



Department
of Health

*From the Lord O'Shaughnessy
Parliamentary Under Secretary of State for Health (Lords)*

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Warwick Smith
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Dear Warwick,

It was very helpful to meet before Easter and to hear first-hand the challenges faced by SecurMed and its Directors in building the UK's system to deliver the Falsified Medicines Directive (FMD). I wanted to thank you again for your ongoing commitment to finding a solution and take this opportunity to provide you with some further reassurance about the Government's ambition to continue to collaborate with the EU in this area in the interest of public health and safety following our exit from the EU.

Our position on medicines regulation remains clear - we want to retain a close working partnership with the EU to ensure patients continue to have timely access to safe medicines and medical innovations.

The Prime Minister reiterated in her Mansion House speech on 2 March that the UK wants the broadest and deepest possible future partnership with the EU – covering more sectors and co-operating more fully than any Free Trade Agreement anywhere in the world today. In particular, the Prime Minister was also clear that this involves us wanting to make sure our regulators continue to work together; as they do with regulators internationally, highlighting that this would be essential in continuing to get new drugs to patients quickly. On goods, including medicines, a fundamental principle is that the UK-EU border is as frictionless as possible and products would only need to undergo one set of approvals to be sold in the EU and UK. In this context, the UK wants to explore with the EU the terms on which we could remain part of EU agencies, including

the European Medicines Agency and the wider EU medicines regulatory framework. Whatever the outcome of those negotiations, 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, and be assured that their safety is protected through ongoing cooperation and the strongest regulatory framework.

We have also sought to agree a time-limited implementation period that gives further certainty to people and businesses. As I know you are aware, the UK and EU negotiating teams reached an agreement on the terms of the implementation period that will start on 30 March and lasts until 31 December 2020. The agreement that has been reached on the implementation period, endorsed by the March European Council, provides a clear political statement of intent from both sides. The implementation period will protect economic and regulatory cooperation, ensuring there is no sudden change as the UK builds our future partnership with the EU.

It is in everyone's interests to secure a good deal for both sides and we believe that this is the most likely outcome. We are increasingly confident that we will secure a deal with the EU and that the prospect of leaving negotiations with 'no deal' has reduced significantly. However, even if we do not achieve our desired future relationship with the EU, the European Union (Withdrawal) Bill will ensure that, as far as possible, the same rules and laws will apply in the UK after exit as the day before. The Bill will convert existing direct EU law, such as EU regulations, into UK law as it applies in the UK at the date of exit. It will also preserve the laws we have made in the UK to implement our EU obligations, such as laws made to implement the FMD. This means that the duties of the regulations under the FMD would continue to apply, unless specifically revoked.

We remain committed to continuing to work closely with SecurMed and I hope that this provides you with the necessary clarity to continue your preparations to implement the FMD in full from February 2019.

Thank you for
all your work on this.

JAMES O'SHAUGHNESSY

