# News story: Veterinary medicines – information about market access during the implementation period following EU exit

The joint guidance published on 6 August outlines what it would mean for market access for medicines during the implementation period, including; licensing and packaging, batch release and testing, and the UK regulatory role.

It also covers other points relating to medicines and implementation plans related to EU legislation during the implementation period.

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# News story: Clinical Trials Regulation

As part of exit negotiations, MHRA is working to ensure that we continue to have the best possible environment in which to support clinical trials. Our overall aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines.

In March, the UK and EU negotiating teams reached agreement on the terms of an implementation period that will start on 30 March 2019 and last until 31 December 2020. During this time, the UK will no longer be a Member State of the European Union, but market access will continue on current terms – and the UK and the EU have agreed that EU rules and regulations will remain in place in order to provide continuity and certainty to businesses and citizens.

The EU's new Clinical Trials Regulation (CTR) specifically is expected to be implemented during 2020 and would therefore apply to the UK under the terms of the time-limited implementation period. The new regulation is a major step forward: it will enable a streamlined application process, harmonised assessment procedure, a single portal for all EU clinical trials and simplified reporting procedures, including for multi-Member State trials. The UK was involved in developing the new regulation that has been widely welcomed by Europe's research sector, including academia, medical research charities and industry.

However, if the new regulation does not come into force during the implementation period, the Government has confirmed that UK law will remain aligned with parts of the EU's CTR legislation that are within the UK's control, in order that researchers conducting clinical trials can plan with

greater certainty. The UK's access to networks, information systems and databases will continue on current terms for the duration of the implementation period. The two key elements of the regulation that the UK would not be able to implement on its own after this time are the use of a shared central IT portal and participation in the single assessment model, both of which would require a negotiated UK/EU agreement regarding UK involvement following the end of the implementation period. We cannot pre-empt the outcome of these negotiations, but the Government has always been clear on its preference for close cooperation with the EU across all aspects of medicines regulations.

It is in the interest of patients and the Life Sciences industry internationally for the UK and EU to find a way to continue cooperation in the field of clinical trials, and for continued sharing of data, even if our precise relationship with the EU will by necessity change.

No matter what the outcome of negotiations, the UK is committed to offering a competitive service for clinical trial assessment.

If the UK is outside of the EU network following the end of the implementation period, it will still be possible for sponsors to run multistate trials involving the UK. Sponsors would have to apply to MHRA, as well as to the EU concerned states; but MHRA would take every effort to ensure this parallel submission is as streamlined and efficient as possible (for example by using the same application dossier). MHRA and UK ethics committees are already internationally recognised for their robust yet timely assessment of trial applications, and the UK would provide an assessment outcome no later than the European timeframe.

The current regulatory approval legislation will stay in place until such time as any changes are needed, so there will be no interruption in UK clinical trials approval (whether for academic or industry-led clinical trials).

The UK's commitment to offering a competitive clinical trials environment does not just cover regulatory approval from MHRA – it also covers services from the Health Research Authority (HRA), the Devolved Administrations, ethics services, National Institute for Health Research (NIHR) and the NHS. For example, MHRA and the HRA, in partnership with the Devolved Administrations, have been exploring opportunities to improve services to sponsors through the Combined Ways of Working Pilot. This is testing a new process that will result in a single UK decision on a clinical trial (consisting of the current ethics opinion and MHRA clinical trial authorisation), in addition to a single clinical trial application route that incorporates both the Research Ethics Service and MHRA.

Following the agreement in March of the implementation period, work to finalise the Withdrawal Agreement as a whole is continuing – with the intention to do so by October, alongside the framework for the future partnership. The Government has always been confident that we will get a good deal – and now that good deal is clearer and closer than ever. Of course as a responsible Government we continue to plan for all scenarios, but with

increased confidence that we will leave with a deal and that a ‘no deal’ scenario in March 2019 is significantly less likely. The Government recognises that in the unlikely scenario of no deal between the UK and the EU, it would be important to reach a suitable resolution to the supply chain questions that would arise, particularly regarding Investigational Medicinal Products.

The Government has been consistent in saying that a key priority through the negotiations is to ensure that the UK remains one of the best places in the world for science and innovation. The Life Science Industrial Strategy set out a clear ambition to remain at the forefront of innovation, which includes a commitment to increase the number of clinical trials and to ensure the UK remains an attractive location for trials to take place, with a view to getting medicinal products licensed in the UK and elsewhere.

In February, Dr Ian Hudson CEO at the Medicines and Healthcare products Regulatory Agency wrote to Dr Wollaston, chair of the Health and Social Care Select Committee about clinical trials.

We are fully committed to continuing a close working relationship with the EU, in the interests of public health and safety.

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# News story: Issues with our online services

*Updated:* Issues with WebFiling, CHD and WebCHeck

Were having issues that are affecting WebFiling, CHD and WebCHeck.

We are working hard to fix the issues and apologise for any inconvenience caused.

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# Press release: Parole Board Chief Executive’s Blog – 1st Edition – August 2018

The last few months have been an exceptionally busy and challenging period for the Board and for me as Chief Executive. Heightened scrutiny and

significant change bring their own challenges, but they also bring opportunities to better explain the work we do and focus on lasting changes that are going to improve the experience of prisoners and victims.

Two weeks ago, I presented at the University of Cambridge to academics and practitioners who are interested in parole. I talked about where we are now and how we can ensure we are effective and efficient in our independent decision making. It was particularly interesting to hear their thoughts and ideas about where things are working well, but also how the Board can improve its practice whilst focused on our primary duty; making independent and fair decisions which ensure the protection of the public.

We have also published our 2017-18 Annual Report and Accounts this month. Last year we held a record number of hearings and have made good progress on IPPs. One of the Parole Board's biggest achievements over the last year has been the steady elimination of the backlog. This means prisoners are not waiting unnecessarily for their case to come before a Parole Board. However, some cases are still being delayed through unnecessary deferrals and adjournments. This is a priority and we are working hard to look at how we can progress cases more effectively and there are a number of initiatives ongoing within the Board to tackle this problem – trying to bring cases to a fair and early resolution.

The Government is considering potential options for an internal review mechanism and possibly changing the rules that we are governed by. These will take some time to work through, I am keen to ensure that any changes improve the way we do things and are properly thought through and resourced. The Board has submitted its formal response to the Ministry of Justice but in essence, we think it is important to have a simple and process, that doesn't create unnecessary delays for victims or prisoners.

This month has also seen our annual staff and members strategy day, outlining where we are focusing our efforts for the year ahead. 2018-19 will see us being a more transparent organisation, so the public can really understand our work and the decisions from our members. I would also like to pay special tribute to Sir Brian Leveson who round off our 50th anniversary celebrations with a fantastic speech dedicated to the work of the Board.

Whilst Sir Brian's speech makes for excellent reading one of the things he said resonated with me:

> At a fundamental level, however, Parole Board decisions should be treated with the same respect for integrity and independence as any other judicial decision.
>
> Independence is the bedrock of all that you do and should be the bedrock of the Parole Board.
>
> There should be no improper influence or interference, whether from the media, the public, or politics, in your decision-making process.

Decisions should be, as I said earlier, made without fear or favour.

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# Speech: UN Security Council signals support for Special Envoy on Yemen

I thank the representative from Kazakhstan for his statement and I now make a statement in my capacity as the representative of the United Kingdom. First of all, to Mr Ging, thank you very much for your briefing. You heard the words of appreciation from Council members today to your team and for everything you do and I'd like to add the United Kingdom's voice to that. We will continue to disperse over $200 million to the people of Yemen to support your efforts.

To the Special Envoy, thank you too for your amazing efforts and also those of your team. I hope the strong unity you have heard from the Council today can be a real spur to efforts in taking this forward:

- I think it's been very good that we've all been able to express concern about the reports we have heard today of the attack on the hospital and on the fish market;

- Very strong reassurance from members of the Council that it's important to uphold the International Humanitarian Law and protection of civilians, and I think that was absolutely unequivocal from the Council, and obviously the United Kingdom joins that;

- Very strong condemnation too for the attacks by the Houthis on the Saudi oil tanker and other attacks in the Red Sea and concern about arms shipments that are coming through the Red Sea. I think we all look forward to the forthcoming panel of experts report;

- And a call from the Council to the Houthis to come and work with you and follow the Security Council Resolutions even as we recognise the commitment to halting attacks in the Red Sea, I think we all feel that it is now time to take this to the next stage.

There was unconditional support for your efforts, Special Envoy, and a real hope that the 6 September talks in Geneva can start a very viable process and I think you could count on all members of the Council to unify around your efforts and build momentum for what you have started.

Thank you very much.