Medical device regulation and the PIP scandal legacy

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PIP IMPLANTS MAY BE OUT OF THE HEADLINES but the considerable impact of the scandal is now shaping the field of product liability and the regulation of medical devices.

When announcing the new proposals for the regulation of medical devices in September 2012, the health and consumer policy commissioner John Dalli said:

> 'Just a few months ago, everybody was shocked by the scandal involving fraudulent breast implants which affected tens of thousands of women in Europe and around the world. As policy makers, we must do our best never to let this happen again. This damaged the confidence of patients, consumers and healthcare professionals in the safety of the devices on which they rely every day'.

Sarah Croft of Shook, Hardy & Bacon, examines the enduring legacy of the PIP scandal in the courts, in EU legislation regarding medical devices and in UK regulation of cosmetic surgery.

CRIMINAL TRIAL OF PIP FOUNDER AND EXECUTIVES

In April 2013, the trial began of five PIP executives for aggravated fraud for using industrial-grade silicone in breast implants over a period of 10 years and for concealing evidence from inspectors. If found guilty the defendants, including the PIP founder Jean Claude Mas, face the possibility of a prison term of up to five years and a fine. More than 5,200 women joined the French case as plaintiffs, including around 220 women from overseas. As many as 300 are reported to have attended the trial opening which, due to the scale of the proceedings, took place in a conference centre in Marseille.

In closing arguments to the court, lawyers for the five PIP executives on trial defended the implants' safety and called for lighter sentences than the jail term requested by prosecutors. Throughout the trial Mas maintained that the gel used by his company was 'not toxic or dangerous'.

The court is due to deliver its verdict on 10 December 2013. Other cases related to the scandal are likely to follow.

In the UK, it is thought that around 47,000 British women have PIP implants. Most procedures were carried out at private health clinics, but around 900 were within the NHS, mainly for breast reconstruction after cancer treatment. In terms of civil proceedings, claims were threatened against several of the private clinics. A group litigation order was granted in March 2013 and the group register of claims was open from 31 May 2012 to 8 April 2013. There have been no further reported developments in the litigation.

REVISION OF EUROPEAN LEGISLATION REGARDING MEDICAL DEVICES

In the meantime, the European Commission has announced its proposals for change to the regulation of medical devices. The regulation of the sector was already in the process of being reformed when the PIP scandal broke, but the revelations have brought new impetus and focus to the proposals for change.

In 2008, the European Commission published a public consultation document to seek the views from stakeholders on the revision of the legal framework for medical devices. In 2010, to complement the first consultation, the European Commission launched a public consultation on technical aspects related to the revision of Directive 98/79/EC on in vitro diagnostic medical devices.

The main reasons for the changes are that the existing EU rules, which date back to the 1990s, have not kept pace with the enormous technological progress in the past 20 years. Regulatory gaps or uncertainties exist, such as with products manufactured from non-viable human tissues or cells and implantable or other invasive products for cosmetic purposes.

Also, as time has passed, substantial divergences in the interpretation and application of the rules have emerged between EU countries. This is not surprising in an internal market with 32 participating countries, each having to respond locally to constant technological and scientific progress.

Further, it is not always possible to trace medical devices back to their supplier. The existing regulatory framework has demonstrated its merits but, in some respects, it has also come under harsh criticism. In particular, the French health

authorities eventually found that PIP had used industrial silicone instead of medical grade silicone in its implants for several years, contrary to the approval issued by the notified body.

The revised regulatory framework for medical devices comprises:

- a proposal for a regulation on medical devices (to replace: Directive 90/385/EEC regarding active implantable medical devices and Directive 93/42/EEC regarding medical devices); and
- a proposal for a regulation on in vitro diagnostic medical devices (to replace Directive 98/79/EC regarding in vitro diagnostic medical devices).

The target date for adoption is 2014 with the expectation that the new rules would then gradually come into effect from 2015 to 2019.

Main elements of the proposals include:

- A wider and clearer scope, which has been extended to include implants for aesthetic purposes and clarification regarding areas such as medical software and genetic tests.
- Reflection of technological advances by the adaptation of the safety and performance requirements applicable to new health technologies, such as in the use of nanomaterials.
- Stronger supervision of independent assessment bodies by national authorities and more powers and obligations for those assessment bodies to ensure thorough testing and regular checks on manufacturers. This will include unannounced factory inspections and sample testing and co-ordination between national surveillance authorities will also be improved.
- An extended database on medical devices, called 'Eudamed', will provide comprehensive and public information on products available on the EU market. The proposal introduces a centralised EU portal where manufacturers must report serious incidents and corrective actions they have taken to reduce the risk of recurrence and the information will be automatically forwarded to the national authorities concerned.
- A requirement that within the manufacturer's organisation a qualified person should be responsible for regulatory compliance. Patients who are implanted with a device should also be given essential information which will allow the device to be identified and contains any necessary warnings or precautions to be taken.
- A unique device identification numbering system will be introduced to make devices easier to trace and thus enhance post-market safety. Economic operators must be able to identify who supplied them and to whom they have supplied medical devices.

UK REGULATION OF COSMETIC SURGERY: THE KEOGH REPORT

In April 2013 the report by NHS medical director Professor Bruce Keogh was published. The report, *Review of the Regulation of Cosmetic Interventions* had been commissioned by the Department of Health, as an independent review of cosmetic surgery following the PIP scandal.

On publication of the review, Health Minister Dr Dan Poulter said:

> 'If anything good can come of awful episodes like the PIP scandal, it is that the safety of the procedures that people may choose to undergo has been questioned. It is clear that it is time for the government to step in to ensure the public are properly protected.'

The main actions that the review group says would contribute to a successful and safe cosmetic surgery industry include:

- making all dermal fillers prescription only;
- ensuring all practitioners are properly qualified for all the procedures they offer, from cosmetic surgeons offering breast enlargement to people offering 'injectables', such as dermal fillers or Botox;
- an ombudsman to oversee all private healthcare including cosmetic procedures to help those who have been treated poorly.

Non-surgical procedures such as Botox, dermal fillers or laser hair removal account for nine out of ten procedures in the UK. However, despite their popularity, the review found that there is almost no regulation of non-surgical procedures.

A number of the proposals echo those made at the European level discussed above. In the wake of the PIP scandal, there was particular frustration in the UK regarding the quality of record keeping, the traceability of implants and the level of reporting on adverse events. These problems are addressed in the recommendations made in the review which include that:

- Surgical providers should provide a record of implants and operations to both the person undergoing a procedure and their GP.
- A registry should be established for breast implants and other devices. This should alert the authorities to any signs of concerns at an early stage and will provide critical intelligence in the event of product failure or recall.
- Providers are obliged to ensure that people are aware of the implications and risks of procedure and that they have adequate time to consider this information before agreeing to surgery.
- An advertising code of conduct should be developed and compliance should be mandatory for all practitioners.
- insurance products should be developed to protect patients in the event of product failure, or provider insolvency.

In April this year, the health minister said that he agrees 'in principle' with the recommendations and that the department would consider them and respond 'in detail in the Summer'. There was no such response by the middle of September.

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