

# Requirement for submission slots extended

News story

Submission opportunities available to applicants of veterinary product marketing authorisations.



The requirement for submission slots to be obtained for new and extension variation applications for biological and bio-pharm products, as described in [our announcement on 7 May 2021](#), has been extended indefinitely.

There is currently no requirement for submission slots for Pharmaceutical applications. However, applicants are now required to provide the VMD with a minimum 6-month forewarning of any new MA Pharmaceutical applications intended to be submitted under Article 12(3) (full) or 13a (well-established use/bibliographic).

Full details can be found in the guidance for [Submission of an application for an animal medicine authorisation](#).

Please contact us at [submissionslot@vmd.gov.uk](mailto:submissionslot@vmd.gov.uk) to arrange a meeting.

Published 13 October 2022

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## Huawei legal notices issued

Huawei technology must be removed from the UK's 5G public networks by the end of 2027 under legal documents handed to broadband and mobile operators today.

The document – called a [designated vendor direction](#) – has been sent to 35 UK telecoms network operators. It puts the government's [previous](#) position to

remove Huawei kit from UK 5G networks on a legal footing.

The ban on Huawei in 5G follows guidance from the world leading National Cyber Security Centre (NCSC) that the security of the company's products – such as equipment used at phone mast sites and telephone exchanges – can no longer be managed due to the impact of US sanctions on its supply chain. The sanctions, imposed by the US Government in 2020, stop Huawei accessing US semiconductor technology on which it previously relied.

Huawei has been issued a separate document – a [designation notice](#) – which categorises the company as a high-risk vendor of 5G network equipment and services. The designation notice sets out all of the reasons for which the government considers Huawei to pose a national security risk, including the impact of the sanctions.

The direction sets out the controls to be placed on operators' use of Huawei, following consultation with Huawei and telecoms operators, including:

- an immediate ban on the installation of new Huawei equipment in 5G networks;
- a requirement to remove Huawei equipment from 5G networks by the end of 2027;
- a requirement to remove Huawei equipment from the network core by 31 December 2023;
- a requirement to limit Huawei to 35 per cent of the full fibre access network by 31 October 2023;
- a requirement to remove Huawei equipment from sites significant to national security by 28 January 2023; and
- a requirement not to install any Huawei equipment that has been affected by US sanctions in full fibre networks.

These decisions have been reached following technical security analysis from the National Cyber Security Centre which takes into account our specific national circumstances and how the risks from the US sanctions are manifested in the UK. The decisions will not cause any delays to the government's digital infrastructure roll out targets.

Having fully considered consultation responses, the key deadline to remove all Huawei equipment in the UK's 5G network by 2027 remains unchanged, as do eight of the other interim deadlines to guide operators in meeting the 2027 deadline.

For a small number of operators, the two interim deadlines for the core and 35 per cent of the full fibre access network could have led to network outages and disruption for customers, due to delays caused by the pandemic and global supply chain issues.

Having considered comments raised by industry in the consultation, the government has formally set interim deadlines that balance the need to remove Huawei as swiftly as possible while avoiding unnecessary instability in networks. The UK's world-leading cyber security experts at the NCSC have agreed this is a sensible balance.

Providers should meet the original target dates for the removal of Huawei from network cores and capping Huawei at 35 per cent in the access network (January and July 2023 respectively) wherever possible, and the government expects most of them will do so.

Digital Secretary Michelle Donelan said:

“We must have confidence in the security of our phone and internet networks which underpin so much about our economy and everyday lives.

“Thanks to this government’s tough new laws we can drive up the security of telecoms infrastructure and control the use of high-risk equipment.

“Today I’m using these powers and making it a legal requirement for Huawei to be removed from 5G networks by 2027.”

NCSC Technical Director Dr Ian Levy said:

“Society increasingly relies on telecoms and the NCSC, government and industry partners work closely to help ensure that these networks are secure and resilient in the long term.

“The Telecoms Security Act ensures we can be confident in the resilience of the everyday services on which we rely, and the legal requirements in this Designated Vendor Direction are a key part of the security journey.”

The decision comes as the government publishes its [response](#) to a targeted consultation on a proposed ban held earlier this year with Huawei and other telecoms companies under the provisions of the [Telecommunications \(Security\) Act 2021](#).

The Act came into force in November last year and gives the government new powers to control the presence of high risk vendors in UK public telecoms networks where necessary in the interests of national security.

Separately, last month the government [introduced](#) tough new security rules broadband and mobile companies will have to follow to better protect UK networks from potential cyber attacks under the Telecommunications (Security) Act.

The new regulations and code of practice are among the strongest in the world and provide much tougher protections for the UK from cyber threats which could cause network failure or the theft of sensitive data.

Ofcom will oversee, monitor and enforce the new regulations and code and have the power to carry out inspections of telecoms firms’ premises and systems to ensure they’re meeting their obligations. If companies fail to meet their duties, the regulator will be able to issue fines of up to 10 per cent of turnover or, in the case of a continuing contravention, £100,000 per day.

ENDS

Notes to editors

In 2020 the NCSC published updated guidance in relation to Huawei. It has also published a number of other documents:

- A [summary](#) of the NCSC's analysis of the May 2020 US sanction of Huawei
  - A [blog](#): 'A different future for telecoms in the UK'
  - An [explainer](#): Why has the NCSC's advice on the use of Huawei technology changed?
  - An [explainer](#): What is 5G, and how will it affect you
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## [Russia's needless war has inflicted suffering on too many: UK statement to the OSCE](#)

Thank you Mr Chair. The Special Permanent Council on Tuesday 11 October denounced Russia's ongoing and indefensible attacks against civilians across Ukraine. Later that day, G7 leaders "condemned these attacks in the strongest possible terms".

Again – yesterday, we heard reports of further Russian missile attacks, including on a market in Avdiivka, killing at least seven people and injuring eight.

We mourn with Ukraine for all those impacted by these unspeakable acts across Ukraine. We will not allow these individuals to be forgotten. Individuals such as Dr Oksana Leontieva. On Monday morning, Oksana woke up, got her five year old son ready for school, then drove to her job at one of Kyiv's children's hospitals. She took the same short route as every week – but on this day, she unknowingly drove straight into the worst missile attack on her country in months – where she was sadly killed. Oksana specialised in treating childhood cancer. Her hospital described her as "a true professional and supporter of her patients and colleagues". Her son is now an orphan.

Mr Chair, Oksana and her son are but two innocent victims of Russia's continued intense barrage of missile attacks on Kyiv and across Ukraine. More civilian infrastructure has been severely impacted in the latest attacks. There have continued to be multiple power blackouts, with areas cut off from water supply and communications. Let us recall: deliberate attacks on innocent civilian populations constitute a war crime. Russia must end its invasion and withdraw all of its forces from Ukraine now.

We condemn Russia's continued actions at Ukraine's Zaporizhzhya Nuclear Power Plant and the pressure exerted on the personnel of the facility. This is a further irresponsible escalation and we will hold Russia responsible for any incident caused by their actions. The safety, security and safeguards of the nuclear facility are paramount and we support the International Atomic Energy

Agency's efforts in this regard.

Mr Chair, as the [latest Moscow Mechanism report](#) made clear – internal repression and external aggression are two sides of the same coin. I want to spotlight the incredible bravery of those who have stood up in defence of human rights and democracy – many of whom have been detained or 'disappeared', notably in Russia and Belarus. We commend the Center for Civil Liberties in Ukraine, Ales Bialiatski in Belarus and Memorial in Russia for being awarded the Nobel Prize – three of the seven recipients of the OSCE Democracy Defenders Award are now Nobel Peace Prize laureates. We are proud to have spearheaded the OSCE award with a group of States championing democracy and supporting human rights defenders at the OSCE. The role of these human rights defenders is as important as it ever has been in our region.

The UK also commends Vladimir Kara-Murza for being awarded the Vaclav Havel Human Rights Prize. He has continued to champion human rights and freedom in the face of Russian state aggression. Vladimir Kara-Murza remains in detention on politically-motivated charges; he should be released without delay. But he is not alone. During the Warsaw Human Dimension Conference earlier this month, we heard directly from the courageous wives, mothers and sisters of Ukrainian political prisoners, detained civilians, and those forcibly disappeared. Many remain detained and missing to this day, their families resolutely searching for scraps of information on their whereabouts. We urge Russia to engage with and provide access to international humanitarian organisations. These families deserve answers. We will continue to raise cases until political prisoners are free and the whereabouts of those forcibly disappeared are revealed.

Mr Chair, [143 countries stand united in condemnation of Putin's illegal attempts to annex four regions of Ukraine, as reflected by the UNGA vote yesterday](#). The UK calls on Russia to cease all hostilities and "immediately, completely and unconditionally withdraw all of its troops and military equipment from Ukraine". [As the G7 leaders have said](#) "we are undeterred and steadfast in our commitment to providing the support Ukraine needs to uphold its sovereignty and territorial integrity. We will continue to provide financial, humanitarian, military, diplomatic and legal support and will stand firmly with Ukraine for as long as it takes". This needless war has inflicted suffering on too many. Those responsible will be held to account and will serve justice. We are committed. We are in this for the long run. We will not forget.

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**[Report 11/2022: Collision between a](#)**

# passenger train and a hand trolley at Challow

## R112022\_221013\_Challow

PDF, 8.68 MB, 59 pages

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### **Summary**

At 06:09 hrs on 21 October 2021, a passenger train travelling at 123 mph (198 km/h) struck a hand trolley on the track near Challow, Oxfordshire. The train was the first to pass through the area after the completion of overnight maintenance work. There were no injuries among the passengers or crew on board and the train did not derail. The hand trolley was destroyed by the impact and debris from it caused damage to equipment under the train. The collision also resulted in minor damage to the track.

A maintenance team had carried out overnight work at Challow and no one noticed the team had left its hand trolley on the track. The checks undertaken before handing back the railway for normal operation also had not identified the hand trolley's presence. A process which formed part of these checks was the line clear verification process. It was used to monitor what vehicles, including hand trolleys, were placed on and taken off the track during the overnight work. However, there were weaknesses within this process, and these were compounded by the maintenance team not following the process as it was required to on the night concerned.

Underlying factors related to the weaknesses within the line clear verification process were:

- It was reliant on human actions for its successful implementation, which the rail industry had recognised, but not yet implemented any measures to avoid or mitigate errors.
- It was separate to the work planning process as defined by Network Rail's company standards. This was a possible underlying factor.
- Network Rail's assurance activities had not detected that staff in the Swindon delivery unit welding and grinding section were not complying with the line clear verification process. This was a possible underlying factor.

A further probable underlying factor was that hand trolleys were being

routinely used at night without displaying any red lights and that no assurance activities were taking place within work sites to monitor compliance to this requirement.

RAIB observed that after the accident, the train was allowed to travel at a speed above that which should have been permitted given the level of damage it had sustained. RAIB also observed that there were multiple issues with how the work at Challow was planned by Network Rail.

## **Recommendations**

RAIB has made five recommendations to Network Rail. The first is to establish how the existing line clear verification process can be improved while the second is to consider what technology could be used by its staff to support the process. The third recommendation is to propose an amendment to the Rule Book so that hand trolleys are required to display an illuminated red light in both directions at all times when on the track. The fourth is for Network Rail to have processes in place to ensure that any hand trolley placed on its track has illuminated red lights displayed in both directions. The fifth recommendation is to review the effectiveness of its safety assurance activities which check that hand trolleys are being used correctly and safely.

RAIB also identified three learning points. The first reminds maintenance staff about the importance of complying with all rules and standards concerning how trolleys and rail skates should be used on Network Rail's infrastructure. The second highlights the importance of clear communication between the staff at a train involved in an accident and those based in control rooms to establish what damage has been sustained by a train, so that the appropriate controls can be put in place before the train is permitted to move. The third is that staff involved in planning maintenance work produce documents that are accurate, appropriate and specific for the task that is being carried out, and involve those responsible for the work in the planning of it.

## **Andrew Hall, Chief Inspector of Rail Accidents said:**

Systems and processes designed to detect any equipment left on the track before lines re-open after maintenance work, should not be reliant solely on human performance in the middle of a dark night. There are technological solutions which can assist with addressing this issue, and this accident is an example of an opportunity missed.

Our investigation found that the railway had identified the risk of equipment, such as hand trolleys, being left on the line and that it could mitigate this risk by improving the line clear verification process. However, it had not yet implemented the changes required when this accident occurred. This meant that the process remained vulnerable to human error. In this case, this vulnerability was made worse because relevant procedures were not

followed correctly. Technology has an important role to play in improving the safety of the railway and it is important that the development of solutions to better support staff are prioritised.

It is also a concern that hand trolleys were routinely being used on the track at night without displaying red lights. But it is of equal concern that no activity to monitor this requirement was being undertaken. Once again, assurance activities intended to check that rules are being followed and that processes are being implemented correctly were not effective.

## Notes to editors

1. The sole purpose of RAIB investigations is to prevent future accidents and incidents and improve railway safety. RAIB does not establish blame, liability or carry out prosecutions.
2. RAIB operates, as far as possible, in an open and transparent manner. While our investigations are completely independent of the railway industry, we do maintain close liaison with railway companies and if we discover matters that may affect the safety of the railway, we make sure that information about them is circulated to the right people as soon as possible, and certainly long before publication of our final report.
3. For media enquiries, please call 01932 440015.

Newsdate: 13 October 2022

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## Recommendations

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