

# EMA urgently reviewing multiple sclerosis medicine Zinbryta following cases of inflammatory brain disorders

02/03/2018

## **Medicine to be voluntarily withdrawn from the market by the company**

The European Medicines Agency (EMA) has started an urgent review of the multiple sclerosis medicine Zinbryta (daclizumab) following 7 cases of serious inflammatory brain disorders in Germany, including encephalitis and meningoencephalitis, and one case in Spain.

In parallel to the start of the review, the company that markets Zinbryta (Biogen Idec Ltd) has informed EMA of its intention to voluntarily withdraw the medicine's marketing authorisations.

Doctors in the EU will be contacted directly in the coming days with further information. Until then EMA advises that:

- doctors should not start new patients on Zinbryta;
- doctors should review patients currently treated with Zinbryta and initiate alternative therapy, as soon as possible;
- patients must not stop their medication without discussing with their doctor;
- patients who have any questions should talk to their doctor.

The company has also informed EMA of its decision to stop ongoing clinical studies with Zinbryta in the EU. Patients in clinical studies who have any question should contact the doctor treating them in their study.

EMA will communicate further as necessary.

## **More about the medicine**

Zinbryta is authorised for treating relapsing forms of multiple sclerosis. Following a 2017 [review](#) of the medicine's effects on the liver, the use of the medicine was restricted to patients who have tried at least two other disease-modifying treatments and cannot be treated with any other multiple sclerosis treatments.

To date over 8,000 patients have been treated with Zinbryta worldwide. The majority of EU patients have been treated in Germany.

More information is available on the [medicine's dedicated webpage](#).

## **More about the procedure**

The review of Zinbryta was initiated following a request from the European

Commission on 26 February 2018, under [Article 20 of Regulation \(EC\) No 726/2004](#).

The initial review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations.

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## **[Speech by Michel Barnier at BusinessEurope Day 2018](#)**

Ladies and Gentlemen,

2018 is an important year. Not only for BUSINESSEUROPE – congratulations on your 60th anniversary – but also for the European Union.

As President Tusk told you this morning, 2018 should be a year when the EU makes progress on many fronts:

- deepening the Economic and Monetary Union;
- building a European defence in coherence with our allies;
- modernising the rules for a Digital Single Market; and,
- addressing Europe's social dimension more strongly, to name but a few.

2018 is also the year when we need to conclude the negotiations with the United Kingdom on its orderly withdrawal and define the framework for our future relationship.

The outcome will have an impact on millions of citizens and many of your businesses.

So, ladies and gentlemen, it is a great pleasure for me to speak to you at the end of your day.

Thank you, Madam President, Emma MARCEGAGLIA, and Markus BEYRER for this invitation to continue our dialogue about Brexit.

On 23 June 2016 the British people made a choice to leave the EU.

We regret the decision but we respect it and now we have to implement it.

Our responsibility is to make sure that the UK's withdrawal is orderly. Because a disorderly withdrawal would be a very bad outcome. And I recommend that everyone, on both sides, measures the consequences of a "no deal".

- So we have worked on this orderly withdrawal, step by step, since the opening of negotiations in June last year.
- In December, we reached agreement on our three priorities: citizens' rights, the need to avoid a hard border on the island of Ireland, and the financial settlement.

We are now in the second stage of the negotiations, and we have three tasks to pursue in parallel. Let me illustrate this with a slide.

1. First, we need to draft the Withdrawal Agreement, which should deal with all consequences of the UK's departure.

For business, important separation issues include customs procedures, the movement of goods, intellectual property, public procurement, data protection and Euratom.

- o Yesterday, the European Commission presented a draft text – a complete text – which we will now discuss with Member States, in close coordination with the European Parliament.
- o We needed to publish this draft because we have to move forward. In 13 months the United Kingdom will leave the European Union. It is time to start negotiating on the basis of a legal text.
- o On the sensitive issue of Northern Ireland, in particular, the moment has come to work on operative solutions. Solutions to a problem arising from the UK's decision to leave the EU, its Single Market and Customs Union.
- o I have said it yesterday, and I am repeating it today: if the UK has better ideas on how to avoid a hard border while preserving the integrity of the Single Market, we are ready to look at them in a constructive way.
- o We are not excluding any of the three options we jointly agreed in December on Ireland and Northern Ireland. And I expect the UK to do the same.

2. The second task, which will be part of our Withdrawal Agreement, is to negotiate the transition period. The UK has requested this transition.

- o Under our proposal, UK citizens, businesses, universities, farmers and regions will continue to have the same rights and the same obligations as they have today up until the end of 2020.
- o But the UK will no longer take part in the EU's decision-making process, as it will have left the Union in accordance with its own decision.

3. Finally, once the European Council, under the authority of Donald Tusk, has given us a mandate, we will be able to start discussing with the UK

the framework for our future relationship.

In order to start on this third task, we will need to know what the UK's vision is.

Not only on trade, which is our main topic today, but also on security, defence and foreign policy, justice and home affairs and some sectors like aviation.

This is what the EU leaders asked the UK in December.

In this context I am looking forward to Theresa May's speech tomorrow and I hope it will help move the negotiations forward by setting out her vision of the future relationship.

My aim today is not to speculate on or prejudge the Prime Minister's proposals.

I simply want to repeat that any vision of the future must take into account the fact that the EU cannot and will not compromise on its founding principles.

We have learnt that the United Kingdom wants to leave the Single Market and the Customs Union. And it also wants to leave our common supervision and enforcement structures.

So, as this slide shows, the UK is closing the doors on itself, one by one, and the only possible model that remains is that of a free trade agreement.

It should be our common goal to make such a free trade agreement ambitious.

All of the models remain available, as long as the UK is willing to accept the balance between rights and obligations.

We need to tell the truth. That means making a number of difficult but necessary choices. Let me mention three of these choices.

I – Does the UK want to regain full decision-making autonomy or does it want to retain the advantages of the Single Market?

So far, we have learnt that the UK wants to regain its decision-making autonomy. We respect this, as the UK should respect our own decision-making autonomy.

This inevitably entails a series of consequences.

The UK Government wants to end the free movement of people, which is indivisible from the other freedoms, such as the free movement of goods and services.

It has, therefore, indicated its intention to leave the Single Market.

One example:

Take the case of personal data: all economic sectors work with personal data, ranging from the financial sector, to the health industry and to the transport sector.

In the Single Market, we have a modern and very detailed regulatory framework that allows for the “free movement” of personal data. This facilitates the collection and exchange of such data. It also provides for supervisory mechanisms, overseen by the Court of Justice of the European Union.

The UK is going to leave this regulatory framework. In the future, the transfer of personal data from the EU to the UK will be subject to strict rules. These rules are designed to protect a fundamental right.

Allow me to be precise on this point.

The transfer of personal data to the UK will only be possible if the UK provides adequate safeguards. One example to ensure that adequate safeguards are in place is an “EU adequacy decision”. This is an autonomous EU decision. There can be no system of “mutual recognition” of standards when it comes to the exchange and protection of such data.

In the Single Market, we have a modern and very detailed regulatory framework that allows for the “free movement” of personal data.

The same rule goes for standards underpinning free movement of products and services.

In the absence of a common discipline, in the absence of EU law that can override national law, in the absence of common supervision and a common court, there can be no mutual recognition of standards.

The Single Market allows for fluid economic exchanges because it is a living system that we adapt permanently.

Ladies and gentlemen, the second difficult choice is linked to the ability to negotiate free trade agreements.

II – Does the UK want to have complete freedom to decide its trade policy, or does it want to continue to benefit from a comprehensive Customs Union?

The UK Government wishes to regain its autonomy in terms of negotiating international agreements. It has indicated its intention to leave the Customs Union.

This choice has consequences.

Being outside of the Customs Union always involves customs procedures and checks, for example to ensure compliance with preferential rules of origin.

Now, as I said, it is always possible to choose a more ambitious model and stay in a customs union with the European Union. But this would imply a balance of rights and obligations.

You can always go up and down the stairs.

In a customs union, the UK would apply the same external tariffs as the EU.

This would involve fewer border controls between the UK and the EU than outside of a customs union.

For example, we would not have to check the rules of origin between us.

But it should be well understood that – even in a customs union – a country which is outside of the Single Market always faces border checks to ensure compliance with European standards. This is the case for instance with Turkey.

As President Donald Tusk clearly said this morning, only the combination of the internal market and the customs union makes frictionless trade possible.

Lastly, Ladies and Gentleman, there is a third choice that will shape our future economic relationship.

III – Does the UK want to move away from or stay close to the European regulatory model?

This is an important choice. Underlying the European regulatory framework are key societal choices that we hold dear: our social market economy, food safety, effective financial regulation, and a precautionary approach to environmental and public health risks.

For an ambitious economic partnership, we will need to find common ground on the rules that apply to social and environmental matters, to consumer protection and to competition.

Take the aviation sector as an example: what would EU airlines say if UK companies could operate with an EU licence within the Single Market?

They would ask several questions: are those companies bound by the same rules on CO2 emissions? Do they have the same rules on working time for cabin crew?

The same professional qualifications for pilots?

The same compensation schemes for passengers in the event of delays and cancellations?

The same rules on competition and state aid?

Ladies and Gentlemen,

These questions are not only economic. They are first economic as far as the level playing field is concerned. They are also political. Why? The answers to all of these questions will be key to the ratification of any future deal in each national parliament, and in certain countries in regional parliaments. We need to be careful about the political conditions of the ratification for any future deal. This will be a mixed treaty. It will

require not only the ratification of the Council and the Parliament, but each of the 27 national parliaments by unanimity. This is the reason why I take the time in each of my visits – tomorrow in Copenhagen – to meet not only the Government, but also the trade unions, the business community, the national parliaments. I want to succeed in this stage and prepare the next.

Not one of the choices I have mentioned is easy. And I recognise the political temptation to avoid making a choice or to downplay the cost of Brexit.

Or indeed to pretend that the UK could obtain a free trade deal with the EU with all the benefits of the Single Market.

Abandoning such ideas will enable us to begin building an ambitious future partnership based on a foundation of realism and in the interest of our citizens and our businesses. This is my objective.

Ladies and Gentlemen,

There are also choices to be made on the EU side.

The 27 Member States wish to minimise the negative impact of Brexit on the European Union and so does business.

But we are all fully aware that the economic and political benefits of the Single Market, of the Customs Union and of staying together in the EU are far bigger than any possible cost of Brexit.

Since December, the EU has done extensive preparatory work on how to manage the negative impact of Brexit and exploring avenues for the future relationship in many sectors.

You will find all details on our website[\[1\]](#).

You, as business leaders, also have choices to make in a context of uncertainty.

The UK will leave the EU on 29 March 2019. That is the only certainty we have at this stage.

It is therefore important that all businesses analyse their exposure to the UK and are ready to adapt their logistics, supply chains and contracts.

Of course, the transition period currently under negotiation would give you more time to adapt.

However, certainty about the transition will only come at the end of the process, with the ratification of the withdrawal agreement by both sides –probably early next year.

Ladies and Gentlemen,

I understand the concerns about Brexit. They are my concerns. But we must not



lose sight of the key point: the Single Market is what makes our businesses in Europe strong.

It will still be a market of 440 million customers and 22 million businesses after the UK leaves.

A market that might not be perfect yet – I know that well – but that is a point of attraction for the world.

And the very strong unity that we have forged at 27 during these negotiations must be used positively to develop this Single Market. This is what the European Commission, with its President Jean-Claude Juncker, is pushing for.

– By strengthening the competitiveness and social cohesion of each of our countries and our Union of 27.

– By continuing to invest in our SMEs, in research, innovation and technology. This is the aim of the Juncker Plan.

– By building, alongside the Banking Union, a true Capital Markets Union.

– And by continuing to build this ‘Global Europe’, which is preparing to offer our businesses new opportunities to export to Japan, Australia, Canada and New Zealand.

For citizens, for your businesses and for each of our countries, my conviction is clear, the future of our Union is more important than Brexit.

[1]

[https://ec.europa.eu/commission/brexit-negotiations/negotiating-documents-article-50-negotiations-united-kingdom\\_en](https://ec.europa.eu/commission/brexit-negotiations/negotiating-documents-article-50-negotiations-united-kingdom_en)

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## [European Commission responds to the US restrictions on steel and aluminium affecting the EU](#)

The European Commission takes note of the announcement by the President of the United States of the imposition of restrictions in the form of an import surcharge on EU exports to the US of steel and aluminium.

President of the European Commission, Jean-Claude **Juncker** said: *“We strongly regret this step, which appears to represent a blatant intervention to protect US domestic industry and not to be based on any national security justification. Protectionism cannot be the answer to our common problem in the steel sector. Instead of providing a solution, this move can only*

*aggravate matters. The EU has been a close security ally of the US for decades. We will not sit idly while our industry is hit with unfair measures that put thousands of European jobs at risk. I had the occasion to say that the EU would react adequately and that's what we will do. The EU will react firmly and commensurately to defend our interests. The Commission will bring forward in the next few days a proposal for WTO-compatible countermeasures against the US to rebalance the situation."*

Commissioner for Trade Cecilia **Malmström** added: *"These US measures will have a negative impact on transatlantic relations and on global markets. In addition, they will raise costs and reduce choice for US consumers of steel and aluminium, including industries that import these commodities. The EU will seek dispute settlement consultations with the US in Geneva at the earliest opportunity. The Commission will monitor market developments and if necessary will propose WTO-compatible safeguard action to preserve the stability of the EU market. The root cause of problems in these two sectors is global overcapacity caused by non-market based production. This can only be addressed at the source and by working with the key countries involved. This go-it-alone action by the US will not help."*

## **Background**

On 1 March, President Trump announced the imposition of additional import duties on EU exports of steel and aluminium to the United States. The import duties are set at 25% on steel and 10% on aluminium. Similar restrictions will also be imposed on exports from other suppliers.

This action follows investigations undertaken between April 2017 and January 2018 by the US Department of Commerce under Section 232 of the US Trade Expansion Act of 1962. These reports concluded that steel and aluminium imports threatened US national security and recommended the imposition of trade restrictions.

However, in essence, these measures are primarily intended to protect the US domestic industry from import competition. Any national security justification appears very weak: the US Secretary of Defence has stated publicly that US military requirements represent no more than 3% of US production and that the Department of Defence is able to acquire the steel and aluminium it needs for US national defence requirements.

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# **[Alicante News February 2018](#)**

March 01, 2018 [About the EUIPO](#)

Alicante News February 2018

The latest edition is out now.

The aim of Alicante News is to provide up-to-date information on EUIPO-related matters, as well as on other general IP issues, to the users of the EU trade mark and design registration systems.



**In this issue:**

- DesignEuropa Awards: Apply or nominate before 15 May!
- Design filing – Tips & best practices for minimizing objections
- The Economic Cost of IPR Infringement in the Tyres and Batteries Sectors
- Change of EUIPO bank account for payment of fees
- EUIPO performance update: Q4 2017