Zantac - MHRA drug alert issued as GlaxoSmithKline recalls all unexpired stock

The MHRA has issued an <u>alert to heathcare professionals</u>, as GlaxoSmithKline is recalling all unexpired stock of four types of Zantac, the medicine used to treat conditions such as heartburn and stomach ulcers.

The four products affected are Zantac 150mg/10ml Syrup, Zantac 50mg/2ml Injection, Zantac 150mg Tablets and Zantac 300mg Tablets. All four are prescription only medicines. Over-the-counter products (Zantac 75 Relief (PL 02855/0081 [GSL]) and Zantac 75 Tablets (PL 02855/0082 [P]) are produced by a different company and are not affected by this recall.

The MHRA is advising that patients should not to stop taking their medication, and do not need to see their doctor until their next routine appointment but should seek their doctor's advice if they have any concerns.

The recall is a precautionary measure due to possible contamination of the active substance in Zantac, ranitidine, with an impurity called NDMA (N-nitrosodimethylamine) which has been identified as a risk factor in the development of certain cancers.

Healthcare professionals have been told to stop supplying the products immediately, quarantine all remaining stock and return it to their supplier.

An MHRA investigation into other ranitidine medicines which may also be affected is continuing and further updates will be provided as this investigation progresses. The MHRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is potentially affected by this issue.

Dr Andrew Gray, MHRA Deputy Director of Inspections, Enforcement & Standards, comments:

"Whilst this action is precautionary, the MHRA takes patient safety very seriously.

"Patients should keep taking their current medicines but should speak to their doctor or pharmacist if they are concerned and should seek their doctor's advice before stopping any prescribed medicines.

"We have asked companies to quarantine batches of potentially affected medicines whilst we investigate and we will take action as necessary, including product recalls where appropriate.

"We have also requested risk assessments from the relevant companies which will include the testing of potentially affected batches.

"Currently, there is no evidence that medicines containing nitrosamines have caused any harm to patients, but the Agency is closely monitoring the situation, and working with other Regulatory Agencies around world."

ENDS

Note to editors:

- 1. <u>Medicines and Healthcare products Regulatory Agency</u> is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- 2. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the <u>National Institute for Biological Standards and Control (NIBSC)</u> and the <u>Clinical Practice Research Datalink (CPRD)</u>. MHRA is an executive agency of the Department of Health and Social Care.

Consultation to update Ofqual's 'Taking Regulatory Action' policy

Ofqual has today (8 October 2019) <u>published a consultation on proposals to update its policy for Taking Regulatory Action against awarding organisations</u> who breach its rules. The changes are intended to better reflect our regulatory strategy and current practice, and include a recommendation to change the name of the policy to 'Supporting Compliance and Taking Regulatory Action.'

The proposals include:

- introducing new measures to manage some instances of non-compliance, including issuing rebukes and imposing fixed penalties
- an explanation of developments in our approach to supporting awarding organisations to remain in compliance, including how we might notify awarding organisations where we have concerns about a training provider, school or college
- an explanation of our approach to making requirements under our conditions
- the removal of the £10,000 lower threshold on recovering our costs where we take regulatory action

Sally Collier, Chief Regulator, said:

Our rules are designed to make sure that those who take or use the qualifications we regulate can be confident they are a reliable and valid assessment of the skills and knowledge acquired. Where awarding organisations breach our rules, we take appropriate and proportionate action to put things right and to deter others from making the same mistakes.

The sector we regulate continues to change and we are proposing changes to how we use our regulatory powers. We welcome contributions from awarding organisations, schools and colleges, and other users of regulated qualifications.

The consultation is open until 2 December 2019.

CDL Commons statement on Brexit preparations: 8 October 2019

Mr Speaker, with your permission I would like to make a statement on our preparations to leave the European Union on 31 October and the steps we are taking to get ready.

Our desire for a deal

It is the strong desire of this Government to leave the EU with a deal.

Our proposals to replace the backstop were published last week. I commend the Prime Minister and the Exit Secretary for their continued efforts to ensure that we can leave the EU with a withdrawal agreement in place.

We have put forward a fair and reasonable compromise for all sides that respects the historic referendum result and we hope that the EU will engage with us seriously.

In setting out these proposals, we have moved - it is now time for the EU to move too. If it does, then there is still every chance we will leave with a new deal.

Preparing for every eventuality

However, if the EU does not move, this government is prepared to leave without a deal on the 31st .

We must get Brexit done so the country can move on and focus on improving the NHS, cutting crime, helping families with the cost of living and further improving school standards

Now, In preparing for every eventuality, we are today publishing our No Deal Readiness Report.

This document is a comprehensive summary of the UK's preparedness for leaving the EU without a deal.

It sets out the preparations that the Government has made, how these have been intensified under the determined leadership of my Rt Hon Friend the Prime Minister, and also it outlines the steps that third party organisations need to take in order to get ready.

Government preparations

Mr Speaker, the actions in this report reflect our top priority: ensuring we maintain the smooth and efficient flow of goods and people from the UK into the EU, and vice versa. The actions are also aimed at ensuring that we continue to support citizens — upholding their rights and helping them to prepare for the changes ahead.

My Rt Hon Friend the Chancellor in order to prepare for Brexit has doubled funding from £4bn to £8bn.

And we have also published a significant volume of material relating to no deal planning, including 750 pieces of guidance setting out the steps that businesses, traders and citizens should take in order to prepare.

We have also published 31 country guides for all EU/EFTA states, setting out what UK nationals living there need to do in order to get ready for Brexit.

And this morning, my Rt Hon Friend the Trade Secretary has published the Temporary Tariff Regime which will apply from the 1 November. In all, it liberalises tariffs on 88% of goods entering the UK by value. It maintains a mixture of tariffs and quotas on 12% of goods, such as beef, lamb, pork, poultry and some dairy products to support farms and producers who have historically been protected through high EU tariffs in the past. I should say that as a result of cutting these tariffs we should see a 15% reduction in the cost of honey from New Zealand, a 9% cut in the cost of grapes from South America and of course a 7% reduction in the cost of wine from Argentina.

Now Businesses have raised a number of points in response to the publication of the original tariff schedule in March. Government listened carefully to these representations and has made three specific changes as a result: we're we're reducinging tariffs on HGVs entering the UK; we'rewe're adjusting tariffs on bioethanol to retain support for UK producers; and we're also applying tariffs to additional clothing products to ensure that developing countries continue to have preferential access.

Third party readiness

But it is not enough just for government to get ready; we need businesses and citizens to get ready too. And even with every government project complete and necessary IT systems in place, flow at the border would still be affected if hauliers don't have the right paperwork.

If companies do not prepare, they will face challenges in trading their goods and services with the EU.

And while the Government can of course lobby EU member states to improve their offer to UK nationals who are living in their countries, we need individuals to act as well, to register for residency and to make arrangements for continued access to healthcare.

For that reason, the Government is investing £100 million in one of the largest Public Information Campaigns in peacetime. Through both mass market and targeted advertising, we are alerting businesses and citizens to the actions they need to take to get ready.

And we are also providing a further £108 million to support businesses in accessing the information and advice they need.

My Rt Hon Friend the Business Secretary is overseeing a series of events with businesses around the country, designed to provide information on all the steps they need to take to get ready, including actions which will support the flow of trade through the short straits..

My Rt Hon Friend the Health Secretary has also today established a trader readiness support unit for suppliers of medical products.

And this week, HMRC is writing to 180,000 businesses setting out the full ange of steps they need to take in order to import and export with the EU after we leave.

And of course in advance of 31 October, we will continue to use every means at our disposal to communicate to business the need to get ready.

I want to pay particular tribute to the automotive, retail and transport sectors, including authorities at the Port of Dover and Calais, as well as Eurotunnel, for the extent of their Brexit preparations.

On a recent visit to the West Midlands, the heartland of our automotive industry, I was impressed by the steps that manufacturers are taking to prepare.

And Retail businesses have also made significant strides: Morrisons, for example, now reports it is "prepared for all eventualities" in the UK, while the Co-op says it is "prepared for the worst case".

Of course, risks remain and challenges for some businesses cannot be entirely mitigated, even with every possible preparation in place. But the UK economy is in a much better position to meet those risks and challenges thanks to the efforts of these sectors and companies and my Rt Hon friend the Chancellor .

It is also the case, Mr Speaker, that the impact of no deal on both the UK and the EU will depend on decisions taken by the EU and its member states.

On citizens' rights, internal security, data protection and of course the vital position of Northern Ireland in the United Kingdom , we have taken

decisions which will benefit UK nationals as well as EU citizens, I hope the EU will match the generosity and flexibility that we have shown.

Through the EU Settlement Scheme, we have ensured that every EU citizen resident here by the 31 October can acquire a formal UK immigration status, protecting their right to live and work in the UK.

To date, 1.7 million citizens have applied and 1.5 million have been granted a status. Those who have not yet applied have until the end of December 2020 to do so.

So far, very few EU member states have made as generous an offer to UK nationals as the UK has made to EU citizens.

We don't believe that citizens' rights should be used as a bargaining chip in any scenario. EU citizens in the UK are our friends and family — we want them to stay. We now hope the EU extends the same hand of friendship towards UK nationals as we have to EU Nationals.

At the same time, keeping our fellow citizens safe should be a priority. My Rt Hon Friend the Home Secretary has written to Commission Vice President Frans Timmermans to ensure effective arrangements are in place on the exchange of Passenger Name Record data, disconnection from SIS II, and working arrangements with Europol, as well as the transfer of law enforcement data. We hope the EU will respond positively, in the interests of the shared security of us all.

And We have also unilaterally ensured that personal data can continue to flow freely — and legally — from the UK to the EU and the EEA. A swift adequacy decision from the EU would reciprocate this arrangement, providing legal certainty to EU entities and companies.

And of course with respect to Northern Ireland, in order to avoid a hard border, we have committed not to introduce any checks at the border between Northern Ireland and Ireland. The limited number of checks which do need to take place, due to international obligations, will all be carried out well away from the border and only will affect a very small number of businesses.

Now The Irish Government and the EU have not yet set out how they will manage the Irish border if we leave without a deal — we urge them now to match our commitment.

Opportunities from Brexit

Mr Speaker, let me finally turn to the opportunities from Brexit as laid out in the report.

For the first time in 50 years, the UK will have an independent trade policy; we'll be able to take our own seat at the WTO.

We will be able to introduce a points-based immigration system which prioritises the skills we need as a country, We will have autonomy over the rules governing our world-leading services sector, and continue our leading

role in setting global standards for financial services.

We can be a beacon for the world in setting progressive policies on farming, fishing and the wider environment.

And, outside the jurisdiction of the European Court of Justice, we will set our own rules, putting in place smarter, more responsive regulation.

Of course, no deal will bring challenges - I have been open about that today, as I have been in the past. It is not my preferred outcome, nor the government's. We want a good deal.

But whatever challenges no deal may create in the short term, and they are significant, these can and will be overcome.

Far worse than the disruption of no deal would be the damage to democracy caused by dishonouring the referendum result.

17.4 million people voted to leave — many of them turning up to vote for the first time in their lives.

They voted to ensure the laws by which we are governed are set by the politicians in this place whom they elect.

They voted for a fairer immigration system, which attracts the brightest and the best

They voted to end vast financial contributions to the EU budget, and instead invest in the people's priorities — such as the NHS and our brave police service.

That is what the British people voted for and that is what this government will deliver.

And I commend this statement to the House.

<u>92nd session of the Executive Council</u> <u>of the OPCW</u>

Thank you Chair. I'll try to set a good example. The UK associates itself with the statement made by the Finnish Ambassador on behalf of the EU.

I do want to give a big welcome to the many new colleagues, it's going to be a busy autumn ahead of us.

The most immediate task is to reflect on the recent weeks of discussions on the Director-General's draft programme and budget for 2020 and then provide a recommendation to the November Conference of States Parties. We studied it carefully and we welcome the efforts made by the Technical Secretariat to ensure that there will be no increase to the 2019 level of assessed contributions. We recognise that this is challenging given States Parties clear preference for core programmes and activities to be funded from the regular budget whenever possible. But the OPCW must continue to evolve and reform in response to new challenges, some of those will have budget implications.

We can also support the proposals for the use of the 2017 cash surplus. Many organisations struggle to deliver large IT projects. But it is clear that there needs to be a real focus now on ensuring the successful delivery of the Enterprise Resource Planning project as soon as possible.

We were particularly pleased to see a proposal to use some of the cash surplus to strengthen capacity in national Laboratories. This was also a focus for part of the UK's additional voluntary contributions this year and should help meet the objective of broadening the network of Designated Labs around the world.

We were, however, concerned to read the Director General's recent note on the overall cash situation. It highlighted the troubling lag in the receipt of assessed contributions and the pressure this puts on the OPCW's finances. We strongly urge all States Parties to settle their outstanding assessed contributions and other financial obligations in full, and urgently.

Mr Chair, the situation in Syria has been a long term and worrying preoccupation of this Council. As we heard in the briefing by Technical
Secretariat experts last week, Syria has made no progress since we last met
in resolving the multitude of outstanding problems with their Declaration.
These issues are significant, and they highlight Syria's failure to fully
disclose and destroy its chemical weapons programme. Syria has had every
opportunity to demonstrate that it is serious about meeting its commitments
under the Convention. And yet still, six years on, they have still failed to
do so.

Instead we are confronted with a pattern of repeated chemical weapons use against the Syrian people. The UK has grave concerns about the most recent chemical attack on 19 May 2019 in Al-Kabaneh. We have shared information about this incident with the OPCW. And we will continue to shine a light on these abuses. Syria's persistent non-cooperation must not continue.

We were pleased to hear about the progress being made by the Investigation and Identification Team to identify those responsible for chemical weapons attacks in Syria. We look forward to their first report issuing in due course.

Mr Chair,

As we start to look ahead to the autumn Conference of States Parties an important issue before us will be the Canadian, Dutch and US proposal to add two families of Novichok to Schedule 1. This Council supported that proposal

in January and we encourage all States Parties to join consensus on the adoption of the draft Decision in November in order to ensure greater oversight of these very dangerous chemical weapons.

We are also aware of the Russian Federation's recent proposal which removes those chemical structures not found to meet the criteria for inclusion in Schedule One. If the Russian Federation brings forward a Decision along the same lines then we would not oppose its adoption, as we indicated back in February.

In advance of the CSP we were deeply concerned to hear that a handful of states are trying to block the attendance of some well-respected civil society organisations as others have mentioned. This runs counter to guidelines previously agreed by us all and is completely unjustified, particularly for NGOs which have attended past CSPs. Bolstering awareness of the OPCW and its important work is something we should all support.

Thank you Mr Chair, and I hope I've set a good example.

The Year of Education 2020: UK and Lebanon together for education

Today, British Ambassador to Lebanon Chris Rampling launched UK-Lebanon Year of Education 2020 campaign during the British Council's partnership agreement with the American University of Beirut (AUB) for Computer Delivered International English Language Testing System)IELTS(in the presence of HE Minister of Education and Higher Education Akram Chehayeb, MP Bahia Hariri, Director of the British Council David Knox, AUB Provost Dr. Mohamed Harajli and Dr Karma El Hassan, Director, Office of Institutional Research & Assessment at AUB, representative of the Lebanese Army Commander, General Camile Faisal, and representative of the HEAD of the Internal Security Forces Colonel Elie El Asmar.

The joint agreement will see the establishment of the first ever in Lebanon computer online delivered IELTS which will make it significantly easier for students to gain necessary English language qualifications, and compete in the global market. More than 10,000 organisations globally trust IELTS, which gives confidence to those taking the test that it is recognised by educational institutions, employers, governments and professional bodies around the world.

The Year of Education 2020 campaign builds on the UK's substantive education support to Lebanon, providing over \$200 million between 2016 and 2021, placing it amongst the top education donors in Lebanon. The Year of Education 2020 campaign will see continued work with the Ministry of Education and Higher Education to expand education access, quality and systems. It will

support more inclusive education for children with special educational needs, promote Lebanon as an important investment opportunity for UK EdTech firms, and strengthen and expand British-Lebanese university links. The campaign will also better celebrate UK educated Lebanese alumni and increase English language training — including in places outside of the capital— and champion the use of UK qualifications.

Following the event, British Ambassador Chris Rampling said:

It is a great privilege for us to be here. Thank you to the American University of Beirut for hosting us and for their collaboration with the British Council on the launch of the Computer Delivered IELTS in Beirut. The partnership is not the first with this highly distinguished institution. But it is a great point of pride to me personally that the British Council, with its excellent history in this country, is partnering with one of Lebanon's top academic institutions.

And there is no better way to launch the UK-Lebanon Year of Education 2020 than with you all: Lebanese — and partners of this amazing country — who are determined to build a bright future for Lebanon and for those who live in Lebanon. Because the UK is proud to partner a country that not only values, promotes and prioritises education, but also a country that has bravely and commendably committed to providing education to all children within the country.

Four of the top 10 universities in the world are British. Over a third of Nobel Prize winners who have studied overseas have done so in the UK. The English language is truly the world's language, and UK qualifications are recognised for their quality and credibility across the globe. As a sign of our education leadership, in the last five years there has been a 90% increase in the number of Lebanese students studying in the UK. Education is not just about schools and universities.

And our support goes beyond further. Over 200 Lebanese students have studied in the UK through the prestigious Chevening programme and are now part of a wider network of over 50,000 Cheveners around the world. When it comes to training support, over 200 Lebanese Army officers have trained at the UK's elite military training institutions — some of the very best military establishments in the World. The UK is also proud to have trained 11,000 Lebanese Army soldiers here in Lebanon, along with training programmes for the Internal Security Forces. And we continue to work closely with the Ministry of Education and Higher Education to support quality formal, non-formal and inclusive education to all children across Lebanon.

Minister of Education and Higher Education Akram Chehayeb:

The year of Education for us is the year of challenges on all levels. The challenge of ourselves to continue providing good learning despite the difficulties. The challenge to develop education and move to the digital era amidst all the pressures and economic difficulties. The challenge of openness on the educational systems adopted in the advanced countries despite the wars and regional tension and blocked horizon.

Today's ceremony is a symbolic event that reveals the level of excellence that we at the Ministry of Education and Higher Education are trying to reach, with the support of our true friends, namely the British Government and the American University of Beirut (AUB), along with the cultural, educational and technological renowned institutions. It is an occasion for us to express our pride of these friendships and fruitful relations, and to express our gratitude to the British and American sides, particularly that the UK is among the leading donors to Lebanon in the educational sector for Lebanese and non-Lebanese.

AUB Provost Dr. Mohamed Harajli said:

We look forward to seeing the impact of this Year of Education being celebrated by the British embassy in Lebanon, with events that will highlight and expand the great work that the uk in Lebanon and the British Council are in this country and the region. We are the American University of Beirut and we all know that America and Britain have a "special relationship" in the world, and we are happy to carry that on between our two organizations.