



Brexit preparedness in the area of Health and Food Safety - Speech by Vice-President Jyrki Katainen

Brussels, 4 April 2019

Ladies and Gentlemen,

As you all know, we have repeatedly stated that the Commission regrets the decision of UK to leave the European Union.

Following the latest developments, a no-deal scenario is highly likely. Let there be no doubt whatsoever: a “no-deal” scenario would be extremely costly and disruptive. The economic consequences would have a significant impact on the UK, and to a lesser extent the EU.

The EU has been preparing for all scenarios – including a no-deal scenario – for a long time. This is particularly true for the two areas currently under my responsibility: **health and food safety**.

The preparations in these two areas, which started back in December 2017, have an immense impact on the life of our citizens and the functioning of businesses.

EU requirements in these areas are designed to protect human, animal and plant health. But also to protect our economy and reputation as the EU is recognised as having one of the safest medicine and food production systems worldwide.

Together with the Member States, the Commission continuously monitors the situation regarding public health risks. If there is no deal, we cannot rely on the fact that the UK used to be a Member State the day before.

The situation can change very quickly and the UK will, unfortunately no longer be part of the cooperation system that underpins the Single Market and makes sure that our medicines and medical devices comply with our high safety standards.

We are not being overly bureaucratic. The protection of EU citizens requires EU oversight. Although some might want to do as if nothing has changed, the reality is that the UK will no longer be bound by EU rules designed to protect our citizens. The UK will no longer be part of the monitoring systems that make sure medicines given to EU patients are safe.

I would like to stress one important point: although the EU and Member States preparations are there to tackle the most disruptive changes, a “no-deal” scenario will be very disruptive. There will be a need to adapt to a new reality where the UK is no longer part of the invisible, but crucial, systems that ensures safety for patients in the EU.

This will have consequences for citizens and companies. But whatever the impact, the EU is ready.

In the **health** area, Brexit will have an impact on two crucial sectors: **medicines and medical devices**.

Extensive preparedness has been done:

For **medicines**, the situation is very clear; we have been working very hard over the last two years together with the European Medicines Agency and national authorities to ensure that everyone is prepared, especially the industry, as they had to adapt the marketing authorisations to the post-Brexit situation.

This requires that certain essential functions (such as being established in the EU, testing and batch release) are performed in one of our Member States. Otherwise, we lose oversight over medicine and create liability gaps, something we cannot afford for medicines, which are not goods like any other. We need to make sure that the medicines sold to EU citizens are safe.

Patients in the EU should not worry about finding the medicines they need. Our rules provide for appropriate procedures to ensure that medicines will reach patients in time and that treatments will

not have to be interrupted. We are prepared to coordinate any necessary action to address any problems which might arise and give guidance to doctors and patients through well-established tools such as the "EU network".

Yet it is crucially important that industry continues to make the necessary arrangements to limit supply disruptions and that Member States are ready to make use of EU legislation to protect patients.

The continued availability of **medical devices** in the EU27 post-Brexit is also a priority for the Commission.

We have been proactively informing stakeholders of the need to ensure certification of medical devices through an authority within the EU27. Since December 2017, we have been encouraging economic operators to prepare for a possible "no-deal" scenario, with the aim of mitigating possible negative consequences for patients and businesses.

At the same time, we remain in intense contact with the UK and EU27 to ensure that all certificates for the medical devices issued in the UK, are transferred to the EU27 before the withdrawal date. With this, we aim to minimise problems with supply of medical devices.

But, if problems were to arise, Member States have the possibility to use the derogation provided in existing legislation which would authorise the temporary placing on the market of medical devices that have not been certified by an EU body.

Strictly linked to the protection of our citizens, is the **food safety** area. The reality is that the EU has the highest food safety standards in the world. Free circulation of animals and food is possible thanks to a stringent system of shared controls.

When the UK leaves the EU, it will be confronted with an obstacle we got rid of a long time ago: borders.

Borders are not there to add red tape or slow things down. They are there to ensure that the food we eat is not a danger for our citizens and to protect our animals and plants and thus our extremely valuable agricultural patrimony. This is also very important for the UK as it imports more than [73%](#) of its agri-food products from the EU.

New controls will have to be carried out at our borders with the UK. Member States are setting up Border Inspection Posts and the Commission is swiftly approving these.

Member States have also recruited the necessary staff to handle customs and safety checks. More than 2,000 professionals have been recruited in the countries most affected (France, Belgium, Ireland, Netherlands, Denmark).

We are taking the necessary measures to allow UK products and animals still to enter the EU provided the UK has adopted the relevant new legislations and the necessary food safety conditions are met. For example, in order to be able to export products of animal origin to the EU the UK has to be 'listed' by the Commission as a third country authorised to export and the food needs to satisfy all EU food safety requirements.

With an agri-food sector representing [130.7 billion euros of exports](#), it is crucial that we guarantee its safety and sustainability or we would put at risk our worldwide reputation.

To conclude, although we regret the UK's decision, on our side all preparations have taken place and we are ready to take extra steps to support Member States and stakeholders the day after the UK leaves the EU.

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Press contacts:

[Anca PADURARU](#) (+ 32 2 299 12 69)

[Aikaterini APOSTOLA](#) (+32 2 298 76 24)

General public inquiries: [Europe Direct](#) by phone [00 800 67 89 10 11](#) or by [email](#)