Disclosure of emails received and sent by Alison Cave and Laura Squire which contain the term 'Sciensus' (date range 10/10/2022 – 10/10/2023)

Contents

Emails common to Alison Cave and Laura Squire

-----Original Appointment-----
From: [redacted]
Sent: Wednesday, July 5, 2023 9:26 AM
To: [redacted] Gray, Christine[redacted]
Cc: [redacted] Cave, Alison; Squire, Laura; [redacted]
Subject: Sciensus issue
When: 05 July 2023 09:30-10:00 (UTC+00:00) Dublin, Edinburgh, Lisbon, London.
Where: Microsoft Teams Meeting

Microsoft Teams meeting

Join on your computer, mobile app or room device

[redacted]

The email chain below includes discussion of an issue outside of scope of this FOI request. Those references have therefore been removed.

From: Raine, Dr June <June.Raine@mhra.gov.uk>
Sent: Friday, July 7, 2023 5:50 PM
To: [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Cc: Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Squire, Laura <laura.squire@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: RE: MEDIA ALERT: The Telegraph (Sciensus issue) and [redacted]

[redacted]

[redacted] you may be able to add the information on the Telegraph overage of Sciensus to the SoS note.

Many thanks

June

Dr June Raine
CEO MHRA
10 South Colonnade
Canary Wharf
London E14 4PU

Tel: [redacted]
Email June.raine@mhra.gov.uk

From: [redacted]@mhra.gov.uk>
Sent: Friday, July 7, 2023 5:43 PM
To: Raine, Dr June <June.Raine@mhra.gov.uk>
Cc: Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Squire, Laura <laura.squire@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: MEDIA ALERT: The Telegraph (Sciensus issue) and [redacted]
Importance: High

Dear June,

We wanted to alert you of two stories that will be published in the coming days.

The Telegraph is preparing a follow up story based on the Guardian Sciensus article that is likely to go online tonight and be in print for tomorrow's paper. We have prepared response for some follow up questions they sent on background that we will be sending you for clearance shortly.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

If you have any questions, please let me know.

Many thanks,
[redacted]

[redacted]
News and Issues Management Lead
Communications Division
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Email: [redacted]@mhra.gov.uk
gov.uk/mhra
Stay connected

Internal email sent to Alison Cave and Laura Squire (sender name withheld under Section 40 (2)) on 08/07/2023, 11:35. It contains a daily news update and references Sciensus as follows:

Agency coverage

Publication	Summary
msn.com dailymail.co.uk The Daily Telegraph The Guardian telegraph.co.uk telegraph.co.uk msn.com theguardian.com	A cancer patient died and three others were hospitalised after being given an unlicensed version of the prostate cancer chemotherapy medicine, cabazitaxel. As far as is known, only four patients were affected in total. The Medicines and Healthcare products Regulatory Agency (MHRA) offered its 'deepest sympathies' and vowed to take 'any necessary regulatory measures' to protect patients. Sciensus, the treatment providers, said: 'As soon as the incident was discovered, we immediately contacted the regulators, the patients and their doctors. 'We are currently conducting a

	thorough investigation into the incident and are working with the regulators.'

Internal email sent to Alison Cave and Laura Squire (sender name withheld under Section 40 (2)) on 13/07/2023, 11:42. It contains a daily news update and references Sciensus as follows:

Agency coverage

Publication	Summary
itv.com	Continued coverage of the Sciensus incident, briefly mentions that the MHRA has launched an investigation into the manufacturer.

Internal email sent to Alison Cave and Laura Squire (sender name withheld under Section 40 (2)) on 17/07/2023, 13:26. It contains a list of items discussed at a meeting and references Sciensus as follows:

Sciensus - notice will be issued today, 17 July 2023

Internal email sent to Alison Cave and Laura Squire (sender name withheld under Section 40 (2)) on 24/07/2023, 10:12. It contains a daily news update and references Sciensus as follows:

Agency coverage

Publication	**Summary**
Burton Mail	The MHRA says that their inspection uncovered serious concerns over Sciensus' IT systems which have led to the partial suspension of its manufacturing license. Includes a quote from Laura S.

Internal email sent to Alison Cave and Laura Squire (sender name withheld under Section 40 (2)) on 25/07/2023, 10:32. It contains a daily news update and references Sciensus as follows:

Agency coverage

Publication	Summary
Itv.com	Sciensus coverage. Dr Laura Squire, MHRA Chief Healthcare Access and Quality Officer said: "After conducting an inspection of Sciensus manufacturing facilities, we have partially suspended their manufacturing licence due to significant deficiencies in relation to Good Manufacturing Practice (GMP) standards. “This immediate partial suspension is a result of identified concerns with one aspect of the set-up of their IT system and will remain in place until corrective actions are implemented. "…. “We are in regular contact with the company and continue to investigate this issue. We will take any further regulatory measures as needed to ensure patients are protected.”

Internal email sent to Alison Cave and Laura Squire (sender name withheld under Section 40 (2)) on 26/07/2023, 09:55. It contains a daily news update and references Sciensus as follows:

Main health stories

- Sciensus’ licence partly suspended after death of cancer patient - Guardian (references the MHRA, please see below)

Main agency stories

- MHRA suspends Sciensus’ manufacturing license

Agency coverage

Publication	Summary
The Guardian msn.com theguardian.com	The MHRA has partially suspended the manufacturing license of Sciensus after the death of a cancer patient who was given the wrong dose of chemotherapy.

From: Pound, James <James.Pound@mhra.gov.uk>
Sent: Wednesday, July 26, 2023 2:33 PM
To: Gray, Christine <Christine.Gray@mhra.gov.uk>; Squire, Laura <laura.squire@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: RE: For awareness: Follow up story from The Guardian on the Sciensus issue (partial licence suspension)

Agreed, that article reads a lot more balanced now.

Thanks for flagging re twitter Chris.

Best wishes,

James

From: Gray, Christine <Christine.Gray@mhra.gov.uk>
Sent: Wednesday, July 26, 2023 1:46 PM
To: Squire, Laura <laura.squire@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Pound, James <James.Pound@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: RE: For awareness: Follow up story from The Guardian on the Sciensus issue (partial licence suspension)

Hi All
[redacted] (Guardian Health Editor) as had a dedicated thread on Twitter for Sciensus since mid June. May be worth keeping a watch on at the moment.
Thanks
Chris

From: Squire, Laura <laura.squire@mhra.gov.uk>
Sent: Wednesday, July 26, 2023 12:56 PM
To: [redacted] <[redacted]@mhra.gov.uk>; Pound, James <James.Pound@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: RE: For awareness: Follow up story from The Guardian on the Sciensus issue (partial licence suspension)

Interesting

It is good he changed the story yesterday in the Guardian though

Well done for making that happen [redacted]

Laura

From: [redacted] <Maria.Lopez@mhra.gov.uk>
Sent: Wednesday, July 26, 2023 12:48 PM
To: Squire, Laura <laura.squire@mhra.gov.uk>; Pound, James <James.Pound@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: RE: For awareness: Follow up story from The Guardian on the Sciensus issue (partial licence suspension)

Hi All,

Just wanted to flag that The Guardian is asking people to share their experiences with Sciensus, so we might see more stories coming out about the company.

UK patients: share your experiences with the healthcare company Sciensus | Health | The Guardian

Best wishes,
[redacted]

From: [redacted]
Sent: Tuesday, July 25, 2023 8:25 PM
To: Raine, Dr June <June.Raine@mhra.gov.uk>
Cc: Squire, Laura <laura.squire@mhra.gov.uk>; Pound, James <James.Pound@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: For awareness: Follow up story from The Guardian on the Sciensus issue (partial licence suspension)
Importance: High

Dear June,

We wanted to make you aware that The Guardian has published today this piece about the Sciensus' partial licence suspension: Sciensus's licence partly suspended after death of cancer patient | Health | The Guardian. We sent them our cleared statement yesterday and today we provided responses to their follow up questions, which were cleared by Laura Squire. See our responses below.

We have also sent our statement to StaffordshireLive and ITV. They have published the following stories:
Sciensus: NHS-contracted company has license suspended after death of cancer patient | ITV News
Burton medical firm's licence 'partially suspended' after death of cancer patient - Staffordshire Live (staffordshire-live.co.uk)

MHRA reactive statement

Dr Laura Squire, MHRA Chief Healthcare Access and Quality Officer said:

"After conducting an inspection of Sciensus manufacturing facilities, we have partially suspended their manufacturing licence due to significant deficiencies in relation to Good Manufacturing Practice (GMP) standards.

"This immediate partial suspension is a result of identified concerns with one aspect of the set-up of their IT system and will remain in place until corrective actions are implemented.

“The company has implemented the necessary corrective actions to ensure that products which are already on their IT system can continue to be manufactured. There is no evidence to suggest that any of their existing products are unsafe or of unacceptable quality.

“We are in regular contact with the company and continue to investigate this issue. We will take any further regulatory measures as needed to ensure patients are protected.”

Background

Cabazitaxel is a licensed chemotherapy medicine used to treat metastatic castration-resistant prostate cancer that undergoes further preparation steps prior to clinical use. The medicine is manually processed guided by instructions from a computerised system. This process involves diluting the licensed medicine within an infusion bag containing Sodium Chloride to achieve a patient-specific dose. After the dilution process, that dose becomes an unlicensed medicine (also known as ‘special’) manufactured under a Manufacturing Specials Authorisation issued by the MHRA.

This incident involved a small number of unlicensed preparations of this product manufactured by Sciensus to meet the clinical needs of individual patients. There are no concerns with licensed cabazitaxel products.

There are legal provisions allowing for unlicensed medicines (specials) to be prescribed and supplied to patients when there are no licensed medicines that are available and capable of meeting the special clinical needs of individual patients. Their use is the responsibility of the prescriber responsible for the care of individual patients. This issue is not related to the supply of an unlicensed medicine itself, which was prescribed under the legal provisions outlined above, but an incident that happened at Sciensus' manufacturing unit involving a small number of products. The investigation found that the product cabazitaxel was set up with the incorrect strength in the company’s IT systems. This manufacturing error resulted in four patients having the incorrect dose.

Companies manufacturing unlicensed medicines are authorised by the MHRA and required to comply with Good Manufacturing Practice (GMP) to ensure the quality of the products they produce and for the protection of public health. Breaches of GMP can result in MHRA suspending or removing the licence from manufacturers.

The MHRA has undertaken an inspection of Sciensus manufacturing facilities as soon as it was notified of an incident involving four unlicensed preparations of the chemotherapy medicine Cabazitaxel. Where deficiencies are identified at an inspection, the MHRA will take rapid regulatory action to ensure patient safety.

An immediate partial suspension is issued in accordance with Regulation 28 of the 2012 Human Medicines Regulations where it appears to the MHRA that in the interests of safety the licence should be suspended.

Responses we sent to The Guardian today

Response to questions 1-3

The Sciensus licence was only partially suspended on July 11 (see below). The Guardian story revealing details of the incident was published on July 7, and the Guardian first approached the MHRA with details of the incident at 12.40pm on July 4. Why did it take so long after the Guardian first approached the MHRA for the agency to suspend the licence?

When was the MHRA first notified of the incident involving four unlicensed preparations of the chemotherapy medicine Cabazitaxel, how was it notified, and by whom?

When did the MHRA undertake its inspection of Sciensus manufacturing facilities, where did this take place (POSTCODE) and how many MHRA officials took part in the inspection?

The MHRA were first notified of this issue on 26 June 2023. This was communicated by Sciensus as a defective medicines report. We assessed the information provided by the company and concluded that the incident was contained. There was no further immediate risk for patients and no medicines needed to be recalled.

To suspend or revoke a licence, the MHRA must act based on its own evidence to ensure that any such action has a legal basis, is necessary, and is proportionate to avoid the interruption of the supply of critical medicines to patients.

Therefore, MHRA inspectors contacted the Sciensus manufacturing site and on Thursday 6 and Friday 7 July 2023 two inspectors and an enforcement officer from the MHRA attended the site. A meeting of the Inspection Action Group was held on Monday 10 July and further regulatory action (the immediate partial suspension) was taken on Tuesday 11 July 2023.

Procedures for revocation and suspension of licences are laid down in law under regulations 26, 27 and 28 of the Human Medicines Regulations 2012.

Response to questions 4-6

Given the extremely serious nature of the incident, involving the death of a patient, why has the MHRA only partially suspended the company's licence? Who at the MHRA made the decision to only partially suspend the licence?
Please explain the difference in practical terms between partially suspending the Sciensus licence and a full suspension? Is there a higher threshold that must be reached for a full suspension of a company's licence?
Why has the MHRA opted for suspension and intentionally opted not to remove the company's licence? Would that require more deaths and/or hospitalisations of patients for the MHRA to take that action?

We take all issues relating to patient safety extremely seriously and have taken appropriate regulatory action to ensure patients are protected.

MHRA inspectors have visited the manufacturer’s facilities with the purpose of assessing the compliance of the company’s operations with Good Manufacturing Practice (GMP) standards and evaluating the impact on other products and any patient risk.

The immediate partial suspension was the appropriate action to take, based on the information held, to enable the UK patients who rely on the medicines manufactured by this company to access them safely whilst assuring further manufacturing errors do not occur.

We continue to investigate this issue and will take any further regulatory measures as needed to protect patients.

We are unable to disclose further details at this time to avoid prejudicing any future action that may need to be taken.

Best wishes,

[redacted]
News and Issues Management Lead
Communications Division

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Email: [redacted]@mhra.gov.uk
gov.uk/mhra

Stay connected

Internal email sent to Alison Cave and Laura Squire (sender name withheld under Section 40 (2)) on 31/07/2023, 23:18. It contains a list of items discussed at a meeting and references Sciensus as follows:

a. Weekend communications
    i. Sciensus
        1. Guardian article 'UK patients: share your experiences with the healthcare company Sciensus'

Emails only relevant to Alison

From: Tregunno, Phil <Phil.Tregunno@mhra.gov.uk>
Sent: Tuesday, July 11, 2023 3:59 PM
To: Cave, Alison <Alison.Cave@mhra.gov.uk>
Cc: [redacted]
Subject: FW: For info: Sciensus [s40]

Alison,

To note from [s40] below in case of any perceived conflict with the current issue. Clearly [s40] is not related to the issues raised last week, so I've said to [s40] that the chair should manage [s40] per standard process. Please let me know if you have any concerns.

Phil

From: [redacted]
Sent: Tuesday, July 11, 2023 3:51 PM
To: Tregunno, Phil <Phil.Tregunno@mhra.gov.uk>
Cc: [redacted]
Subject: For info: Sciensus [s40]

Hi Phil,

As discussed, just putting this into an email for you.

Just to be aware, [s40]

Kind regards,

[redacted]
Yellow Card Strategic Development Team
MHRA, 10 South Colonnade, Canary Wharf, London E14 4PU

Internal email sent to Alison Cave (sender name withheld under Section 40 (2)) on 05/07/2023, 17:25. It contains a list of items for sign off and has a section on Sciensus as follows:

> Sender: [redacted] RE: TO CLEAR: Sciensus and chemotherapy - The Guardian – review updated lines – spokesperson

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Internal email sent to Alison Cave (sender name withheld under Section 40 (2)) on 07/07/2023, 16:43. It contains a list of items for sign off and has a section on Sciensus as follows:

> Sender: [redacted] RE: TO CLEAR: Sciensus and chemotherapy - The Guardian

Internal email forwarded to Alison Cave (sender name withheld under Section 40 (2)) on 02/08/2023, 21:30. It contains a Communications update and has a section on Sciensus as follows:

> There was a number of national news articles on the Sciensus issue, see below:
> https://www.theguardian.com/society/2023/jul/07/patient-dies-hospitalised-sciensus-chemotherapy-incident
> https://www.dailymail.co.uk/news/article-12277003/Cancer-patient-dies-three-hospitalised-given-unlicensed-chemotherapy.html
> https://www.mirror.co.uk/news/health/cancer-patient-dies-4-hospitalised-30419257
> Sciensus's licence partly suspended after death of cancer patient | Health | The Guardian
> Sciensus: NHS-contracted company has license suspended after death of cancer patient | ITV News
> Burton medical firm's licence 'partially suspended' after death of cancer patient - Staffordshire Live (staffordshire-live.co.uk)

Emails only relevant to Laura

From: Squire, Laura
Sent: Wednesday, April 26, 2023 1:09 PM
To: News Centre <newscentre@mhra.gov.uk>
Cc: [redacted]@mhra.gov.uk>
Subject: RE: Lines to clear: ITV request on Sciensus - By COP today

This is clear

Thank you

These can go

Laura

From: News Centre <newscentre@mhra.gov.uk>
Sent: 26 April 2023 11:01
To: Squire, Laura <laura.squire@mhra.gov.uk>
Cc: [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: Lines to clear: ITV request on Sciensus - By COP today
Importance: High

Hi Laura,

Please see some lines for your review as soon as you can (deadline is COP today) in response to an ITV request for a statement on this investigation they published on homecare pharmaceutical services provider Sciensus: 'Chronically ill patients go without vital drugs amid delays by NHS-contracted firm'. They asked us whether we have any concerns - Chris Gray's team contributed to lines and James Pound has signed off on the below.

Thanks very much in advance.
BW,
[redacted]

****
MHRA LTTS:

An MHRA spokesperson said:

"The MHRA is responsible for the regulation of the manufacture and wholesale distribution of medicines, but this does not include dispensing and supply. The issues reported are therefore not within our regulatory remit.

"Patient safety is our top priority, and we continue to work with the General Pharmaceutical Council and the Care Quality Commission to ensure that any concerns identified as being within our remit are dealt with appropriately."

Background

We can confirm that Sciensus hold current MHRA authorisations for their manufacturing and wholesale distribution activities.

[redacted]
News and Media Specialist, Press Office

Email forwarded from Julian Beach (MHRA) to Laura Squire on 27/04/2023, 17:04. It contains a long chain of emails regarding a supply issue with one mention of Sciensus as follows:

- Sciensus homecare provider – 2 packs (waiting on info from other providers)

From: [redacted]@mhra.gov.uk>
Sent: Saturday, July 8, 2023 10:41 AM
To: Squire, Laura <laura.squire@mhra.gov.uk>
Subject: RE: TO CLEAR: media enquiry from The Telegraph on the Sciensus issue

Lets hope that holds for the weekend

From: Squire, Laura <laura.squire@mhra.gov.uk>
Sent: Saturday, July 8, 2023 10:06 AM
To: News Centre <newscentre@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Cc: [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted] <[redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; Raine, Dr June <June.Raine@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Subject: RE: TO CLEAR: media enquiry from The Telegraph on the Sciensus issue

Morning

There has been further coverage this morning

Please do get in touch if any additional lines needed.

Laura

Dr Laura Squire *(she/her)*
Chief Healthcare Quality and Access Officer
10 South Colonnade, Canary Wharf, London E14 4PU
Project Manager & Business Support: [redacted]

From: News Centre <newscentre@mhra.gov.uk>
Sent: Friday, July 7, 2023 6:46 PM

To: [redacted]@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; Raine, Dr June <June.Raine@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Cc: Squire, Laura <laura.squire@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Subject: RE: TO CLEAR: media enquiry from The Telegraph on the Sciensus issue
Importance: High

Thanks June for reviewing the lines so quickly. We have incorporated your edits and have added '**at this time'** at the end of the 2nd sentence in point 4 as suggested by @Gray, Christine to clarify our current position. We will be sending this to the journalist shortly, but if you have any concerns please let us know.

Many thanks,
[redacted]

MHRA response

We are unable to disclose patient information received from third parties during ongoing investigations concerning the safety of medicines, but please find below response to questions 3 and 4.

3. Is the investigation on this specific incident or into the practices of Sciensus?
We are urgently investigating the manufacturing activities being conducted by Sciensus and their ongoing analysis of the root cause of this tragic incident. The MHRA will take any necessary regulatory measures to ensure patients are protected

4. Are you recalling unlicensed versions of cabazitaxel from Sciensus?
The impacted products are unlicensed medicines manufactured to meet the specific needs of individual patients. Sciensus has confirmed that all patients who received impacted doses of unlicensed cabazitaxel have been identified. No other unlicensed cabazitaxel products need to be recalled by the manufacturer at this time.
A licenced medicine may be used to produce a patient specific medicine that meets the individual clinical needs of that patient. These medicines are referred to as unlicensed medicines or "specials" and are used to treat patients for whom there is no appropriate licensed product.

From: [redacted]@mhra.gov.uk>
Sent: Friday, July 7, 2023 6:32 PM
To: Gray, Christine <Christine.Gray@mhra.gov.uk>; Raine, Dr June <June.Raine@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Cc: Squire, Laura <laura.squire@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Hallworth, Stephen <Stephen.Hallworth@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]

[redacted]mhra.gov.uk>
Subject: RE: TO CLEAR: media enquiry from The Telegraph on the Sciensus issue

Dear Chris

Thanks you for that. I am copying in [redacted] to this email chain: she is deputising for James next week, so want to ensure she is up to speed.

Many thanks
[redacted]

From: Gray, Christine <Christine.Gray@mhra.gov.uk>
Sent: Friday, July 7, 2023 6:28 PM
To: Raine, Dr June <June.Raine@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Cc: Squire, Laura <laura.squire@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Subject: RE: TO CLEAR: media enquiry from The Telegraph on the Sciensus issue

Dear All
One minor addition in green to further clarify that this is the current position.
We could reword further to state:
"The current MHRA and company investigations have not identified any products that require recall" if the preference is to use more active language.
Kind regards
Chris

From: Raine, Dr June <June.Raine@mhra.gov.uk>
Sent: Friday, July 7, 2023 6:12 PM
To: [redacted]@mhra.gov.uk>
Cc: Squire, Laura <laura.squire@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Subject: RE: TO CLEAR: media enquiry from The Telegraph on the Sciensus issue

Dear [redacted]

The 2nd sentence in point 4 could be clearer. The phrase 'we have not received any information that' sounds passive and will not reassure. Please check with the Inspectors. Otherwise OK to go back on the Telegraph's Qs.

With the current focus on MHRA performance, I would ask that you are ready for this issue to escalate over the weekend and to have a statement if needed assuring on what MHRA does to ensure the safety of specials etc and maybe some more quotes.

Kind regards
June

Dr June Raine
CEO MHRA
10 South Colonnade
Canary Wharf
London E14 4PU

Tel: [redacted]
Email June.raine@mhra.gov.uk

From: [redacted]@mhra.gov.uk>
Sent: Friday, July 7, 2023 5:50 PM
To: Raine, Dr June <June.Raine@mhra.gov.uk>
Cc: Squire, Laura <laura.squire@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Makwana, Himal <[redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: TO CLEAR: media enquiry from The Telegraph on the Sciensus issue
Importance: High

Dear June,

Telegraph is preparing a follow up story based on the Guardian Sciensus article that is likely to go online tonight and be in print for tomorrow's paper. We provided our statement and they have sent some follow up questions on background. Could you please review our responses for clearance? We need to go back today.

Questions from The Telegraph

Is it accurate to report that the three other patients who received unlicensed versions of this drug needed hospital treatment?

Are you able to give any more basic details such as age/gender on the patients?

Is the investigation on this specific incident or into the practices of Sciensus?

Are you recalling unlicensed versions of cabazitaxel from Sciensus?

MHRA response

We are unable to disclose patient information received from third parties during ongoing investigations concerning the safety of medicines, but please find below response to questions 3 and 4.

3. Is the investigation on this specific incident or into the practices of Sciensus?
We are urgently ~~looking into~~ investigating the manufacturing activities being conducted by Sciensus and their ongoing ~~investigations into~~ analysis of the root cause of this tragic incident. The MHRA will take any necessary regulatory measures to ensure patients are protected

4. Are you recalling unlicensed versions of cabazitaxel from Sciensus?
The impacted products are unlicensed medicines manufactured to meet the specific needs of individual patients. Sciensus ~~have~~ has confirmed ~~to the MHRA~~ that all patients ~~that~~ who received impacted doses of unlicensed cabazitaxel have been identified. ~~To date,~~ ~~we have not received any information~~ ~~regarding~~ No other unlicensed cabazitaxel products ~~products that~~ need to be recalled by the manufacturer at this time.
~~Please note that in this instance~~ A licenced medicine may be used to produce a patient specific medicine that meets the individual clinical needs of that patient. These medicines are referred to as unlicensed medicines or "specials" and are used to treat patients for whom there is no appropriate licensed product. ~~There are no concerns with licensed cabazitaxel products.~~

Many thanks,

[redacted]
[redacted]
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Stay connected

From: [redacted]@mhra.gov.uk>
Sent: Friday, July 14, 2023 8:36 PM
To: Raine, Dr June <June.Raine@mhra.gov.uk>; Squire, Laura <laura.squire@mhra.gov.uk>
Cc: [redacted]@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: TO CLEAR: Reactive LTT/Q&A on Sciensus' licence partial suspension - Cabazitaxel incident

Dear June and Laura,

Grateful if you can review for clearance our updated reactive lines and Q&A about the Cabazitaxel/Sciensus incident following the decision to partially suspend their licence.

Considering that the suspended list will be updated on Monday morning and the lines were approved by colleagues this afternoon, I'm sending this to you at the same time for review over the weekend. See them attached and below.

We wanted to be a bit more clear about the specific deficiencies we found and what the suspension means in practice (which are the current restrictions), but [redacted] has explained to us that we never provide information about the nature of deficiencies which lead to the suspension of a licence and that we are in danger of setting an unfortunate precedent if we provide more details at this stage – while this is still under IAG. We have therefore limited the amount of information in the main statement and some of the responses in our Q&A. Once the investigation is over, the inspection report will be FOI-able.

Please let us know your views.

Reactive Ltt

Dr Laura Squire, MHRA Chief Healthcare Access and Quality Officer said:

"After conducting an inspection of Sciensus manufacturing facilities, we have partially suspended their manufacturing licence due to significant deficiencies in relation to Good Manufacturing Practice (GMP) standards.

“This immediate partial suspension is a result of identified concerns with one aspect of their IT system and will remain in place until corrective actions are implemented.

“The company has implemented the necessary corrective actions to ensure that products which are already on their IT system can continue to be manufactured. There is no evidence to suggest that any of their existing products are unsafe or of unacceptable quality.”

Background

Cabazitaxel is a licensed chemotherapy medicine used to treat metastatic castration-resistant prostate cancer that undergoes further preparation steps prior to clinical use. The medicine is manually processed guided by instructions from a computerised system. This process involves diluting the licensed medicine within an infusion bag containing Sodium Chloride to achieve a patient-specific dose. After the dilution process, that dose becomes an unlicensed medicine (also known as ‘special’) manufactured under a Manufacturing Specials Authorisation issued by the MHRA.

This incident involved a small number of unlicensed preparations of this product manufactured by Sciensus to meet the clinical needs of individual patients. There are no concerns with licensed cabazitaxel products.

There are legal provisions allowing for unlicensed medicines (specials) to be prescribed and supplied to patients when there are no licensed medicines that are available and capable of meeting the special clinical needs of individual patients. Their use is the responsibility of the prescriber responsible for the care of individual patients. This issue is not related to the supply of an unlicensed medicine itself, which was prescribed under the legal provisions outlined above, but an incident that happened at Sciensus' manufacturing unit involving a small number of products. The investigation found that the product cabazitaxel was set up with the incorrect strength in the company’s IT systems. This manufacturing error resulted in four patients having a single dose three times greater than prescribed.

Companies manufacturing unlicensed medicines are authorised by the MHRA and required to comply with Good Manufacturing Practice (GMP) to ensure the quality of the products they produce and for the protection of public health. Breaches of GMP can result in MHRA suspending or removing the licence from manufacturers.

The MHRA has undertaken an inspection of Sciensus manufacturing facilities as soon as it was notified of an incident involving four unlicensed preparations of the chemotherapy medicine Cabazitaxel. Where deficiencies are identified at an inspection, the MHRA will take rapid regulatory action to ensure patient safety.

An immediate partial suspension is issued in accordance with Regulation 28 of the 2012 Human Medicines Regulations where it appears to the MHRA that in the interests of safety the licence should be suspended.

ENDS

Q&A

1. What is the root cause of the incident?
The investigation found that the product Cabazitaxel was set up with the incorrect strength in the company's IT systems. This manufacturing error resulted in four patients having a single dose three times greater than prescribed.

The company has implemented the necessary corrective actions to ensure that products which are already on their IT system can be manufactured correctly.

2. Did the manufacturing error cause the death of this patient?
The relationship between the manufacturing error and the death of the patient has been referred to the coroner. The coroner will determine the cause of death.

3. Is the company being prosecuted?
MHRA inspectors have visited the manufacturer's facilities with the purpose of assessing the root cause of this manufacturing error, determining the required corrective actions, and evaluating the impact on other products to ensure patients are protected.

The MHRA's enforcement unit has also visited the manufacturer's facilities and is actively investigating this issue. We will take enforcement action if breaches, or suspected breaches, of medicine regulations are identified.

4. What is the root cause of the manufacturing error?
The investigation found that a human error and the absence of a standards operating procedure on how the company's products are checked led to this manufacturing error.

5. Which deficiencies in relation to GMP did you find?
This immediate partial suspension relates to concerns about one element of their IT system and will remain in place until corrective actions are implemented.

[if needed]

We are unable to disclose further details at this time. Once the investigation is completed, this information will become available.

6. What this partial suspension means in practice? Which are the restrictions?
The MHRA has used its regulatory powers under Regulation 28 of the Human Medicines Regulation 2012 to immediately restrict activities at the site to only those manufacturing activities that the inspection of the site has confirmed have received additional checking to ensure patient safety. This restriction will remain in force until corrective actions are implemented.

7. Is the investigation still ongoing?

We continue to assess the corrective actions that need to be implemented by Sciensus and closely monitoring their progress towards compliance in relation to Good Manufacturing Practice (GMP) standards.

The MHRA's enforcement unit has also visited the manufacturer's facilities and is actively investigating this issue.

8. Are you recalling unlicensed versions of cabazitaxel from Sciensus?
The impacted products were patient-specific unlicensed preparations that were manufactured to meet the special needs of individual patients. Sciensus has confirmed that all patients who received impacted doses of unlicensed cabazitaxel have been identified. No other unlicensed cabazitaxel products need to be recalled by the manufacturer at this time.

A licenced medicine may be used to produce a patient specific medicine that meets the individual clinical needs of that patient. These medicines are referred to as unlicensed medicines or "specials" and are used to treat patients for whom there is no appropriate licensed product.

9. If asked specific questions about the patients including their clinical situation (i.e. is it accurate to report that the three other patients who received unlicensed versions of this drug needed hospital treatment? Are you able to give any more basic details such as age/gender on the patients?)
We are unable to disclose patient information received from third parties during ongoing investigations concerning the safety of medicines

Many thanks,

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From: News Centre <newscentre@mhra.gov.uk>
Sent: Friday, July 21, 2023 12:01 PM
To: Squire, Laura <laura.squire@mhra.gov.uk>; Gray, Christine <Christine.Gray@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>
Cc: [redacted]@mhra.gov.uk>; [redacted]@mhra.gov.uk>; News Centre <newscentre@mhra.gov.uk>
Subject: FW: Sciensus
Importance: High

Hi All,

We've been asked about and update in our investigation on Sciensus. They haven't asked directly about the suspension but since that's the update, we plan to send our cleared updated lines.

If you have any concerns with this approach please let me know by 2 pm.

Many thanks,
[redacted]

Cleared LTT

Dr Laura Squire, MHRA Chief Healthcare Access and Quality Officer said:
"After conducting an inspection of Sciensus manufacturing facilities, we have partially suspended their manufacturing licence due to significant deficiencies in relation to Good Manufacturing Practice (GMP) standards.
"This immediate partial suspension is a result of identified concerns with one aspect of the set-up of their IT system and will remain in place until corrective actions are implemented.
"The company has implemented the necessary corrective actions to ensure that products which are already on their IT system can continue to be manufactured. There is no evidence to suggest that any of their existing products are unsafe or of unacceptable quality".
Background
Cabazitaxel is a licensed chemotherapy medicine used to treat metastatic castration-resistant prostate cancer that undergoes further preparation steps prior to clinical use. The medicine is manually processed guided by instructions from a computerised system. This process involves diluting the licensed medicine within an infusion bag containing Sodium Chloride to achieve a patient-specific dose. After the dilution process, that dose becomes an unlicensed medicine (also known as 'special') manufactured under a Manufacturing Specials Authorisation issued by the MHRA.
This incident involved a small number of unlicensed preparations of this product manufactured by Sciensus to meet the clinical needs of individual patients. There are no concerns with licensed cabazitaxel products.
There are legal provisions allowing for unlicensed medicines (specials) to be prescribed and supplied to patients when there are no licensed medicines that are available and capable of meeting the special clinical needs of individual patients. Their use is the responsibility of the prescriber responsible for the care of individual patients. This issue is not related to the supply of an unlicensed medicine itself, which was prescribed under the legal provisions outlined above, but an incident that happened at Sciensus' manufacturing unit involving a small number of products. The investigation found that the product cabazitaxel was set up with the incorrect strength in the company's IT systems. This manufacturing error resulted in four patients having the incorrect dose.
Companies manufacturing unlicensed medicines are authorised by the MHRA and required to comply with Good Manufacturing Practice (GMP) to ensure the quality of the products they produce and for the protection of public health. Breaches of GMP can result in MHRA suspending or removing the licence from manufacturers.
The MHRA has undertaken an inspection of Sciensus manufacturing facilities as soon as it was notified of an incident involving four unlicensed preparations of the chemotherapy medicine Cabazitaxel. Where deficiencies are identified at an inspection, the MHRA will take rapid regulatory action to ensure patient safety.
An immediate partial suspension is issued in accordance with Regulation 28 of the 2012 Human Medicines Regulations where it appears to the MHRA that in the interests of safety the licence should be suspended.

From: [redacted]>
Sent: Friday, July 21, 2023 11:18 AM
To: [redacted] News Centre <newscentre@mhra.gov.uk>;
[redacted]
Subject: Sciensus

Morning guys,

Can we please have an update on your respective investigations into this incident - https://www.theguardian.com/society/2023/jul/07/patient-dies-hospitalised-sciensus-chemotherapy-incident - ? Can you also please issue us with the statements you've sent to the Guardian? It'd be brilliant if you could send the above through by 5pm today.

Many thanks

[redacted]

An internal email received by Laura Squire (sender name withheld under Section 40 (2)) on 26/07/2023 17:56. There was one reference to Sciensus:

> Sciensus – [redacted] has put in our most recent Q&A on that but has advised that this is subject to change. She will update the lines in this document too, and flag to you when she does, so that you're aware of any moving position.

An internal email received by Laura Squire (senders name is withheld under Section 40 (2)) on 11/08/2023 21:32 following a recent visit to a hospital. The email discussed the visit and various elements of regulation. There was one reference to Sciensus:

> It's a tricky one when we are met with cases in the wider specials landscape like [redacted] and Sciensus but in a nutshell, it is indeed easier, faster and cheaper to manufacture all specials outside of the UK as it is always easier, faster and cheaper to do things outside of a supervised regulatory framework.