

Donald, Laura

From: LUDLAM, Christopher (NHS NATIONAL SERVICES SCOTLAND) <GRO-C@GRO-C>
Sent: 13 November 2019 14:21
To: Donald, Laura
Subject: IBI Fw: Batch Numbers questions - 9 digits
Importance: High

Dear Laura

You will recall the batch number record of 9 digits in Alice Mackie's statement and that SNBTS sent a document stating that they changed to 9 digit number around the end of 1983 beginning of 1984 ('implicated' batch transfused in March April 1984). I have now got further relevant information - the 'implicated' batch with 9 digits was the first 9 digit batch sent to RIE - that is why it was written out in full (previously 3 digits, subsequently 4 digits were used as these made each batch specific for our records). See emails below from SNBTS in response to my specific questions.

BW
Christopher

From: TURNBULL, Tracey (NHS NATIONAL SERVICES SCOTLAND)
Sent: 10 November 2019 18:15
To: LUDLAM, Christopher (NHS NATIONAL SERVICES SCOTLAND)
Cc: JARDINE, Louise (NHS NATIONAL SERVICES SCOTLAND); MCNICOLL, Kelsey (NHS NATIONAL SERVICES SCOTLAND); TURNBULL, Tracey (NHS NATIONAL SERVICES SCOTLAND)
Subject: Batch Numbers questions

Dear Christopher,

In relation to your request for information from the SNBTS as to batch numbering, please see their undernoted response.

Kind regards,

GRO-C

Tracey Turnbull

Senior Solicitor
Litigation Team B

Central Legal Office | Anderson House | Breadalbane Street | Edinburgh | EH6 5JR

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www.clo.scot.nhs.uk

From: MURRAY, Susan (NHS NATIONAL SERVICES SCOTLAND) <GRO-C>
Sent: 31 October 2019 14:30
To: TURNBULL, Tracey (NHS NATIONAL SERVICES SCOTLAND) <GRO-C>
Cc: CLO-IBI <nss.CLO-IBI@nhs.net>

Subject: Batch Numbers questions

Importance: High

Dear Tracey,

Here are the answers from SNBTS to Professor Ludlam's further questions regarding batch numbers. As you will see, Prof Ludlam's originating questions are in the email chain for ease of reference. We hope that these answers are of assistance to him.

Kind regards

Susan

Susan A. Murray

Senior Solicitor - Litigation Team B
Accredited Specialist in Medical Negligence

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Question 1

Is this the first batch numbered using the 9 digits?

- It was not the first batch numbered in this way. Batch 023100010 was the first batch prepared in Dec 1983

Question 2

Was this one of the first batches to go the RIE?

- Yes 023110090 was the first batch to go to EDI. Previous batches went to GLA, ABD and Belfast

From: LUDLAM, Christopher (NHS NATIONAL SERVICES SCOTLAND) <

GRO-C

Sent: 03 October 2019 17:28

To: TURNBULL, Tracey (NHS NATIONAL SERVICES SCOTLAND) <

GRO-C

Cc: GRO-C

Subject: Re: UK IBI Alice Mackie - Batch Numbers

Dear Tracey

Again thank you for the document from SNBTS about batch numbers which is exceedingly useful. It is especially interesting that the 'example' batch number in the document is i think the 'implicated' batch. Please could you inquire of SNBTS whether batch 023110090 was in fact the first batch to be labelled in this way? Was it the first, or one of the first, '9 numbered' batches to be sent to the RIE? My recollection is that part of this batch was sent to Aberdeen.

My interpretation of the batch number is that the batch was manufactured in November 1983 (3 and 11 in the code) which fits well with is being given to patients in the Spring of 1984.

With many thanks
Christopher

From: TURNBULL, Tracey (NHS NATIONAL SERVICES SCOTLAND)
Sent: 03 October 2019 12:08
To: LUDLAM, Christopher (NHS NATIONAL SERVICES SCOTLAND)
Cc: MCNICOLL, Kelsey (NHS NATIONAL SERVICES SCOTLAND); JARDINE, Louise (NHS NATIONAL SERVICES SCOTLAND)
Subject: UK IBI Alice Mackie - Batch Numbers

Dear Christopher,

Kelsey has been doing some research. Please see attached Alice Mackie's transcript. She makes reference to the batch numbers at the end of page 16, it is discussed through pages 17-20, then mentioned again on pages 25 and 26.

Alice Mackie states in the transcript that the batch number was written out in full in March and April 1984. The document regarding batch numbering states *"Where a 9 digit number is quoted, this will be the full batch number assigned by SNBTS post- July 1983"*

This may be of assistance to you when addressing the criticism made.

Kind regards,

GRO-C

Tracey Turnbull

Senior Solicitor
Litigation Team B

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3 Digit numbers

Initially, all FVIII batches were numbered consecutively using a 3 digit number. This system was in use from the first batch of product, up to batch number 807, when a new system was employed, from 15 July 1983.

These 3 digits were used both in house and on the label.

9 Digit batch Numbers (1983- 1985)

From 13 July 1983, a 9 digit number was used for the label. This system was composed of the following elements:

Batch Number 023110090

Product code	2 digits (eg 02 for unheated FVIII, NY)
Year of manufacture	1 digit (eg 3 for 1983)
Month of manufacture	2 digits (eg 11 for November)
Batch code	3 digits (eg 009)
Code for rework or split	1 digit (eg 0 for normal batch not reworked or 1 for a reworked batch or for a batch split into sub-batches)

Thus batch 023110090 was unheated FVIII made in November 1983. It was batch 009 in this system and was neither a reworked nor a split batch.

For in house purposes, this number was considered a bit unwieldy and was often condensed into the year and the sequential (unique) portion of the batch number, ie 023110090 became NY 3-009 for in house purposes, but the full batch number was printed on the label and the outer packaging.

9 Digit batch Numbers (1985 onwards)

From 16 January 1985, the system was modified to provide increased clarity and to be relevant to all products prepared by the PFC, as follows:

Batch Number 3405-50260

Product code	2 digits (eg 34 for heated FVIII, NY 68 °C/24 hours)
Month of manufacture	2 digits (eg 05 for May)
Year of manufacture	1 digit (eg 5 for 1985)
Batch code	3 digits (eg 026)
Code for rework or split	1 digit (eg 0 for normal batch not reworked or split into sub-batches)

Thus batch 026 of the FVIII product, heated at 68°C and prepared in May 1985, would have been given the code 3405-50260. This made it clearer how it cross-related to the in house code, which would have been NY 5-026.

Batch numbers quoted by external parties

Where a 3 digit number is quoted, this will be the full batch number assigned by SNBTS pre- July 1983.

Where a 9 digit number is quoted, this will be the full batch number assigned by SNBTS post- July 1983.

Where a 4 digit number is quoted, there is room for error of interpretation, since the clinical personnel have clearly recorded only part of the number from the label.