UK Government
Llywodraeth y DU

Ref: 056SOS21

Rt Hon Simon Hart MP
Secretary of State for Wales
Ysgrifennydd Gwladol Cymru

T: 0292 092 4216
E: Correspondence@ukgovwales.gov.uk

Rt Hon Stephen Crabb MP
Chair
Welsh Affairs Select Committee
House of Commons
London
SW1A 0AA
Email: welshcom@parliament.gov.uk

19 February 2021

Dear Stephen,

Thank you for your 8 February letter regarding the flow of pharmaceutical products between the UK and the EU. Please be assured that both my Office and relevant UK Government departments are fully aware of the issues you mention, including the specific case raised by Ian Price during your Committee's latest evidence session.

To answer your questions in turn:

Are you aware of the pharmaceutical company mentioned by Ian Price and of the alleged difficulties they have experienced in exporting goods to the EU?

- ***If so, what discussions have you held with the firm and what assistance has been offered to them by the UK Government?***
- ***If not, what discussions have you had, or propose to have, with the pharmaceutical industry in Wales to investigate this claim?***

On 29 December, I hosted a roundtable with key Welsh businesses and representative organisations to discuss the UK-EU Trade and Co-operation Agreement (TCA). The Agreement had been announced five days before, on Christmas Eve. At the meeting, Ian Price raised the issue of the TCA not including reciprocal arrangements on medicines regulation, and that approval of pharmaceutical products by the Medicines and Healthcare products Regulatory Agency (MHRA) would not be recognised by the EU after the end of the Transition Period.

Following this, officials from HM Revenue and Customs, my Office and other government departments have liaised closely with the company concerned to seek to resolve a range of issues relating to exporting medicines to the EU. I am not in a

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position to comment on the specific circumstances of the company concerned nor the nature of the support provided by HMRC, save to say there has been a great deal of engagement between the UK Government and the company concerned.

Has the UK Government been informed about other instances of pharmaceutical firms experiencing issues importing or exporting products, including but not limited to cancer drugs, since 1 January?

- ***(If yes) What discussions has the UK had with the EU to explore how these issues can be resolved?***

It may be helpful if I set out some background relating to pharmaceuticals and medicines and the UK EU Trade and Co-operation Agreement (TCA). The Agreement does not include the wholesale mutual recognition of regulatory regimes in relation to pharmaceuticals and medical devices, except for the mutual recognition of Good Manufacturing Practice (GMP) certificates. Other than this, these products are now regulated in the UK separately from the EU and companies must comply with the relevant requirements for the market in which the product will be sold.

There are certain transitional arrangements for medicines being placed on the market in the UK. The UK has accepted some EU rules on medicines transitionally, for two years after the end of the Transition Period. This is to ensure continuity in the supply of medicines and give industry time to adjust.

However, companies must meet all EU requirements in full to place medicinal products on the EU market. Whilst the Agreement includes mutual recognition of good manufacturing practice of medicinal products and associated information sharing, we were not able to agree mutual recognition of batch testing. An effect is that a Qualified Person in the EU/EEA must certify each batch of finished product before it is placed on the market in the EU/EEA.

There would need to be a clear shift in the EU's position for the bloc to recognise UK operators; we do not foresee a shift in the short term.

The TCA also requires each party to give notice to the other of changes to their existing regulatory frameworks and points to international standards as the starting point for any new regulation. It also provides for a working group to discuss regulatory co-operation in future, leaving the door open to future regulatory cooperation on medicines.

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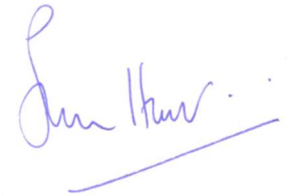
The Government is continuing to support businesses to ensure they have a clear understanding of the new rules and procedures which now need to be followed to export their products to EU countries.

Yours sincerely,



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