

Self- and Co- Regulation: The Register of Injectable Cosmetic Providers

Quick Summary

In a rapidly growing market for injectable cosmetic treatments (botulinum toxin and dermal fillers), the providers of treatment were unregulated. Beginning in 2007, the cosmetic industry

has developed an online register for providers who meet a set of requirements for competence and in whose safe treatment the public can have confidence.

What was the context?

The Policy Challenge.

In a rapidly growing market for non-surgical cosmetic treatments (botulinum toxins and dermal fillers), traditional providers such as the doctors and registered nurses of the private healthcare industry were facing new entrants, many with no formal clinical training and operating in inadequate premises. The challenge was to ensure public safety without costs of formal regulation being borne by business and government.

Why was taking action required?

The actual administration of the treatments was unregulated although a number of existing regulatory frameworks governed supply (prescription only medicine), and premises used for treatment (Health and Safety at Work Act). These procedures don't count as therapeutic healthcare, although there is a health risk if they are botched. As such treatments became more affordable and popular, a growing potential risk to consumers was identified. Media interest and high profile celebrity cases combined with a consumer belief that all providers must already be regulated added to the risk of harm.

Why was statutory regulation not chosen? Whilst the potential threat existed, the cost and burden of statutory regulation was judged to disproportionate to the risk of harm caused to consumers as a result of poor treatment, and the consumers themselves were not considered a particularly vulnerable population. With existing significant healthcare risks, for example the issues of hospital acquired infections, government resources were focused on clearly high risk areas.

Why was self-regulation preferred as an alternative? The industry faced the risk of loss of profit and reputation should consumers be harmed, a risk the industry is already working hard to avoid for cosmetic surgery itself. Self-regulation through membership of a quality assurance scheme provided the best way to establish a register of safe providers of treatment which could reassure consumers and also avoid underplaying the potential risks.

What was delivered (mechanism)?

What was put in place?

A representative body for the private health care industry, Independent Healthcare Advisory Services, developed the Register of Injectable Cosmetic Providers, launched under the name www.treatmentsyoucantrust.co.uk. This register was opened for membership in May 2010 and launched publicly in September 2010. The aim is to ensure that consumers can find providers who are adequately trained and who use safe premises.

Over whom does it apply?

In the first year the register is open to a restricted list of trained medical professionals, but it will soon accept applications from other practitioners who can give evidence that they meet the required professional standards.

How does it operate?

Applicants are required to certify compliance with a set of professional standards and training principles, pay an annual fee for inclusion and submit to inspection. Registration assessment and ongoing inspections are managed through an independent third party organisation. The register is available to consumers for use when choosing a practitioner.

How is compliance achieved?

Random inspections are carried out and a complaints process is offered to patients. The scheme has a Clinical Governance Board which adjudicates on standards and performance.

Sanctions include removal from the register and the scheme works closely with the General Medical Council, the General Dental Council and the Nursing and Midwifery Council who have statutory powers to impose sanctions on their respective members.

How is it funded?

By the registration and annual fees paid by individuals and organisations. Some development funding was provided by the Department of Health and support from the industry.

How is it held to account?

The operation of the scheme is overseen by its Governance Board.

What is the role of Government?

BRE originally provided the self-regulation framework used to implement the scheme and the Department of Health has supported the launch of the scheme.

Process

Self-regulation

The IHAS, Better Regulation Executive and Department of Health worked together to deliver the scheme.

1. Establish working group of the IHAS Cosmetic Surgery Group to develop the scheme with secretariat support from the IHAS.
2. The Better regulation Executive developed the self-regulation framework which was used as the basis of the scheme.
3. Identify and meet stakeholders to brief on plans and obtain their input. Included professional bodies, consumer groups and regulators.
4. A standards subgroup developed the required standards and training.
5. Stakeholder conference to present proposal and gain comments.
6. Define membership and inspection criteria and tender for contract to provide.
7. Working group establish and consult on costs, governance and branding.
8. Launch scheme with PR campaign.

Co-Regulation

A number of activities in the provision of injectable cosmetic treatments were already covered by regulation. The scheme was developed in conjunction with these bodies.

Botulinum toxins are prescription only medicines and access to them is thus only permitted via registered Doctors, Dentists and Nurse Practitioners. These communities are regulated by the General Medical Council, General Dental Council and Nursing and Midwifery council respectively and may be subject to disciplinary action from them. Those practising illegally can face criminal prosecution.

Dermal fillers are classified as medical devices and subject to regulation by the Medicines and Healthcare products Regulatory Agency. The MHRA also regulates the advertising of all of these treatments.

Unsafe practices in administration of treatment from non clinically qualified staff can be subject to investigation by local authority Environmental Health Officers and providers may even face criminal prosecution for assault.

Providers are subject to trading standards regulations and may be investigated and prosecuted by their local authority.

Risks to staff from unsafe practices are subject to the Health and Safety at Work Act, enforced by the Health and Safety Executive and local authority Environmental Health.

Lessons Learned

Enlist the support of all influential stakeholders during the development and especially when launching the scheme, ideally including those who stand to lose out. In this case this included consumer and patient representative groups as well as regulators and potential providers.

Be prepared for the fact that any scheme operating in a competitive market will have detractors. To face down accusations that any non statutory scheme will lack 'teeth' it was important to refer to and gain the support of bodies who possess statutory regulatory powers over related aspects of the industry.

The industry group should not under-estimate the work involved in bringing the scheme to fruition and there should be a plan to deal with dissenting voices, inside and outside the industry.

There may be a temptation to exclude particular groups through, for example, the setting of standards. It is essential that any requirements set will stand up to scrutiny and will be justifiable and proportionate.

There may be consumer suspicion of industry involvement in its own regulation. This can be addressed by having transparent processes, independent governance and a clear appeals process which delivers outcomes the public will consider fair.

Contacts

Contacts

- Mary Newman– Department of Health
- Richard Ward - Better Regulation Executive
- Sally Taber - Independent Healthcare Advisory Services

Want to know more about alternatives?

- Contact alternatives@bis.gsi.gov.uk at the Better Regulation Executive

Further information

- The Register of Injectable Cosmetic Providers at www.treatmentsyoucantrust.co.uk/Pages/home.aspx:
- The Independent Healthcare Advisory Services www.independenthealthcare.org.uk
-

