FOI 23/683

Dear

Thank you for your request of 18 September 2023, under the Freedom of Information Act. You requested:

> *"How many Parallel Import licence applications were not approved/were awaiting approval (e.g. Pending) ?*
>
> - *Furthermore, of these "pending" applications for August 2023, please can the MHRA confirm the number of Parallel Import licence applications that were awaiting the commencement of assessments?"*

From a data snapshot taken at end of August 2023:

255 - initial parallel import applications are ready and awaiting assessment.
54 - initial applications are with MHRA but undergoing data validation, not with parallel import team yet.
129 - initial applications are awaiting verification of the imported product prior to start assessment.

Further information on the application process is available here:
https://www.gov.uk/guidance/medicines-apply-for-a-parallel-import-licence
If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk
Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

FURTHER RESPONSE: INTERNAL REVIEW OF FOI 23/683:

We have reviewed the correspondence related to 23/683,

On 18 September 2023, your request asked:

> *"[…]Therefore, for August 2023, please can the MHRA confirm:*
>
> - *How many Parallel Import licence applications were not approved/were awaiting approval (e.g. Pending) ?*
>
> - *Furthermore, of these "pending" applications for August 2023, please can the MHRA confirm the number of Parallel Import licence applications that were awaiting the commencement of assessments?"*

On [CEC to provide date], we replied:

> *"[…] 255 - initial parallel import applications are ready and awaiting assessment.*
> *54 - initial applications are with MHRA but undergoing data validation, not with parallel import team yet.*
> *129 - initial applications are awaiting verification of the imported product prior to start assessment.[…]"*

We noted your follow-up and as per FOI procedure logged this as an internal review.

We concluded that your follow-up was accurate and our original response had unintentionally omitted a subsection of results, those for which review/assessment had commenced but which were not yet approved for whatever reason at the end of August 2023.

To redress this omission, the figure is as follows:

Pending applications assessment step before 31 Aug 2023 = **129**

We are also providing, *PLPIs granted since 31 Aug 2023*, the total for this parameter is **51** applications, this figure is provided for context because many of the applications pending at the assessment step before Aug 2023, will have since have been granted.

Please remember to quote the reference number above in any future communications.

If you are not satisfied with the outcome of the above internal review, you have the right to apply directly to the Information Commissioner for a decision.
The Information Commissioner can be contacted online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/
Or

by writing to:
Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Yours sincerely
MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU