

Responses from pharmaceutical companies who supply Anti-Epileptic drugs (AEDs) to Irish patients regarding plans to ensure supply of AEDs in the case of a no-deal Brexit.

UCB Pharma

(Keppra, Briviact, Vimpat)

Ensuring patients avoid any disruption to the supply of their medicines is a primary priority for UCB. Because of this UCB continues to actively and routinely engage both Irish and UK Governments to encourage the development of policies that will avoid disruption to UK patients receiving their medicines.

As a precautionary measure against a “hard” / “no deal” Brexit, UCB will ensure that all medicines destined for Irish patients will be supplied to Ireland via another EU country and not via the UK after March 29th 2019.

UCB are separating Ireland from the UK to avoid any regulatory disconnect following a hard/no Brexit which will come into effect on the 1st June 2019, and in the meantime there is sufficient stock to bridge to July.

UCB would therefore like to assure patients that we have taken steps to mitigate as best as possible any disruptions from a hard / “no deal” Brexit.

Eisai

(Zonegran, Inovelon, Fycompa)

Eisai is well prepared for whatever the outcome is of the ongoing discussions with regards to the United Kingdom (UK) leaving the European Union (EU). Eisai began its risk evaluation and preparations immediately after the result of the UK referendum in 2016. The objective has always been to continue to supply our neurology and oncology medicines to patients throughout the EU 27 and the UK in the event of a no-deal /hard Brexit, and to ensure full continuity of our business operations. We have essentially completed the transfer of all our EU Centralised Authorisations to our German affiliate. We have established a new product batch release and compliance approval system in the EU 27 and have recruited a Qualified Person Responsible for Pharmacovigilance (QPPV) to be based at our German affiliate in Frankfurt. Importantly we have increased our supplies of products and have six months of stock in the pipeline - not the minimum six weeks as suggested by the UK Government. We are as well prepared as we can be, but clearly there could be events outside of our control which might still impact upon our operations.

Sanofi

(Epilim, Frisium)

Our main priority is to ensure people in the European Union (EU) and UK have continued access to the medicines and vaccines they need. Sanofi is working to ensure that Brexit does not negatively impact the supply capacity, processes and time-frames for new and existing medicines and vaccines reaching EU and UK patients.

The uncertainty in the Brexit negotiations means that Sanofi has been planning for a 'no deal' scenario, as recommended by the European Federation of Pharmaceutical Industries and Associations (EFPIA). Patient safety and continuity of supply is our main priority and, amongst other actions taken, we have restructured our supply chain to exclude the UK from inter-EU-27 distribution routes.

Sanofi is confident that its contingency plans will ensure that patients and citizens in the EU-27 can continue to access the treatments they need after the UK leaves the European Union.

Novartis
(*Tegretol, Trileptal*)

Novartis' primary concern is that patients in Ireland continue to have supply of medicines after Brexit. It is for this reason we are investing heavily to be ready, as best we can, for every eventuality. We have been preparing since June 2016, changing the packaging of hundreds of medicines, so that delays can be avoided. We have been working closely with the HPRA (Health Products Regulatory Authority), the HSE (Health Service Executive) and the DoH (Department of Health) to ensure plans are in place to avoid any possible disruption to the supply of medicines in Ireland. This is to ensure that patients in Ireland will continue to have access to medicines in a timely manner. Our aim is that patients, should not feel the need to worry about medicines shortages and should not feel the need to get additional supplies of their medicines, as this may disrupt the normal supply of medicines.

Pfizer
(*Epanutin, Lyrica, Neurontin*)

In order to minimize any potential patient impact we have undertaken work to ensure we can continue to supply in the EU and the UK covering all Brexit scenarios. We have carried out detailed assessments of the supply of all our medicines with the focus on ensuring we will continue to have them available for our patients.

Janssen Cilag
(*Topamax*)

Janssen's first priority is to patients and healthcare providers. We are preparing for a variety of Brexit scenarios and taking the appropriate steps, in collaboration with our partners, to help ensure that patients in Ireland have ongoing access to our medicines.

Essential Pharma
(*Zarontin*)

Oral preparation of Zarontin will remain in continued supply before and after the 29th March 2019 Brexit date; confirmed by manufacturer.

Shire (Takeda)

(Buccolam)

Takeda has been working on and planning for Brexit since the UK referendum result was announced in 2016. Our primary focus throughout this process has been to ensure that we are able to continue to deliver our innovative medicines without interruption to the patients who benefit from them, in both Ireland, the UK and EU, beyond March 2019.

Takeda is closely monitoring the evolving situation and is planning for all scenarios including that of a 'no-deal'. Takeda continues to work closely with the Department of Health as well as relevant trade bodies, at Irish, UK and European levels, on Brexit planning.