the EU institutions before the European Courts, she also advises on EU law relating to government contracts.

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