Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00740**

10 August 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 9 July 2026. You wrote:

> *'Information request for Public assessment reports, non-clinical/clinical expert reports and/or lists of references for the following three well established products - MAH = Alturix*
> *Phosphate Sandoz (PL 44490/0002)*
> *Sando-K (PL44490/003)*
> *Slow Sodium (PL 44490/004)*
> *If you are not able to provide assessment reports or expert reports themselves then just pivotal literature references which formed the well established use basis on which these three products were granted registration. Thank you very much'*

MHRA Response

Following a search of our paper and electronic records, we have established that the information you requested is not held by this Agency. No public assessment reports, non-clinical/clinical expert reports or list of references are held for the requested products Phosphate Sandoz (PL 44490/0002), Sando-K (PL 44490/0003), or Slow Sodium (PL 44490/0004).

To be as helpful as possible, we have tracked the licence history as far as possible within the scope of this FoI request and provide it below to help refine your request.

Phosphate Sandoz (PL 44490/0002)

We have noted that Phosphate Sandoz (PL 44490/0002), previously known as PL 00101/5038R, is the subject of your 3 following FoIs:

- FOI2026/00679, received 24 June 2026; response sent on 16 July 2026
- FOI2026/00740, received 9 July 2026; this current request
- FOI2026/00782, received 18 July; pending response.

In the response to the first request, FOI2026/00679, we provided the licence history to help refine the request.

We have provided the MHRA response again below for completeness:

'A marketing authorisation for Phosphate Sandoz Effervescent Tablets (PL 44490/0002) was granted to Alturix Limited following a Change of Authorisation holder (CoA) on 18 August 2020. The original marketing authorisation for this was a Product Licence of Right, which was granted to Novartis Pharmaceuticals UK Limited (PLR 00101/5038). This means that the product licence was approved at the inception of the Agency on the basis that the medicine is already in use on the UK market. This was then converted into a subsequent reviewed product licence wherein suitable data were submitted by the marketing authorisation holder and assessed by the agency, with the reviewed licence granted on 18 September 1990 (PL 00101/5038R). As the original grant of this marketing authorisation predates when MHRA would have been required to publish Public Assessment Reports (PARs), no PAR has been published and we hold no PAR for this product.'

The refined request was provided in the latest FoI, FOI2026/00782. As such, the request for information for Phosphate Sandoz will be addressed under FOI2026/00782.

Please note for the future that when requestors submit multiple FoIs in a short time period, these may be considered vexatious due to the burden they place on the Agency. We request that a single FoI is submitted at one time.

Sando-K (PL44490/003)
A marketing authorisation for Sando-K (PL 44490/0002) was granted to Alturix Limited following a Change of Authorisation holder (CoA) application in August 2020. No public assessment report, non-clinical/clinical expert report or list of references is held for PL 44490/0002.

The first electronic record we have for this product is as Sando-K Effervescent Tablets (PL 00101/5044R), a reviewed licence owned by Novartis Pharmaceuticals UK Limited. We have located records that the product licence was renewed in 1990 and 1996.

The Marketing Authorisation was then transferred through a CoA to HK PHARMA LIMITED as PL 16784/0001 in 1998. A final CoA occurred in August 2020 to the current holder, Altrurix Limited.

Slow Sodium (PL 44490/004)
A marketing authorisation for Slow Sodium (PL 44490/0004) was granted to Alturix Limited following a Change of Authorisation holder (CoA) application in August 2020. No public assessment report, non-clinical/clinical expert report or list of references is held for PL 44490/0004.

The first electronic record we have for this product is as Slow Sodium Tablets 600 mg (PL 00008/0101R), a reviewed licence owned by CIBA-GEIGY PLC. PL 00008/0101R was transferred through a CoA to Novartis Pharmaceuticals UK Limited in 1997 as Slow Sodium Tablets 600 mg (PL 00101/0451). This was followed by a transfer to HK PHARMA LIMITED in 1998 as Slow Sodium (PL 16784/0003). The final CoA transferred the product to Alturix Limited as Slow Sodium (PL 44490/0004).

Advice and assistance

For the outstanding request FOI2026/00782 regarding Phosphate Sandoz (PL 00101/5038R), the MHRA will search paper documentation from the archives to ascertain if any data is held regarding any clinical or non-clinical overviews, clinical study reports or clinical data, literature references or MHRA assessment of data.

For Sando-K (PL 00101/5044R) and Slow Sodium (PL 00008/0101R), to attempt to trace the licences back further would require searches for any pre-1990s paper documentation from storage archives. As these licences were not the subject of this FoI request, this was out of scope. If you wish to submit a new request, this could focus on the original licences for Sando-K or Slow Sodium.

However, the MHRA requests that only a single FoI request is submitted to the MHRA at one time, that previous requests are answered before any new requests are submitted and that FoI requests focus on a single product at a time.

Furthermore, due to the age of the licences, it is unlikely that the MHRA holds any Public Assessment Reports or overviews for these licences, as the licences original approval pre-dates when these would have been required.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU
Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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