Medicines & Healthcare products Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

September 2024

August summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	6	51	96
Validation for variations – all submission routes	4	800	98
Work type	**Average time to determination in days***	**Numbers granted**	**% granted within statutory time**
Type IA variations – national	13	607	100
Type IB variations – all submission routes	16	679	89
Type IB IRP variations	1	156	99
Type II variations – all submission routes**	115	184	66
Type II IRP variations	18	55	98
Initials – NAS MAA national	237	2	50
Initials – established medicines MAA***	504	72	13
Initials – established meds IRP route A	54	24	100
Initials – established meds IRP route B	104	2	100
Initials – NAS IRP route A	15	5	100
Initials – NAS IRP route B	74	3	100
Work type	**Average assessment time in days**	**Numbers assessed**	**% assessed within statutory time**
PIQU	46	70	99
Compliance – national MAAs only	47	47	64

Work on hand as of 2 September 2024 ****	
Overdue ‘ringfenced’ individual Product Licences (n=1167) over 210 days on 9 January 2024	201
Total overdue individual Product Licenses (inclusive of ‘ringfenced’ Product Licences, above)	490

- * 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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