Medicines & Healthcare products Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

July 2024

July summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	4	62	98
Validation for variations – all submission routes	6	780	99
Work type	**Average time to determination in days***	**Numbers granted**	**% granted within statutory time**
Type IA variations – national	13	724	100
Type IB variations – all submission routes	19	757	85
Type IB IRP variations	1	241	100
Type II variations – all submission routes**	66	187	76
Type II IRP variations	14	88	100
Initials – NAS MAA national	320	2	0
Initials – established medicines MAA***	455	72	15
Initials – established meds IRP route A	45	12	100
Initials – established meds IRP route B	66	4	100
Initials – NAS IRP route A	40	5	100
Initials – NAS IRP route B	-	-	-
Work type	**Average assessment time in days**	**Numbers assessed**	**% assessed within statutory time**
PIQU	42	96	100
Compliance – national MAAs only	30	67	69

Work on hand as of 5 August 2024 ****	
Overdue ‘ringfenced’ individual Product Licences (n=1167) over 210 days on 9 January 2024	366
Total overdue individual Product Licenses (inclusive of ‘ringfenced’ Product Licences, above)	580

- * 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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