



Medicines & Healthcare products  
Regulatory Agency

# MHRA performance

Assessment of New Marketing  
Authorisation Applications  
and Variations

December 2024



# December summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	7	56	98
Validation for variations – all submission routes	6	839	99
Work type	Average time to determination in days*	Numbers granted	% granted within statutory time
Type IA variations – national	18	431	99
Type IB variations – all submission routes	14	656	96
Type IB IRP variations	5	190	97
Type II variations – all submission routes**	73	256	76
Type II IRP variations	21	75	95
Initials – NAS MAA national	252	2	0
Initials – established medicines MAA***	558	57	9
Initials – established meds IRP route A	55	22	100
Initials – established meds IRP route A extended	75	8	100
Initials – established meds IRP route B	90	6	100
Initials – established meds IRP route B extended	110	3	100
Initials – NAS IRP route A	-	-	-
Initials – NAS IRP route A extended	-	-	-
Initials – NAS IRP route B	98	5	100
Work type	Average assessment time in days	Numbers assessed	% assessed within statutory time
PIQU	36	99	100
Compliance – national MAAs only	30	42	62
Work on hand as of 3 January 2025 ****			
Total overdue individual Product Licences			261

- \* Regulatory clock on days from validation to determination
- \*\* Type II variations – This is a crude estimation of 90 days as there are different work types and different procedure types grouped together

- \*\*\* Includes national and reliance route conversions
- \*\*\*\* Overdue individual Product licences (past the 210) days shows all pending abridged (biologicals removed) national licences (with current clock on or off) with regulatory clock on days over 210

# Copyright information

© Crown copyright 2025

Open Government Licence



Produced by the Medicines and Healthcare products Regulatory Agency.

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit <http://www.nationalarchives.gov.uk/doc/open-government-licence> or email: [psi@nationalarchives.gsi.gov.uk](mailto:psi@nationalarchives.gsi.gov.uk).

Where we have identified any third-party copyright material you will need to obtain permission from the copyright holders concerned.

The names, images and logos identifying the Medicines and Healthcare products Regulatory Agency are proprietary marks. All the Agency's logos are registered trademarks and cannot be used without the Agency's explicit permission.