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The Medicines and Medical Devices Act became law in February 2021.

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Medicines and Medical Devices Bill: Emergencies

Top Lines

- UK legislation on medicines and medical devices is highly safeguarded, to ensure patient safety. However, where there is a risk of serious harm to public health we may need to temporarily relax certain regulatory requirements to respond effectively.
- This Bill provides the power to disapply provisions of medicines and medical devices legislation in emergency situations, allowing the Government to respond quickly and protect public health in the UK.

What does the Bill do?

- The powers in the Bill strengthen the UK's ability to respond to threats to public health by ensuring that we can make appropriate changes to the regulation of medicines and medical devices where there is a need to protect the public from harm.
- The powers allow the Secretary of State to make emergency provisions in response to a wider range of public health threats than current legislation provides for. The powers can be used both pre-emptively and reactively, allowing us to plan for and respond promptly and effectively to emerging threats.

What is the system we have now?

- The UK already has a number of emergency powers in existing legislation to help us respond effectively to public health issues. For example, the Human Medicines Regulations 2012 (HMRs) allow certain requirements in how we regulate the use of medicines to be disapplied in a pandemic.
- However, existing emergency powers do not allow us to respond as comprehensively in other potential emergency situations.
- For instance, powers in the HMRs could not be used to respond to either a localised disease outbreak, or a non-infectious disease public health emergency.
- The Civil Contingencies Act 2004 also contains emergency powers, but these can only be used reactively once the emergency situation has manifested.

What circumstances could give rise to a need to protect the public from a risk of serious harm to health?

- There are various events that may give rise to a risk of serious harm to the health of the public.
- This may include a disaster, significant outbreak of an infectious disease, or other significant or catastrophic event, for example relating to a chemical, biological or nuclear release, that cannot be responded to within routine healthcare response.

Example of how the powers under the Bill could be used

- Powers could be used to allow for the supply of particular medicines without a prescription in order to protect or treat the public in an emergency.
- In order to ensure that patient safety is protected, emergency arrangements can be made subject to conditions set out in a protocol. For instance, by providing a list of criteria which would make a person eligible to receive the emergency medicine.

How similar powers have been used in the past

- Emergency powers under the Public Health (Control of Disease) Act 1984 have recently been used for the outbreak of novel Covid-19 or – Coronavirus.
- Regulations have been made giving powers to require people to be screened, quarantined and isolated as needed.
- Whilst these regulations do not relate to medicines or medical devices, they are a good example of the wider context that the emergency powers in the Bill will fit within.