Energy-based Devices in the cosmetic sector

Medical Device Regulation

1.0 Executive Summary

The Clinical Advisory Group for the JCCP has established a subgroup to investigate the use of energy-based devices in the UK cosmetic sector and possible improvements to patient safety. The following key areas have been identified by the subcommittee for further investigation:

- Concern about lack of regulation of energy-based devices intended for cosmetic use
- The role of the MHRA in providing vigilance and oversight for medical devices in the UK
- Concern about variability of training and support offered by medical device suppliers
- Possible new technologies and how these should be captured under new or existing legislation

This paper briefly sets out the regulatory requirements for medical devices in the EU (CE marked under the relevant medical devices legislation) and the current situation in the UK post-Brexit (including requirements around UKCA marking in Great Britain). Consideration is given to the new regulation in EU, which has brought into scope of medical device regulation, certain products for which a manufacturer claims only an aesthetic or another non-medical purpose, but which are similar to medical devices in terms of their functioning and risk profile. The EU Medical Devices Regulation applies in Northern Ireland, but not in Great Britain. With respect to domestic requirements for the regulation of the above products, it is recommended that the JCCP await the outcome of a recent MHRA consultation on the future regulation of medical devices in the United Kingdom (Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)). However, it is also recommended that further work is required from the JCCP to investigate the other key areas listed above.

2.0 EU Medical Devices Regulation and the UK Position

Following a four-year transition period, the EU Medical Devices Regulation (EU MDR) (2017/745) took effect in the EU on 26 May, 2021, subject to certain transitional arrangements. The EU MDR also applies in Northern Ireland under the terms of the Northern Ireland Protocol. The EU MDR repeals the Medical Devices Directive (MDD) (93/42/EEC). In the EU, manufacturers must now comply with the EU MDR when seeking to place medical devices on the EU market or if they wish to get their devices re-certified. The EU MDR introduces stricter requirements than the MDD (some of which will have application in the aesthetics sector). New obligations include more stringent requirements for clinical evaluation, post-market surveillance, and clinical investigation, as well as the bringing into scope certain: “products without an intended medical purpose” which are similar to medical devices in terms of their functioning and risk profiles.

The UKCA (UK Conformity Assessed) marking is a UK product marking used for certain goods, including medical devices, being placed on the Great Britain market (England, Wales and Scotland). Manufacturers of medical devices can use either the UKCA marking or the CE marking on devices they place on the GB market until 30 June 2023. From 1 July 2023, a UKCA marking will be required in order to place a device on the Great Britain market.

In Great Britain, devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, prior to the end of the transition period, gave effect in UK law to Directive 90/385/EEC on active implantable medical devices (EU AIMDD), Directive 93/42/EEC on medical devices (EU MDD), and Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD). This means that the Great Britain route to market and UKCA marking requirements are currently based on the requirements derived from the above EU legislation.

As noted above, the EU MDR applies in Northern Ireland. Although the UKCA marking is available for use in Great Britain, a CE marking is needed for devices placed on the Northern Ireland market and EU rules need to be met.

All medical devices must be registered with the MHRA before being placed on the Great Britain market. The MHRA will only accept registration of devices from manufacturers where the manufacturer is based in the UK. If the manufacturer is based outside the UK, they must appoint a UK Responsible Person. This UK Responsible Person will then assume certain responsibilities on behalf of the manufacturer, including registering the device with the MHRA.

It is unlawful to place a medical device on the market in Great Britain without having first registered it with the MHRA. Furthermore, the MHRA now monitor medical devices as follows:

"The MHRA performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK."

REF:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#overview

https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices#medical-devices-legislation-section

2.1 Definition of a Medical Device

The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) define a medical device as:

'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control of conception

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these'.

REF:

https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements

2.2 Products without an Intended Medical Purpose (Cosmetic Devices)

The EU MDR brings into scope "products without an intended medical purpose", for which a manufacturer claims only an aesthetic or another non-medical purpose, but which are similar to

medical devices in terms of their functioning and risk profile. This expansion of scope is intended to capture products which are placed on the market (by the manufacturer or economic operator), such as those intended to treat purely cosmetic indications, yet which have similar functions and risk profiles to medical devices. Under the EU MDR, manufacturers of such "cosmetic" devices would be required to follow the relevant requirements applicable to these products. Under the MDD, such cosmetic products were not subject to the same level of scrutiny as medical devices (despite their similarity as set out above). The EU MDR brings into scope six broad groups of products with the two following categories for energy-based devices being relevant in the Aesthetics industry:

- Equipment intended to be used to reduce, remove or destroy adipose tissue such as equipment for liposuction, lipolysis or lipoplasty - [Example: Body sculpting equipment]

- Electromagnetic radiation (e.g., infrared, visible light and ultraviolet) emitting equipment intended for use on the human body including coherent and non-coherent sources, both monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatments - [Example: Intense pulsed light (IPL) machines for body hair removal]

3.0 MHRA Consultation

The MHRA recently undertook a consultation on the future regulation of medical devices in the United Kingdom (the consultation closed on the 25th November, 2021). The consultation sought input from various stakeholders on how the MHRA could update the current regulatory regime for medical devices in the UK. The results from the consultation are due to be published shortly and the consultation set out that: *"amendments to create the new regime are scheduled to be in force at the beginning of July, 2023 to align with the date from which we are due to stop accepting CE marked medical devices in Great Britain and will require the use of the UKCA marking"*.

REF:

https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom

4.0 Recommendations

The JCCP submitted a response to the MHRA consultation (submitted by Jon Exley on behalf of the JCCP and the BMLA). Where relevant, the JCCP submission sought to bring the future regulatory framework for medical devices in line with the EU MDR – particularly to adopt a similar approach to products without an intended 'medical' purpose but which have similar risk profiles. As such, it is recommended that the JCCP await the outcome of the MHRA consultation process (with the expectation that cosmetic devices will be incorporated into regulation as they are with the EU MDR).

In addition to supporting the inclusion within the scope of the UK Regulations, of products for which a manufacturer claims only an aesthetic or another non-medical purpose (as outlined above), the working party convened by the JCCP Clinical Advisory Group has identified some additional key issues that are worthy of consideration in the application of energy-based devices in the cosmetic sector which we believe would improve patient safety and public protection. These are:

- To improve patient safety by applying the medical device standards to cosmetic devices, including the registration of such under the UKCA, the testing and certification of such devices, together with the ongoing reporting, and monitoring of adverse events

- To ensure that the full scope of cosmetic devices are appropriately regulated by the MHRA. The scope should include those contained within the EU MDR as well as any other devices marketed for cosmetic purposes which:
    - Make use of any of the following modalities, either in isolation or in combination - radiofrequency/radiofrequency, micro-needling, ultrasound/high intensity frequency ultrasound, electrocautery (including 'plasma'), cryotherapy, thermocoagulation, cryolipolysis, electromagnetic muscle stimulation, thermomechanical ablation, carboxytherapy, hydradermabrasion.
    - Devices which are intended to be inserted into or placed under the skin (whether temporarily, semi-permanently or permanently) or which are used for delivering any materials into the skin including such devices as micro needling, threads or sutures for cosmetic purposes, mesotherapy as well as 'no-needle' mesotherapy devices, hair transplant devices, and radiofrequency/ultrasound/laser devices used to modify skin or fat invasively
    - The establishment of standard clinical training for the safe and effective use of cosmetic devices and the registration and monitoring of such training
- The possible role of the JCCP and the CPSA (Cosmetic Practice Standards Authority) in horizon scanning for emerging technologies which may be considered within the context of future regulation of medical devices.

Further work is required by the JCCP to investigate these additional objectives which are unlikely to be addressed by the UKCA regulation.

5.0 JCCP Sub-Group Members

Dr Paul Charlson: *Past President of the British College of Aesthetic Medicine (BCAM) / Co-chair of JCCP Clinical Advisory Group*

Dr Selena Langdon: *Founder & Medical Director Berkshire Aesthetics*

Dr Jon Exley (Ph.D.): *British medical Laser Association / Director of Lynton Lasers Ltd*