

VOLUNTARY ADMISSION BY SUNOVION

Disclosure of funding to a patient organisation and provision of inaccurate information

Sunovion Pharmaceuticals Europe voluntarily admitted a breach of the Code in relation to its failure to disclose support to patient organisations as required by the Code and the provision of inaccurate information to the PMCPA.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Sunovion.

Sunovion admitted that in its comments on the PMCPA audit report in relation to Case AUTH/2935/2/17 it had stated that it had not worked with any patient organisations. However, the company regretted that it had now found this not to be so. In 2016, Sunovion entered in to an agreement with a registered charity supporting patients with mental health problems. In September 2016 and June 2017 Sunovion paid the patient organisation to support administration and general running costs. In addition, Sunovion paid for the development of an early intervention guide for patients with schizophrenia and their families. Part of this was paid in October 2016 and the remaining amount in February 2017. The support provided was declared on the company's website from 15 March 2018.

The detailed response from Sunovion is given below.

The Panel noted that the Code required, *inter alia*, that each company must make publicly available, at a national or European level, a list of patient organisations to which it provided financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that was sufficiently complete to enable the average reader to form an understanding of the significance of the support. The list of organisations being given support must be updated at least once a year. The relevant supplementary information stated that companies were encouraged to be prepared to make available up-to-date information about such activities at any time in response to enquiries.

The Panel acknowledged that it was not entirely clear whether as a minimum companies could update their lists on a certain date once a year covering the previous twelve months of payments in which case no payment would ever be disclosed more than twelve months after it was made or whether the annual update could be by no later than the 31 March each year in relation to payments made in the previous calendar year. This latter approach would be consistent with the relevant supplementary information in the 2012 edition of the Code and similar to the permitted approach when disclosing transfers of value under the Code. The Panel noted that as a minimum the published list of patient organisations had to be updated annually.

The Panel considered that the approach adopted by a company should be made clear on its website. Sunovion made no submission in this regard. The Panel considered it prudent and good practice for a company to update its list as soon as reasonably possible and noted that the relevant Clause referred to updating the list at least once a year.

The Panel noted that Sunovion had paid a patient organisation in October 2016 to support administration and general running costs. A copy of the certified agreement covering the payment in 2016 was provided. The agreement also covered payments in 2017 and 2018, but neither of these payments had been made contrary to the company's disclosure on 15 March 2018. That disclosure was updated on 27 March.

The Panel noted that in addition Sunovion had paid for the development of an early intervention guide for patients; part of this was paid in October 2016 and the remaining amount was paid in February 2017. The Panel noted Sunovion's submission that there was no written agreement to cover this payment and that the amount of support was less than that originally thought and disclosed on 15 March 2018 and was therefore updated on 27 March 2018.

The Panel noted the ambiguity of the Clause which covered disclosure of payments to patient organisations as described above but considered that regardless of the approach taken the two 2016 payments had not been disclosed as required by the Code and a breach of the Code was ruled in relation to both 2016 payments.

The Panel noted that the incorrect February 2017 payment was disclosed by 15 March 2018 and updated on 27 March 2018 to accurately reflect the amount actually paid. The Panel noted the ambiguity of the relevant Clause and considered on balance that disclosure prior to 31 March the following calendar year was not unacceptable and ruled no breach of the Code in relation to the 2017 payment.

The Panel noted the sensitivities surrounding the pharmaceutical industry working with patient organisations; robust agreements setting out the arrangements, and certification of those agreements were important steps in ensuring that such interactions complied with the Code and in that regard they underpinned the self-regulatory compliance system. That projects and sponsorship were able to go ahead without a certified agreement in place was unacceptable. Further, public disclosure of support was an important means of building and maintaining confidence in the industry.

The Panel noted that Sunovion had sponsored the development of an early intervention guide without first having a certified agreement in place and the company's support for the patient organisation in 2016, was not properly disclosed until March 2018. Whilst a certified agreement was in place for the separate payment to the patient organisation in 2016 overall the Panel considered that high standards had not been maintained. A breach of the Code was ruled.

The Panel was further concerned that the information provided in response to the PMCPA's audit report was incorrect and further that only in response to the case preparation manager's request for further comments, did Sunovion discover that the amount of financial support paid was less than stated in its initial voluntary admission. This, coupled with the fact that there was no certified agreement for one payment, in the Panel's view, indicated that there was poor governance and control of materials. The Panel noted that self-regulation relied, *inter alia*, upon the provision of complete and accurate information and that Sunovion had already been criticised for not providing accurate information in the case that led to the company being audited, Case AUTH/2935/2/17. The Panel considered that Sunovion had brought discredit upon or reduced confidence in the industry and therefore the Panel ruled a breach of Clause 2.

Sunovion provided the requisite undertaking and assurance and the Appeal Board received the case report as set out in Paragraph 13.4 of the Constitution and Procedure.

The Appeal Board noted the Panel's rulings of breaches of the Code regarding the voluntary admission from Sunovion about disclosure of payments made to patient organisations. The Panel had considered it was a serious matter.

The Panel's concerns included that the information provided in response to the PMCPA's audit report in another case concerning Sunovion, Case AUTH/2935/5/17 was incorrect. Further only in response to the case preparation manager's request for further comments in Case AUTH/3027/3/18 did Sunovion discover that the amount of financial support paid was less than stated in its initial voluntary admission. This coupled with the fact that there was no certified agreement for the payment of £2,750 in the Panel's view indicated that there was poor governance and control of materials. The Panel noted that self-regulation relied, *inter alia*, upon the provision of complete and accurate information and that Sunovion had already been criticised for not providing accurate information in Case AUTH/2935/2/17.

The Appeal Board considered that Case AUTH/3027/3/18 raised serious issues including about the provision of incomplete and/or inaccurate information. The Appeal Board was of the view that consideration should be given to imposing further sanctions under Paragraph 11.1 of the Constitution and Procedure.

The company was advised that the Appeal Board was considering imposing additional sanctions and asked to respond in writing, as well as be given the opportunity to appear before the Appeal Board when the matter was considered. Sunovion was provided with a copy of the papers.

The detailed comments from Sunovion about the possible imposition of further sanctions is given below.

The Appeal Board noted that the company had apologised and admitted that it had made errors.

The Appeal Board was concerned that due to poor judgement and/or absence of the necessary process the company had made a series of errors about its disclosure of payments in its responses to the PMCPA including during the re-audit required in Case AUTH/2935/2/17 in which it had already been criticised for not providing accurate information. Notwithstanding Sunovion's submission that it now had a process in place to ensure such errors did not recur, the Appeal Board noted that self regulation relied, *inter alia*, upon the provision of complete and accurate information from pharmaceutical companies.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Sunovion should be publicly reprimanded for providing inaccurate information to the PMCPA. Following consideration of the re-audit report and Sunovion's comments on it the Appeal Board's decision to require a further re-audit in Case AUTH/2935/2/17, the Appeal Board decided that the issues that had arisen in Case AUTH/3027/3/18 should be the subject of an audit which would take place April 2019 at the same time as the re-audit in Case AUTH/2935/2/17. On receipt of the report of the audit the Appeal Board would consider whether further sanctions were necessary.

Sunovion was audited in April 2019 and on receipt of the report of the audit in July 2019 the Appeal Board noted that there had been significant progress at Sunovion since the re-audit in June 2018 in Case AUTH/2935/5/17. The Appeal Board noted that Sunovion had a compliance action plan to address recommendations from the re-audit. The Appeal Board noted some actions were already completed and that others were due to be completed very shortly. On the basis that this work was completed, the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that no further action was required.

Sunovion Pharmaceuticals Europe Ltd voluntarily admitted a breach of the Code as it had not disclosed support it had given to a patient organisation.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Sunovion.

VOLUNTARY ADMISSION

In its voluntary admission Sunovion stated that in its comments on the PMCPA audit report in relation to Case AUTH/2935/2/17 it had stated that it had not worked with any patient organisations. However, the company regretted that it had now found this not to be so. In 2016, Sunovion entered into an agreement with a registered charity supporting patients with mental health problems. In September 2016 and June 2017 Sunovion paid the patient organisation £10,000 to support administration and general running costs. In addition, Sunovion paid £4,900 for the development of an early intervention guide for patients with schizophrenia and their families. £600 of this was paid in October 2016 and the remaining £4,300 was paid in February 2017. The support provided was declared on the company's website from 15 March, 2018.

To prevent this happening in the future, the company introduced a standard operating procedure (SOP) covering work with patient organisations as part of its SOP action plan. It would ensure that all personnel who might become involved with patient organisations were trained on this. Sunovion would not initiate new activities with patient organisations until this was in place.

The company apologised unreservedly for providing inaccurate information in response to the audit report and accepted that Sunovion had breached Clause 27.7 by failing to publicly declare this support in good time.

Sunovion was asked to respond to Clauses 9.1 and 2 in addition to Clause 27.7.

RESPONSE

Sunovion stated that it had investigated the payments to the patient organisation and confirmed that the following payments were made. The amount of financial support was less than originally thought. In October 2016, £10,000 was provided. In addition, £600 was provided in October 2016 to support the development of an early intervention guide for patients, and a further £2,150 was provided in February 2017. A copy of the certified agreement covering the payment of £10,000 in 2016 was provided. The agreement also covered payments of £10,000 in 2017 and 2018, but these payments had not yet been made. Sunovion had searched its records and could not locate an agreement covering the £2,750 for the development of an early intervention guide. It appeared that an agreement was not put in place.

Sunovion submitted that the following appeared on its website:

'We believe in working transparently with the patient organisations that we engage with. In October 2016 we paid [a patient organisation] £10,000 to support administration and general running costs. In addition, we paid £2,750 for the development of an early intervention guide for patients. £600 of this was paid in October 2016 and the remaining £2,150 was paid in Feb 2017....'

The initial disclosure went live on 15 March 2018, and the information was amended as above on 27 March.

In addition to a breach of Clause 27.7, Sunovion stated that it had also breached Clause 27.3 by failing to have an agreement in place covering all work with the patient organisation in this case. It was with regret that Sunovion acknowledged that high standards had not been maintained and accepted that a breach of Clause 9.1 had occurred. Sunovion submitted that the matter did not bring discredit upon, or reduce confidence in, the industry and therefore a breach of Clause 2 had not occurred.

PANEL RULING

The Panel noted that Clause 27.7 stated, *inter alia*, that each company must make publicly available, at a national or European level, a list of patient organisations to which it provided financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that was sufficiently complete to enable the average reader to form an understanding of the significance of the support. The list of organisations being given support must be updated at least once a year. The relevant supplementary information stated that companies were encouraged to be prepared to make available up-to-date information about such activities at any time in response to enquiries.

The Panel acknowledged that it was not entirely clear whether as a minimum companies could update their lists on a certain date once a year covering the previous twelve months of payments in which case no payment would ever be disclosed more than twelve months after it was made or whether the annual update could be by no later than the 31 March each year in relation to payments made in the previous calendar year as set out in previous versions of the Code. This latter approach would be consistent with the relevant supplementary information in the 2012 second edition of the Code and similar to the permitted approach when discussing transfers of value under Clause 24.4. The Panel noted that as a minimum the published list of patient organisations had to be updated annually.

The Panel considered that the approach adopted by a company should be made clear on its website. Sunovion made no submission in this regard. The Panel considered it prudent and good practice for a company to update its list as soon as reasonably possible and noted that the Clause referred to updating the list **at least** once a year.

The Panel noted that Sunovion had paid a patient organisation, £10,000 in October 2016 to support administration and general running costs. A copy of the certified agreement covering the payment of £10,000 in 2016 was provided. The agreement also covered payments of £10,000 in 2017 and 2018, but neither of these payments had been made yet contrary to the company's disclosure on 15 March 2018. The disclosure was updated on 27 March.

The Panel noted that in addition Sunovion had paid £2,750 for the development of an early intervention

guide for patients; £600 of this was paid in October 2016 and the remaining £2,150 was paid in February 2017. The Panel noted Sunovion's submission that there was no written agreement to cover this payment and that the amount of support was less than that originally thought and disclosed on 15 March 2018 and was therefore updated on 27 March 2018.

The Panel noted the ambiguity of Clause 27.7 as described above but considered that regardless of the approach taken the two 2016 payments had not been disclosed as required by Clause 27.7 and a breach of that Clause was ruled in relation to both 2016 payments.

The Panel noted that the incorrect February 2017 payment of £4300 was disclosed by 15 March 2018 and updated on 27 March 2018 to accurately reflect the amount of £2150 actually paid. The Panel noted the ambiguity of Clause 27.7 and considered on balance that disclosure prior to 31 March the following calendar year was not unacceptable and ruled no breach of this clause in relation to the 2017 payment.

In its response Sunovion raised Clause 27.3 of the Code which required that companies working with patient organisations have a written agreement in place which set out exactly what had been agreed, including funding, in relation to every significant activity or on-going relationship. Clause 14.3 required such agreements to be certified in advance. The Panel could make no ruling under this clause as it had not been raised in Sunovion's initial voluntary admission nor had Sunovion been asked to respond to it. Whilst not the subject of the voluntary admission *per se* it was nonetheless relevant to the matters before the Panel.

The Panel noted the sensitivities surrounding the pharmaceutical industry working with patient organisations; robust agreements setting out the arrangements, and certification of those agreements were important steps in ensuring that such interactions complied with the Code and in that regard they underpinned the self-regulatory compliance system. That projects and sponsorship were able to go ahead without a certified agreement in place was unacceptable. Further, public disclosure of support was an important means of building and maintaining confidence in the industry. The Panel noted that Sunovion had sponsored the development of an early intervention guide without first having a certified agreement in place and the company's support for the patient organisation in 2016, was not properly disclosed until March 2018. Whilst a certified agreement was in place for the separate payment of £10,000 to the patient organisation in 2016 overall the Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel was further concerned that the information provided in response to the PMCPA's audit report was incorrect and further that only in response to the case preparation manager's request for further comments, did Sunovion discover that the amount of financial support paid was less than stated in its

initial voluntary admission. This, coupled with the fact that there was no certified agreement for the payment of £2,750, in the Panel's view, indicated that there was poor governance and control of materials. The Panel noted that self-regulation relied, *inter alia*, upon the provision of complete and accurate information and that Sunovion had already been criticised for not providing accurate information in the case that led to the company being audited, Case AUTH/2935/2/17. The Panel considered that Sunovion had brought discredit upon or reduced confidence in the industry and therefore the Panel ruled a breach of Clause 2.

APPEAL BOARD CONSIDERATION OF CASE REPORT

Sunovion provided the requisite undertaking and assurance and as the case completed at Panel level the Appeal Board was provided with certain papers (the Panel minute and the case report) as was usual for such cases (Paragraph 4.1 of the Constitution and Procedure).

The Appeal Board noted the Panel's rulings of breaches of Clauses 2, 9.1 and 27.7 regarding the voluntary admission from Sunovion about disclosure of payments made to patient organisations. The Panel had considered it was a serious matter.

The Panel's concerns included that the information provided in response to the PMCPA's audit report in another case concerning Sunovion, Case AUTH/2935/2/17 was incorrect. Further only in response to the case preparation manager's request for further comments in Case AUTH/3027/3/18 did Sunovion discover that the amount of financial support paid was less than stated in its initial voluntary admission. This coupled with the fact that there was no certified agreement for the payment of £2,750 in the Panel's view indicated that there was poor governance and control of materials. The Panel was further concerned that the information provided in response to the PMCPA's audit report was incorrect. The Panel noted that self-regulation relied, *inter alia*, upon the provision of complete and accurate information and that Sunovion had already been criticised for not providing accurate information in Case AUTH/2935/2/17.

The Appeal Board considered that Case AUTH/3027/3/18 raised serious issues including about the provision of incomplete and/or inaccurate information. The Appeal Board was of the view that consideration should be given to imposing further sanctions under Paragraph 11.1 of the Constitution and Procedure.

The company was advised that the Appeal Board was considering imposing additional sanctions and asked to respond in writing, as well as be given the opportunity to attend the next meeting of the Appeal Board when the matter would be considered. Sunovion was provided with a copy of the papers.

COMMENTS FROM SUNOVION

Sunovion submitted that it understood and accepted the serious nature of the concerns the Appeal

Board had in relation to this case as well as Case AUTH/2935/2/17. Sunovion apologised unreservedly for providing inaccurate and incomplete responses to these cases and to the PMCPA's audit report.

Sunovion summarised the background to these events, in 2016, a Sunovion employee (no longer with the company) commenced relations with a patient organisation, a registered charity supporting patients with mental health problems. In September 2016, a certified agreement was put in place to pay the patient organisation £10,000 per annum over a period of three years to support its administration and general running costs. Payments for this purpose were made in October 2016 for the fiscal year 2016 payment, April 2018 for the fiscal year 2017 payment and July 2018 for the fiscal year 2018 payment. The support Sunovion provided was declared on its website from 15 March 2018. This declaration reflected the scheduled payment dates as set out in the certified agreement with the patient organisation rather than the actual dates of payments which subsequently ensued. Additionally, as identified during the PMCPA re-audit on 30 June 2018, the initial payment of £10,000 in October 2016 was included in the company's submission to Disclosure UK for 2016, as a payment to a healthcare organisation; this was subsequently removed and the support disclosed on Sunovion's website as a patient organisation payment. Sunovion acknowledged and regretted these errors and to prevent future occurrences it would ensure that payment details, including dates were checked against the finance payment system rather than the agreement payment schedule.

In addition, the same employee arranged for Sunovion to financially support the patient organisation to produce an early intervention guide for patients with schizophrenia and their families. To this end, £600 was paid in October 2016 and the remaining £2,150 was paid in February 2017. Sunovion had not been able to locate an agreement covering the development of this guide, indicating that one was not in place. This support was disclosed on Sunovion's website from 15 March 2018 and updated on 27 March 2018 when the original figure disclosed ie £4,300 was found to be incorrect; the figure was amended to £2,150. This was due to an incorrect reading of data from the company's finance system. In future, all such figures would be double checked by a member of the finance team before public declarations were made. Again, Sunovion acknowledged and regretted this error.

In preparation for the PMCPA audit in Case AUTH/2935/2/17 in June 2018, Sunovion noted that it was asked to produce all papers in relation to disclosures of transfers of value on Disclosure UK (2016 data disclosed in 2017) for: a patient organisation, £103.98. Prior to the day of the audit following the PMCPA document request, Sunovion became aware that two copies of prescribing guidelines were provided to a patient organisation in March 2016. The total value of the books was £103.98. On discovering this, Sunovion engaged an independent expert to re-audit its records. Two further incidents were found:

- A meeting was organised by Sunovion in December 2015 involving four members of patient organisations. A grant of £187.10 was provided to support one patient organisation, and a grant of £192 was provided to another patient organisation to cover travel and accommodation. This support was covered by a certified agreement signed by the patient organisation and Sunovion Pharmaceuticals Europe in both cases.
- A further copy of prescribing guidelines was supplied to a patient organisation in 2016, with a value of £51.99.

Sunovion submitted that all were disclosed as transfers of value to a healthcare organisation or a health professional. The support for a patient organisation, was disclosed on Disclosure UK in 2016 as part of Sunovion's 2015 disclosures, and the support for another two patient organisations were disclosed in 2017 as part of Sunovion Pharmaceuticals Europe's 2016 disclosures. The support for one patient organisation was treated as a transfer of value to a health professional. The individual declined consent to disclose and this was disclosed in aggregate as part of Sunovion Pharmaceuticals Europe's 2015 disclosures in 2016. However, the individual was not a health professional. It was clear that these should all have been processed and disclosed as financial and indirect/non-financial support to a patient organisation under Clause 27.7. As the Authority would be aware, these irregularities were identified on the day of the PMCPA audit and Sunovion expressed its regret at this time.

Sunovion submitted that these payments were disclosed on its website on 9 July 2018, and the entries removed from Disclosure UK by 13 July 2018. Details of the statement on Sunovion's website of declaration of Sunovion's involvement with patient organisations were provided.

Sunovion submitted that to prevent this happening in the future a new policy had been written to encompass all interactions with patient organisations. Every member of Sunovion staff had received face-to-face training, as well as passed a validation on this policy. In addition, working with patient organisations had been incorporated into the Annual Monitoring Plan. The monitoring activities would include six monthly checks within the electronic approval system, checks within the financial systems as well as annual checks on Sunovion's transfer of value declaration prior to its submission to the Disclosure UK portal to ensure accurate disclosures.

Sunovion deeply regretted the events that had led to this case. As an organisation, Sunovion submitted that it was committed to developing a strong and robust compliance culture and that it was making considerable progress in this direction, whilst acknowledging that it still had some way to go.

In relation to the possibility of further sanctions, Sunovion submitted that the original issues did not reflect current company practice and indeed

the individual involved had left the organisation some time ago. The recent mistakes in disclosures, identified during responding to the PMCPA and the preparation for audit, had been acknowledged and the company proposed actions to prevent recurrence. Although at the time of the response in Case AUTH/3027/3/18 Sunovion had not yet received the PMCPA's report following the re-audit in June, Sunovion anticipated that this would demonstrate the progress made recently in establishing and embedding compliance systems and culture within its organisation. Sunovion accepted the jurisdiction of the Appeal Board and its authority to impose further sanctions but anticipated that these be considered in context, particularly the re-audit report.

At the consideration of this matter the Sunovion representatives presented an outline of the company's commitment to a compliant culture, a brief summary of Case AUTH/2935/2/17 and Case AUTH/3027/3/18 and noted key changes since the November 2017 audit. Sunovion's representatives also apologised unreservedly for its failings and stated that the company acknowledged and regretted these errors and to prevent future occurrences it would ensure that figures would be checked by the finance team before public declarations were made. A new policy and standard operating procedure would ensure that payments were disclosed correctly.

APPEAL BOARD CONSIDERATION

The Appeal Board noted the Panel's rulings of breaches of Clauses 2, 9.1 and 27.7 of the Code. The Appeal Board noted that the company had apologised and admitted that it had made errors.

The Appeal Board was concerned that due to poor judgement and/or absence of the necessary process the company had made a series of errors about its disclosure of payments in its responses to the PMCPA including during the re-audit required in Case AUTH/2935/2/17 in which it had already been criticised for not providing accurate information. Notwithstanding Sunovion's submission that it now had a process in place to ensure such errors did not recur, the Appeal Board noted that self regulation relied, *inter alia*, upon the provision of complete and accurate information from pharmaceutical companies.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Sunovion should be publicly reprimanded for providing inaccurate information to the PMCPA.

Following consideration of the re-audit report and Sunovion's comments on it and the Appeal

Board's decision to require a further re-audit in Case AUTH/2935/2/17, the Appeal Board decided that Case AUTH/3027/3/18 should be the subject of an audit which would take place April 2019 at the same time as the re-audit in Case AUTH/2935/2/17. On receipt of the report of the audit/re-audit the Appeal Board would consider whether further sanctions were necessary.

APPEAL BOARD FURTHER CONSIDERATION

Sunovion was audited in April 2019 and on receipt of the report of the audit in July 2019 the Appeal Board noted that Sunovion Pharmaceuticals Europe had continued to build on the improvements described in the report of the June 2018 re-audit in Case AUTH/2935/5/17. Staff had spoken positively about the steps taken by Sunovion Pharmaceuticals Europe to improve its compliance infrastructure. Compliance was now the top priority for the global Japanese parent, Sumitomo Dainippon. Sunovion Pharmaceuticals Inc in the US accepted that Sunovion Pharmaceuticals Europe was the subject matter expert on the Code. It was noted that the general manager continued to give strong and consistent messages about the importance of compliance and that compliance was now part of everybody's objectives.

The Appeal Board noted that the re-audit report still highlighted concerns including with regard to updating standard operating procedures and policies.

The Appeal Board noted that there had been significant progress at Sunovion since the re-audit in June 2018. The Appeal Board noted that Sunovion had a compliance action plan to address recommendations from the re-audit. The Appeal Board noted some actions were already completed and that others were due to be completed very shortly. On the basis that this work was completed, the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that no further action was required.

Voluntary admission received	16 March 2018
Undertaking received	26 June 2018
Appeal Board consideration	13 September 2018, 11 July 2019
Interim case report first published	30 November 2018
Case completed	11 July 2019