The Medicines and Medical Devices Bill

The Medicines and Medical Devices Bill ('the Bill') was formally brought to Parliament on Thursday 13 February 2020. The Bill extends and applies to the whole of the UK. The government plans to use the powers granted in the Bill to develop new or amended regulations that improve the speed of access to new and innovative medicines post-Brexit. The government has also stated an ambition to soften regulations governing the life sciences sector and foster an environment in which the UK takes a lead role in global research.

Background to the Bill

Currently, the regulation of human medicines and medical devices falls within EU competence and law. The UK has implemented the EU legislation, most notably through *The Human Medicines Regulations 2012, The Medicines for Human Use (Clinical Trials) Regulations 2004*, and *The Medical Devices Regulations 2002*.

Currently the UK can amend and update these pieces of legislation. However, after the end of the Brexit transition period, the UK will no longer be part of the EU regulatory framework. It will retain EU law corresponding to medicines and medical devices, but will not be able to update its legislation, except through primary legislation.

The Bill therefore provides the delegated power to amend or supplement the law relating to medicines and medical devices.

Marketing authorisations

The Bill allows provision to be made in relation to marketing authorisations. The government wants to prevent UK patients waiting longer than European counterparts for new treatments because of pharmaceutical companies choosing to seek EU-wide approval (from EMA) before UK approval (from MHRA). The exact details of how it will achieve this have yet to be provided – we might learn more during the Second Reading stage in the first week of March.

However, it could amend the application process for marketing authorisation, remove bureaucracy and maintain alignment with the EU. For example, the EMA's marketing authorisations could be accepted in the UK after the Brexit transition period.

Trials

The Bill enables provisions to be made in relation to the authorisation and ethical approval of clinical trials.

There are few details contained with the Bill, but the Queen's speech revealed that the government plans to reduce regulation around the running of low risk clinical trials so that medicines can be tested faster. However, EU legislation defines 'low risk' as trials that have minimal additional risk compared to normal clinical practice, amongst other things. Therefore, it is difficult to see how 'low risk' clinical trials will translate into improving access to innovate medicines. Rare disease trials are particularly unlikely to meet these criteria as they often have considerable morbidity to manage.

A clause allows for the future introduction of charges relating to trials. Although this is just a provision, there have yet to be indications that the government will look to develop this into policy.

Medical devices

A new regulation system for medical devices is proposed by the Bill. It confers a delegated power to amend or supplement the Medical Devices Regulations 2002.

The Secretary of State has a duty to consider three factors before making any changes: the safety of medical devices, the availability of medical devices and the attractiveness of the UK as a place to develop and supply medical devices.

Companies will be required to register medical devices with the MHRA and will be subject to the "highest standards of regulation".

The Secretary of State for Health and Social Care will be able to impose civil sanctions in the form of monetary penalties in response to breaches of the Medical Devices Regulations 2002. They will also have the power to disclose information about devices to the public when there are serious patient safety concerns and regulators can issue a "suspension notice" suspending the availability of a medical device.

The Bill allows for regulations to be made about fees in respect of functions conferred by a medical device provision.

The new *EU Regulation on Medical Devices* covers all general medical devices and will apply across the EU and UK from 26 May 2020. There will also be a new EU *In Vitro Medical Devices (IVD)* regulation from May 2022. These new regulations aim to increase patient safety and confidence in the system of conformity assessment. The UK will not be a member of the EU in 2022, so will need to make its own decisions about the future regulation of IVDs using the powers proposed in this Bill.

Personalised medicines

The Queen's speech indicated (and it has been reported in the media) that the Bill will provide new powers for hospitals to use patient DNA to tailor personalised treatments. At this stage, however, the details are not clearly outlined in the current version of the Bill.

If this is developed, then new personalised medicines, such as targeted genetic therapies, will widen the therapeutic armamentarium of clinicians and be particularly transformative in the treatment of rare diseases.

Prescribing

The Bill proposes new powers for healthcare professional to prescribe "low risk medicines". This could include midwives, physiotherapists and paramedics. The government is hoping this will reduce the burden on GPs. The medicines to be designated as low risk are yet to be announced and is a potential battleground for industry.

The Bill allows provision to be made in relation to changing the labelling and packaging of human medicines. For example, it could make it a requirement to place medicine information online.

Emergency supply of medicines & medical devices

The Bill allows regulations to be made that relate to the emergency supply of human medicines and medical devices. In particular, it allows for the relaxing of certain regulatory requirements if there is a threat of serious harm to the health of the general public.

Examples provided in the explanatory note include stocks of medicines being shared between persons who do not hold wholesale dealers' authorisations, larger packs of pills split into smaller packs, and accessing medicines without a prescription.

In such cases, there would be a time limited protocol published by the Secretary of State and the Department of Health in Northern Ireland.

Other

The Bill provides scope for new provisions in the prevention of the supply of falsified medicines.

Veterinary medicine is also covered extensively by the Bill.

Conclusion

The government press around the Bill suggests that changes in the regulation could speed up adoption of innovative technologies, or treatments for rare disease. For example, DHSC announced that it would "slash red tape, [and] support uptake of treatments for people with rare diseases". However, even if the UK adopts a more ambitious regulatory position, technologies must still be approved by payers and HTA bodies in order to be adopted.

The domestic life sciences sector will also be disappointed that many of the details of how the government will improve access to innovative medicines are missing. The MedTech industry may be particularly concerned with the increased regulatory burden for medical devices. This could stymie innovation and early access in the sector and place a particular burden on smaller MedTech companies.

ENDS
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