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

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Medicines and Medical Devices Bill: Access to Innovative Treatments

Top Lines

- It is a Government priority to ensure patients can access innovative and life-saving medication rapidly and to reinforce the UK's position as a world leader in the licensing and regulation of medicines.
- We are also committed to ensuring our thriving UK clinical trials environment go from strength to strength so that companies can continue to develop innovative, safe and effective treatments, that both benefit patients and boost growth.
- The Bill will allow us to refresh and strengthen regulations on the approval, manufacturing and supply of medicines as health technology continues to advance.

What does the Bill do?

- The Bill will enable the regulatory framework for clinical trials and approval of medicines to be updated in line with the latest advances in science and technology.
- It will ensure the UK remains at the forefront of the global life sciences industry now we have left the EU, giving us the powers to provide NHS patients faster access to treatments and technologies while supporting the growth of our world-class life sciences sector.
- The provision we will be able to make under this Bill will position the UK as a world-leader in innovation and life sciences.

What is the system we have now?

- The approval process for new medicines in the UK is currently covered by the Human Medicines Regulations 2012 and the Medicines for Human Use (Clinical Trials) Regulations 2004.
- Nationally approved medicines and Clinical trials are regulated by the Medicines and Healthcare products Regulatory Agency and the Health Research Authority.
- The National Institute for Health and Care Excellence (NICE) make recommendations on whether selected drugs and treatments are a cost-effective and clinically-sound use of NHS money and resources.

Clinical Trials

- The Medicines for Human Use (Clinical Trials) Regulations 2004 set out a comprehensive scheme for regulating clinical trials such as the authorisation for clinical trials, ethical approval, conduct of trials and the manufacture and importation of the products used in trials.
- The Bill will give the UK flexibility to adapt our regulatory framework for clinical trials at the time the EU Clinical Trials Regulation comes into force, in a way which best suits the interests of UK patients.

Case-study

- The Bill could support manufacture and use of innovative, personalised medicines for rare diseases, including those that need to be prepared at the bedside, allowing more patients to access tailored treatments that they may not have been able to access previously. The ability to make regulations that are based on the needs of point of care manufacture will stimulate investment in new types of products which can only be made in this way.
- For example, this could allow patients such as diabetics to benefit from the most ground-breaking medicines as they come into clinical trials and then onto the market. Regulations made under the Bill could enable a new treatment for diabetic ulcers based on processing the patient's blood, with a shelf-life of less than a minute, to be manufactured in the operating theatre.