

MHRA launches public consultation on future of medical device regulation

Launched today by the Medicines and Healthcare products Regulatory Agency (MHRA), the 10-week consultation gives everyone the opportunity to draw on their own experiences and contribute to the improvement of the regulatory framework and therefore patient safety in the future.

From hearing aids and walking sticks, to insulin pumps and thermometers, for many of us, medical devices are an essential part of our everyday lives. We all want to know that the devices we use are safe and effective, so regulation of medical devices really matters, especially where fast-developing technology has changed, and continues to influence, the landscape for medical devices, bringing new, innovative devices to the UK market, including some health apps.

The MHRA is the regulator for medical devices used in the UK. We are seeking views from across the medical devices and healthcare sectors, medical practitioners, patients and the wider public, to inform our future approach. We would like to hear from those who research, manufacture, supply and use medical devices.

Medical devices in the UK are currently regulated under the Medical Devices Regulations 2002. Following the UK's departure from the European Union, the MHRA now has the opportunity to create a world-leading regime that prioritises patient safety while fostering innovation, including streamlining the approval of medical devices.

This consultation is comprehensive – covering a broad range of regulatory issues – from requirements for running clinical investigations, to how devices are assessed before being placed on the market through to importer and distributor obligations and post-market surveillance to transparency and the role of patients. It provides a once in a generation opportunity to ensure the safety and quality of medical devices that many of us rely on, and from which we all benefit.

Dr June Raine, Chief Executive of the MHRA, says:

The launch of this consultation is an exciting step towards a more robust, world-leading regulatory framework for medical devices in the UK, one that enhances medical device safety and quality, access to devices, and has patients at its heart.

We know that a problem with a medical device can have a significant impact on people's lives. This consultation offers a once in lifetime chance to help shape the regulations. In order to reach

this goal, we want to hear from a wide range of people. Delivering for patients is central to our work and we fully recognise the importance of the public and patients' perspectives and encourage them to share their views during this consultation.

This is your chance to make a difference to people's experiences with devices by helping shape the regulations around medical devices – from how much scrutiny they face before they reach the market, to how they are tracked and monitored, and what actions are taken if problems with a device arise. It is also an opportunity to impact what products the MHRA regulates – for example, should the MHRA have a role in the regulation of other products which are similar to medical devices such as cosmetic coloured lenses or dermal fillers?

We encourage everyone to share their views on the future of medical devices regulation through this public consultation.

Health and Social Care Secretary Sajid Javid said:

The UK is home to one of the world's most renowned regulators, ensuring the safety and effectiveness of the medicines and medical devices that we all rely on.

This consultation will allow us to revolutionise the regulation of medical devices, making sure our pioneering life sciences sector can continue to lead the world and safeguard the health of our nation.

From pacemakers to contact lenses, wheelchairs to pregnancy tests, medical devices play a vital role for the vast majority of us and I encourage everyone who wants to be a part of this mission to put forward their views.

[The consultation will close at 11.45pm on 25 November 2021.](#)

We have already hosted two webinars this October, one aimed at industry and one focussing on patients and the wider public. The webinars provided more information about the background to, and scope this consultation and how to respond. Both webinars were recorded and the video recording will be published on Gov.UK in due course.

Notes to editors

1. The [Medicines and Healthcare products Regulatory Agency](#) is responsible for regulating all medicines and medical devices in the UK.
2. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the [National Institute for Biological Standards and Control \(NIBSC\)](#) and the [Clinical Practice Research Datalink \(CPRD\)](#). The MHRA is an executive agency of the Department of Health and Social Care.
3. This consultation is on a future UK-wide scheme for regulating medical devices. It recognises the Government is seeking a new balance to the Northern Ireland Protocol to place it on a more sustainable footing as expanded on in its Command Paper – [Northern Ireland Protocol: The way forward](#).
4. Under the current approach to the Northern Ireland Protocol, EU rules on medical devices continue to apply in Northern Ireland. The EU Medical Devices Regulation (2017/745) (EU MDR) therefore took effect in Northern Ireland on 26 May 2021 and the in vitro Diagnostic Medical Devices Regulation (2017/746) (EU IVDR) will take effect from 26 May 2022. The EU MDR and EU IVDR will not apply in Great Britain. We welcome views on alignment across all of the UK nations as part of this consultation. The Government is also seeking a new balance to the Protocol and, as set out in its Command Paper, has proposed a dual regulatory regime in Northern Ireland where goods that meet either UK or EU rules could circulate within Northern Ireland.

For any other enquiries about this consultation, please contact futuredevicesregulations@mhra.gov.uk

[Address by the President of the OSCE Parliamentary Assembly: UK response](#)

On behalf of the United Kingdom, I would like to welcome you, Madam President, to the Permanent Council. Congratulations on your election to the role and thank you for your address. We share your views on the importance of the work the OSCE does to support women including through the Chair's focus on Women, Peace and Security and also Women's Economic Empowerment.

OSCE priorities and commitments – in all areas – need to be realised and implemented in partnership with parliamentarians. For this reason, Parliamentary diplomacy and the role parliamentarians play in holding us to

account is an important element of the work we do throughout the OSCE area. The Parliamentary Assembly (PA) can remind states of what is needed in areas ranging from human rights and support for democratic institutions to sharing knowledge and expertise on security challenges. And through election observation and the sharing of experience of rule of law and the checks and balances which strengthen accountability of democratic institutions. I would like to thank the OSCE Parliamentary Assembly and its members for its efforts in this regard, and encourage these to continue.

I was very pleased to join a panel last week for an OSCE Parliamentary Assembly discussion on Women, Peace and Security (WPS) and UNSCR 1325 in the OSCE area. I spoke about why it is so important that women have full, equal and meaningful participation in peace processes, the supportive role men can play, the importance of national action plans and the toolkit already available in the OSCE which can be boosted and needs to be implemented.

I would like to speak now in my capacity as Chair of the Security Committee. In my remarks to the Acting President of the Parliamentary Assembly at the Permanent Council earlier this year, I spoke about the important role that parliamentarians can play in shaping policy. I also expressed my desire to ensure continued engagement between the Security Committee and the Parliamentary Assembly under the UK's Chairpersonship. At our Security Committee meeting in July, devoted to the topic of 'tangible actions in preventing terrorism – terrorist financing, money laundering and passenger data exchange systems', I was delighted to welcome Mr Reinhold Lopatka, Vice President of the OSCE PA and Chair of the Ad-Hoc Committee on Countering Terrorism, to brief the Security Committee on the latest OSCE PA efforts to prevent and counter terrorism. The unique perspective and role that parliamentarians bring to the broader fight against transnational threats was an important and welcome contribution to our meeting. I would like to once again thank the Parliamentary Assembly for its continued cooperation with the Security Committee.

In conclusion – we welcome and support the important role the Parliamentary Assembly plays within the OSCE area. We recognise the important contribution made by Ambassador Bothelle over many years and welcome Ambassador Panceski to his new role from the start of October. We look forward to even greater co-operation and collaboration between the parliamentary and intergovernmental parts of the OSCE in years to come.

Teletext Holidays could face legal action over package holiday refunds

- Over £7 million in refunds secured so far but many customers remain unpaid

On 26 May 2021, the Competition and Markets Authority (CMA) announced that Truly Holdings Ltd, the company that operates Teletext Holidays, and its sister company, the travel operator Alpharooms.com, signed undertakings committing to address failures to refund package holiday customers for holidays cancelled during the pandemic.

These undertakings required Truly Holdings to use all reasonable endeavours to pay outstanding refunds to passengers at the latest by the end of August, and going forward to ensure that refunds due for package holidays cancelled after the date of the undertakings are paid promptly and no later than 14 days after cancellation.

After reviewing Truly Holdings's final report on progress with repayments, the CMA is concerned that some customers whose package holidays were cancelled since it signed up to the undertakings have not been repaid within the 14 days required by the law. Although Truly Holdings has paid back a significant number of customers within this 2-week period, too many have been left waiting longer for the refunds due to them.

The CMA is also concerned that Truly Holdings has not done enough to repay customers who were already owed refunds at the time the undertakings were given.

As a result of the CMA's action, Truly Holdings has paid £7.2 million of the £7.8 million owed to package holiday customers, but almost £600,000 in refunds remains outstanding. Truly Holdings has reported that the outstanding amount is owed to customers whose current bank details it does not have and whom it has been unable to refund through their original payment method because the purchases were made more than a year ago.

The CMA does not consider that enough has been done to ensure that Truly Holdings is able to provide refunds to package holiday customers with outstanding claims. In addition, the CMA does not consider that Truly Holdings has done enough to make sure that it pays all refunds that may in future become due within 14 days, as required by law.

The CMA has therefore written to notify Truly Holdings that it will take court action unless the firm takes immediate steps to rectify the situation and to ensure that, in the future, customers who are entitled to a refund are repaid in the timeframe specified by law.

Andrea Coscelli, Chief Executive of the CMA, said:

It is unacceptable that some package holiday customers are still not receiving refunds within the timeframe that they are legally entitled to.

While we are pleased that many consumers have now received the refunds they were due because of our intervention, we are clear that Truly Holdings must comply with the law. Unless it urgently takes steps to address the failures we have identified, we will take court action.

Although the CMA does not currently have powers to impose fines for this, this is the kind of issue that could be resolved at pace and met with fines if the CMA receives the consumer powers that the Government is currently consulting on.

Read more on our [COVID-19 cancellations: package holidays casepage](#).

1. Teletext Holidays is the trading name of Truly Travel Limited, which is a subsidiary of Truly Holdings Limited. Truly Travel Limited and Alpha Holidays Limited (which trades as Alpharooms.com) are both subsidiaries of Truly Holdings Limited.
2. It should not be assumed at this stage that Truly Holdings Limited has breached the law. Ultimately, only a court can decide whether a breach has occurred.
3. Truly Holdings Ltd agreed to a schedule of repayments, where it would use all reasonable endeavours to ensure customers who are still owed cash refunds for package holiday bookings cancelled due to the COVID-19 pandemic on or before 31 July 2020 would be refunded by 30 June 2021; customers with bookings cancelled between 1 August 2020 and 31 October 2020 would be refunded by 31 July 2021; and customers with bookings cancelled between 1 November 2020 and 24 May 2021 (inclusive) would be refunded by 31 August 2021.
4. An undertaking is a voluntary agreement a firm makes to address an enforcement authority's concerns and resolve an investigation.
5. Truly Holdings reported to the CMA that it was unable to refund certain customers via their original method of payment. This is because its payment system does not allow refunds to the original payment method for payments that were made more than twelve months ago. People owed refunds for their cancelled package holiday should go to the dedicated COVID refund pages on the Teletext or Alpharoom.com's website to ensure the businesses have up to date details.
6. Truly Holdings has reported that it has attempted to get in touch with the people affected to obtain updated details so it can issue these refunds, but it has been unable to contact many of the customers.
7. The CMA's investigation relates to package travel holidays booked with Teletext Holidays and Alpharooms.com, not flights or accommodation booked on a standalone basis.
8. Where package holidays are cancelled and consumers are entitled to a full refund under the Package Travel Regulations, those refunds must be provided within 14 days of the cancellation.
9. Media queries should be directed to: press@cma.gov.uk or 020 3738 6460.

[Liverpool security business fined](#)

£50,000 for breaching the Private Security Industry Act

James and Jason Battle, of Nationwide Management Services Ltd, also individually pleaded guilty to failing to provide information to Security Industry Authority (SIA) investigators.

James Battle was sentenced at Liverpool and Knowsley Magistrates' Court on 09 September while Jason Battle was sentenced on 19 August. One of the Battles' employees, Paul Fry, was also sentenced following a guilty plea to working without an SIA licence.

Nationwide had supplied Fry in February 2021 to work illegally without a licence at a construction site in Liverpool's Welsh Streets. The company was ordered to pay costs of £589.80 in addition to the £50,000 fine, plus a victim surcharge of £190. The amount is to be paid in full within eight months.

Jason Battle failed to provide SIA investigators with information they had asked for, even though they granted him an extension. This is an offence for which the court fined him a total of £1,500 and required him to pay a victim surcharge of £75 plus court costs of £852. He was given 28 days to pay the total amount. He has incurred a criminal record and his SIA licence has been suspended with a view to it being revoked.

James Battle also failed to provide information to SIA investigators. In addition, he gave them information that proved to be false. The SIA established that he acted as the controlling mind of Nationwide Management Services, although he is not a director. He was fined £3,000 and ordered to pay court costs of £824.80 plus a victim surcharge of £190. The amount must be paid in full within three months.

Paul Fry had previously failed to attend SIA requests for an interview. On 09 September he pleaded guilty to working unlicensed and was sentenced to a community order with a four-week curfew between the hours of 8pm and 7am daily. He is also required to pay court costs of £300 and a victim surcharge of £95.

The SIA brought the prosecutions against the three men and the business following several investigations conducted in partnership with Merseyside Police and Her Majesty's Revenue and Customs.

Nathan Salmon, the SIA's Criminal Investigations Manager, said:

This is a complex case of criminality involving a prestigious construction site in Liverpool. It illustrates that we will prosecute illegality wherever we find it in the private security industry. Each of the people here has now got a criminal record and will not be able to work in the industry in the future. This case

is a reminder for security buyers to undertake due diligence when identifying a supplier to protect valuable sites and assets.

Notes to editors:

- By law, security operatives working under contract must hold and display a valid SIA licence. Information about [SIA enforcement and penalties](#) can be found on GOV.UK.
- The offences relating to the Private Security Industry Act (2001) mentioned above are:
 - Paul Fry – 1 x Section 3 (working without a licence)
 - James Battle – 1 x Section 5 by 23 (deploying unlicensed guard by consent, connivance or neglect of directors); 1 x Section 22 (providing false information to the SIA).
 - Nationwide Management Services Ltd – 1 x Section 5 (supplying unlicensed security).
 - Jason Battle – 2 x Section 19 (failing to provide information relating to an investigation).
- The Private Security Industry Act 2001 is [available online](#).

Further information:

- The Security Industry Authority is the organisation responsible for regulating the private security industry in the United Kingdom, reporting to the Home Secretary under the terms of the Private Security Industry Act 2001. Our main duties are: the compulsory licensing of individuals undertaking designated activities; and managing the voluntary Approved Contractor Scheme.
- For further information about the Security Industry Authority visit www.gov.uk/sia. The SIA is also on [Facebook](#) (Security Industry Authority) and [Twitter](#) (SIAuk).

[WELL prepared for the new term](#)

The Western Excellence in Learning and Leadership (WELL) Project is an ambitious programme of targeted investments and interventions to improve educational outcomes in the region, particularly for the most disadvantaged.

It launched in 2019 with £1.7 million of funding from Sellafield Ltd and the Nuclear Decommissioning Authority and was co-created with Cumbria County Council and local schools.

Earlier this year it was granted additional funding of almost £4 million over the next 3 years.

WELL is a collaborative project that draws on national and international

research and works closely with the Education Endowment Foundation (EEF) and their Research School network.

The funding will be targeted at areas of need in schools and colleges in the boroughs of Copeland and Allerdale, and the project independently evaluated by the University of Nottingham in partnership with the Centre for the Use of Research and Evidence in Education.

Gary McKeating, Sellafield Ltd's head of community and development, said:

The WELL Project is a key strand of Sellafield Ltd's Social Impact Multiplied (SiX) programme, which has a central commitment to helping communities unlock a sustainable and prosperous future.

WELL is already making significant progress in its work to help improve teaching, raise pupil achievement and enhance the health and wellbeing of students in our communities, and there is much more to come.

It's a great example of how we can multiply our collective impact when we work collaboratively and take an evidence-led approach.

The strengths of this partnering and evidence-led approach were demonstrated last year when the COVID-19 pandemic led to many planned WELL activities being paused.

The impact of COVID-19 on the achievement and wellbeing of pupils meant there was an immediate need to support young people and teachers to aid their recovery and help them catch up on learning.

In response, over £500,000 of WELL funding was provided to eligible schools with disadvantaged pupils to provide technology for remote learning, development and support for teachers and students, and breakfasts for vulnerable and key workers' children.

Lindsay Burnett, headteacher at Montreal CofE Primary School, Cleator, said:

The WELL project has given a drive to schools and the capacity to be able to rethink how we can support our most vulnerable pupils.

It has increased conversations and actions about what we can do to support those that are disadvantaged. "More children are receiving high quality educational experiences through funding support for physical resources but also development of our leaders and teachers.

Professor Becky Francis, CEO of the Education Endowment Foundation, said:

It is extremely encouraging, particularly in these challenging

times, to see projects such as WELL facilitating Cumbrian schools' engagement with evidence-informed approaches to teaching and learning.

Its central focus -on broadening access to research-based training and high-quality educational programmes to improve pupils' academic outcomes- is one that mirrors the core mission of the EEF nationally. The appointment of Ashfield Junior School in Workington as a Research School will be a valuable source of support for others in the region.