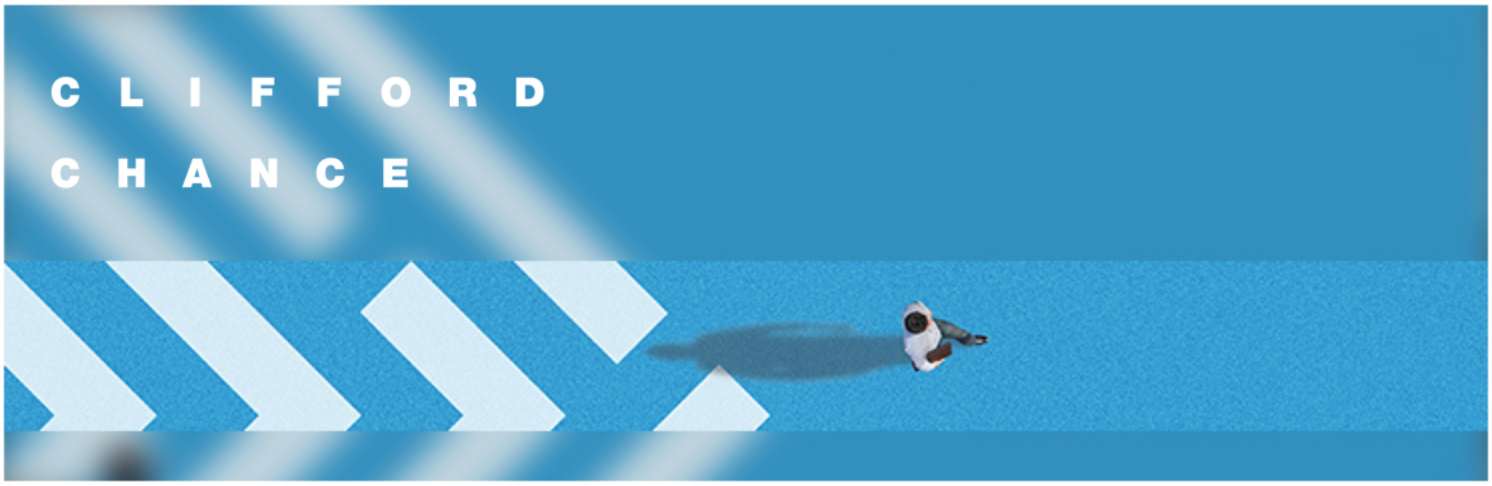

UK REGULATION OF MEDICINES AND MEDICAL DEVICES IN THE EVENT OF A 'NO-DEAL' BREXIT

On 23 August 2018 the UK government published several technical notices on how to prepare for Brexit in a 'no-deal' scenario. Although rather general in nature, the documents reveal first indications of how the UK government intends to regulate the health and medical sector after Brexit. While some general implications for the industry have become clear, specific effects and detailed consequences will be subject to further preparatory work and consultation.

THE UK'S PREPARATIONS FOR A 'NO-DEAL' SCENARIO

The implications for a 'no-deal' Brexit in which there is no agreement on a future relationship between the UK and the EU or on a transition arrangement are the subject of the UK government's programme to ensure the UK will be ready in all possible Brexit scenarios. As part of this programme, a first batch of 25 technical notices has been published, aiming to provide guidance for businesses and citizens to make informed plans and preparations.

REGULATION OF MEDICINES AND MEDICAL DEVICES

Concerning the health and medical sector, the UK government has published five guidance documents which provide first indications of the intended regulatory regime after a 'no-deal' Brexit and the implications this would entail. Focus areas cover batch testing, the regulatory regime for medicines, medical devices and clinical trials, the submission of regulatory information and quality and safety of organs, tissues and cells.

Although the details and specifics of the post-Brexit regulatory regime are far from clear, the implications give a first look into the challenges the industry would face in the event of a 'no-deal' scenario. As part of the above-mentioned programme, and pending a consultation by the Medicines and Healthcare Products Regulatory Agency (MHRA) said to follow in the early autumn covering the UK's regulation of medicines, medical devices and clinical trials, further information can be expected in the next few months.

On a separate note, preparations on the European side have also advanced. In addition to the guidance documents issued during the past months, most recently a 'Notice to Stakeholders' was published on 6 September 2018 dealing with the European regulation of clinical trials after Brexit.

Key implications for medicines in the UK

- Medicines already authorised at the time of Brexit: marketing authorisations obtained in an EU-centralised, mutual recognition or decentralised procedure will be converted into UK marketing authorisations;
- Centralised procedures still pending at the time of Brexit: applications filed with the EMA also need to be submitted to the MHRA;
- New medicines: national UK marketing authorisation applications will be required; new generic applications may only refer to products authorised in the UK;
- Legal presence in the UK required for UK marketing authorisations (marketing authorisation holder, qualified person for pharmacovigilance, etc.);
- The UK will accept batch testing carried out in the EU/EEA.

Key implications for medical devices in the UK

- Temporarily, CE marks on medical devices will be recognised by the UK;
- Notified bodies located in the UK will no longer be able to operate under the EU legal framework.

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