FOI 23/656

Dear

Thank you for your request of 05 September 2023, under the Freedom of Information Act. You requested:

> **"My question is:** for 2022-2023, and moving forward, what is the target the MHRA hopes to achieve with regards to assessing marketing applications (NAS)? At what rate, on average, did the MHRA assess new marketing applications (NAS) over the past year?
>
> Lastly, from the 2021-2022 report, when it says that's 92% of marketing applications (NAS) were assessed within 80 days, what EXACTLY does "assessed" mean? Does that mean a decision has been made on the approval or rejection of the application? Or does that only refer to Phase 1 of the assessment pathway?"

We confirm that we hold the information you have requested.

For your first question, the performance metrics for applications assessed up to December 2022 are available on the MHRA website, via the link below:

https://www.gov.uk/government/statistics/medicines-licensing-time-based-performance-measures

On page 33 of our Annual Report and Accounts, PM2a provides a target for new active substances (NAS) assessed via the national route of 97% within 210 days (excluding time waiting for applicant responses).

[see table below]

PM2 – Licensing of medicinal products

	Measure	Target	Total 2022/23	Total 2021/22	Met / Not Met 2022/23
PM2a	Percentage of medicines assessed via national route which contain a new active substance within 210-days (excluding time awaiting applicant responses)	97%	88%	New metric	Not met
PM2b	Percentage of medicines assessed via recognition within published recognition pathway timeline (excluding time awaiting applicant responses)	80%	29%	New metric	Not met
PM2c	Percentage of established products assessed via national route within 210-days (excluding time awaiting applicant responses)	50% (Target increasing for 2023/24)	13%	New metric	Not met
PM2d	Percentage of products approved via recognition of another regulator's decision:				
	New Active Substance (NAS) Reliance	Establishing baseline	70%	New metric	N/A
	Established products Reliance	Establishing baseline	19%	New Metric	N/A
PM2e	Percentage of Type 1B and Type II variations assessed within the following timelines (excluding time awaiting applicant responses):	Variations assessments – Type IB changes include simple 'tell and do' changes such as changing location of manufacture, with Type 2 changes being complex changes with changes of formulation such as new or replacement excipients			
	I. 30 days (Type 1B)	50% (Target increasing for 2023/24)	60%	New metric	Met
	II. 30 days (Type II expedited timetable)	50% (Target increasing for 2023/24)	97.5%	New metric	Met
	III. 90 days (standard or complex Type II timetable)	50% (Target increasing for 2023/24)	82.4%	New metric	Met
	I. 120 days (extended complex Type II timetable)	50% (Target increasing for 2023/24)	77.8%	New metric	Met
PM2f	Number of Parallel Imports determined:	Parallel Imports – Where there is a product available in an EEA country which is needed in the UK, provided the product has no therapeutic difference from a licensed product in the UK, subject to certain other conditions we can allow it to be imported			
	I. Parallel Imports – Number of initial applications determined	Establishing baseline	375	New Metric	N/A
	II. Parallel Imports – Number of variation applications determined	Establishing baseline	7573	New Metric	N/A
PM2g	Unlicensed Medicines	We review and verify medical items imported for supply to patients under prescriber oversight, where no UK licence exists. MHRA role is to determine if there are any issues where we would object to importation, e.g., issues with controls in place for distribution to a patient or concerns about adequate controls in the supply chain			
	Unlicensed Medicines – Total number of notifications determined	Establishing baseline	109068	New metric	N/A

On your second question, it means Phase 1 of the assessment.
We hope you find this information helpful.

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
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