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

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