Written evidence submitted by the Federation of Manufacturing Opticians (MMDB04)

Executive summary

- The Federation of Manufacturing Opticians fully supports the need to ensure that medical devices are properly regulated.
- Regulations must be proportionate to the level of risk posed by the medical devices concerned, be made following full consultation with all stakeholders, including industry, and should so far as possible reflect regulatory practice in Europe, in order to minimise the risk to industry of the bureaucratic and financial burden of duplicate regulation.
- We would like to see two amendments to the Bill:
    - Clause 12, the power to make regulations in relation to medical devices, should be amended to require the Secretary of State to take account of the impact on manufacturers, ensuring that any regulatory burden is proportionate to the risk posed by a particular medical device.
    - Clause 40, the duty to consult, should be amended to specify who should be consulted, rather than leaving the decision solely to the discretion of the relevant authority.

Full evidence

1. The Federation of Manufacturing Opticians (FMO) represents optical manufacturers, distributors and suppliers of spectacle and contact lenses, spectacle frames, ophthalmic equipment, business service providers and IT companies.

2. Our interest is in Part 3 of the Bill. Most of the products made by our members are classified as medical devices, regulated under current medical device regulations, and would fall within the ambit of any new regulations that this Bill enabled the Secretary of State to make.

3. The FMO fully supports the need to ensure that medical devices are properly regulated and that the Secretary of State should have ongoing powers to maintain and as necessary amend and update regulations. It will however be important that any regulations made are proportionate and that there has been full consultation with all stakeholders, including industry. We would also hope that any regulations made would continue to reflect regulatory practice in Europe, which is an important market for many of our members, in order to minimise the risk of industry having to manage the bureaucratic and financial burden of duplicate regulation, with no commensurate gain in public safety.

4. FMO members have concerns in relation to two specific areas of the Bill:

- Ensuring that any proposed register of medical devices and system for device identification is proportionate to the level of risk posed by a particular device.
- Ensuring that industry is fully engaged and properly consulted prior to any changes being made to the UK regulatory system under the proposed new powers.

5. Our reason for raising these two concerns is demonstrated by the problems that have occurred as the EU Medical Device Regulations 2017 have been implemented. It has become apparent that there are significant problems in relation to the treatment of spectacles (and certain other low risk, Class 1 medical devices), which we would not wish to see replicated in any future UK regulatory system. Discussions at EU level are still ongoing to try and resolve these issues. Had the optical industries been fully involved from the outset in developing the EU MDR, in particular the

system of medical device registration and unique device identification, and had the impact on both manufacturers and healthcare providers (in this case optometrists and dispensing opticians) been properly taken into account, then these issues would have been better understood and the problems we now face could potentially have been avoided.

6. When making new regulations using the powers in Clause 12 of the Bill, Clause 13 then specifies the areas of activity the regulations may cover. This includes requirements on manufacturers in relation to materials and composition of a device, providing information about the device, packaging and labelling, and the power to create registers of medical devices and what information should be contained in that register. It will be essential that any regulations made using these powers are proportionate in relation to the risk posed by each medical device. We believe that it would be beneficial to include on the face of the Bill a requirement to take account of the level of risk and demonstrate that for each class of medical device the proposed regulation is proportionate, before making any regulations. We therefore propose the following amendment to Clause 12(2):

> ***(d) the impact on manufacturers of the proposed regulations, ensuring that any requirements are proportionate to the level of risk posed by all relevant medical devices.***

7. The current powers to amend or make medical device regulations are used to implement regulatory changes already made in the European Parliament that have already been seen, consulted on and widely debated. It will be important that in the future new regulations made under these proposed powers receive similar high levels of consultation and engagement. We are concerned that Clause 40 of the Bill only imposes a duty to consult "such persons as the authority considers appropriate". In our view this leaves too much discretion when deciding who to consult. We therefore believe that this Clause would benefit from the inclusion of the following amendment (in bold italics) to Clause 40(1):

> Before making regulations under sections 1(1), 8(1) or 12(1), or paragraph 9 of Schedule 1, the relevant authority must consult such persons as the authority considers appropriate. ***This should include, but not be limited to:***
>
> ***a) healthcare institutions and providers***
>
> ***b) healthcare professionals***
>
> ***c) healthcare industry bodies and manufacturers***

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