# FPM Governmental and Healthcare Policy Expert Group and Medical Devices Expert Group and Medical Devices Expert Group

# Response to RCP Consultation on the Medicines and Devices Bill 2020.

The FPM were invited to provide initial comments on the Medicines and Devices Bill which has undergone a first reading in February 2020 and will undergo the second reading on 2 March 2020. The President of the FPM invited members of the Governmental and Healthcare Policy Expert Group and the Medical Devices Expert Group to read the bill and accompanying documentation and provide initial comments.

## The Medicines and Devices Act 2020

The Medicines and Devices Bill is an example of an ‘enabling’ act. It permits the Secretary of State (working together where required with devolved authorities) to vary existing UK law and make regulations pertaining to medicines, veterinary medicines and medical devices via issuing statutory instruments rather than requiring the submission of a specific Bill for parliamentary scrutiny. This mechanism has been used successfully in the regulation of medicines in the UK for a substantive period of time without adverse effect and thus there is some experience in this practice: for example the Faculty has previously issued comments on instruments which amended the HMR 2012 in respect of provisions related to a ‘no deal’ Brexit.

The current bill is designed to enable the Secretary of State to amend existing UK law and also enables the adoption of additional EU regulations into UK practice following the UKs exit from the EU. The powers permitted under this act, if passed, are wide ranging, however there is a duty on the Secretary of State to have regard to the safety and availability of medicines, veterinary medicines or medical devices as well as the attractiveness of the United Kingdom as a place in which to develop or supply these.

As written the provisions of the bill would have the immediate effect of enabling the secretary of state to continue to align UK law with EU regulations in these fields, assuming that any amendments to EU regulations are considered appropriate for the UK. This enables the passage into UK practice of existing EU legislation coming into force in the next few years – particularly the clinical trial regulations, implementation of which has been delayed pending availability of the EU Clinical Trials portal, and the medical devices (MD) and invitro diagnostics regulations which come into force in May 2020 (MD) and 2022 (IVD). These directives were passed at a time when the UK was a full member of the EU and contributed to the provisions of the relevant regulations. However, in future, it may be that the UK will want to diverge from EU regulation. It is presumed in this case that a major revision of regulations might require a new Act of Parliament but this might be clarified.

**Recommendation:** Clarify whether this mechanism will be followed in the event that the UK wishes to diverge significantly from the cited EU regulations in future.

In the explanatory notes, it is stated that changes made may be implemented within 2 months of the Bill receiving royal assent. Dependent on the timeframe for the completion of the Bills passage through parliament, it is possible that changes could be implemented prior to the completion of the Brexit transition period: it may be useful to clarify this point.

**Recommendation**: Clarify whether the timetable for the Bill is intended to permit changes to be implemented prior to the completion of the Brexit transition period.

## Sections 6 and 15: Emergencies

The Bill includes language enabling the Secretary of State to disapply a human medicines or medical devices provision in circumstances which give rise to a need to protect the public from a risk of serious harm to health. These sections also enable the regulatory authority to issue a protocol in regard to such an emergency. It is presumed that these provisions may enable emergency use of a previously unapproved/unlicensed medicine/device to enable effective diagnosis/treatment of an emerging health threat – an excellent example might be the current COVID-19 threat, where emergency provision for an in vitro diagnostic test to identify cases, quarantine provisions and use of unlicensed medicines/vaccines for outbreak control might be considered.

**Recommendation:** Clarify whether these sections enable the secretary of state to provide for emergency availability of novel diagnostics/therapeutics to protect the public from a risk of serious harm to health.

## Medical Devices – Chapter 1, Section 12 (2)

States that *the Secretary of State (SOS) must have regard to safety and availability of medical devices (MD) and make UK attractive place to develop and supply MDs.*

These objectives can only be met if UK regulation of medical devices, registration procedures and safety data collection are compatible with processes followed across the EU and other major regulatory authorities in areas in which the same devices are used or are under investigation.

**Recommendation:** Clarify that the UK should take into account international requirements for the data to be acquired during development and supply of medical devices and in vitro diagnostics in order to ensure that the UK is able to access relevant safety information and remain an attractive place to develop and supply these.

## Medical Devices - Chapter 1, Section 13 (c)

This section enables the regulation to make provision for the *appointment of one or more persons (whether or not established in the United Kingdom) who meet criteria set out in the regulations* *(i) to assess whether relevant requirements are met, and (ii) if appropriate, to confirm that they are.*

As medical devices may be imported into the UK from many countries it would be helpful to clarify which countries/notified bodies might be considered competent to make such an assessment on behalf of the UK.

**Recommendation:** Clarify countries/notified bodies which are considered competent to make assessments concerning devices meeting relevant UK requirements.

## Medical Devices Sections 34, 35 and 36

The general provisions of these sections enabling the Secretary of State to disclose information for the purposes of informing the public in relation to safety of a device, as well as to facilitate others to act in the interests of public safety are appreciated. The introduction of civil procedures to enforce regulations is appropriate as are the range of provisional penalties. The role the MHRA may play in these activities is unclear.

**Recommendations**:

1.Clarify the role of the MHRA in the qualification of the efficacy and safety of medical devices and in vitro diagnostics including the role they may play in constructing and maintaining a Registry of products approved for use and their ability to ensure regular surveillance during use of products CE marked by other notified bodies.

2. For medicines, the Commission on Human Medicines (CHM) plays a role in the oversight of the risk benefit balance of medicines and an argument may be made that it would be useful for the Commission to expand its competence to include provision of expert advice on Medical Devices.

## Section 40: Consultation

Section 40 of the Bill requires the appropriate regulatory authority to consult on the proposed changes to be made: under this provision the authority can determine the persons/bodies to be consulted. It may be preferable to provide a minimum list of bodies which should be consulted in this provision.

**Recommendation**: Consider providing a list of bodies required to be consulted on changes to relevant legislation.

Paragraph 2 of this section enables changes to be made without consultation where these are considered necessary to prevent serious harm to health provided that *the person making them considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health*. However there is no guidance within the Bill as to who ‘the person making them’… might be, and additionally any provision would need to be enacted by the medical and healthcare workforce who may consider the provision unworkable. The no deal Brexit activities demonstrated that consultation with relevant expertise can take place rapidly when required and thus this provision could be omitted.

**Recommendation:** Remove Paragraph 2 of Section 40.

Paragraph 3 of this provision states: *The duty to consult imposed by subsection (1) may be satisfied by consultation carried out before this Act was passed.* However, as the act enables the amendment of UK law by statutory instrument in perpetuity, this might enable changes to be introduced routinely without any additional consultation. It is suggested that this provision be reworded to define a time period over which this provision applies.

**Recommendation:** Section 40 paragraph 3 be amended to include a defined time window for this provision to apply.

## Section 41 Procedure

This section clarifies the statutory instrument procedures. The wording of these require that a draft of the relevant instrument must have been laid before and approved by a resolution of each House of Parliament or other devolved authority depending on the regulation being amended. Additionally, some sections enable annulment of the instrument by a resolution in these assemblies. It is assumed that this procedure describes is the current procedure for these instruments. This could be clarified.

**Recommendation:** Clarify whether Section 41 contains new provisions concerning review and approval of statutory instruments by parliament/devolved bodies.