Medicines & Healthcare products Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

April 2024

April summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	7	72	92
Validation for variations – all submission routes	5	884	97
Work type	**Average time to determination days***	**Numbers granted**	**% granted within statutory time**
Type IA variations – national	10	232	99
Type IB variations – all submission routes	35	659	71
Type IB IRP variations	7	130	100
Type II variations – all submission routes**	69	178	76
Type II IRP variations	9	51	100
Initials – established medicines MAA***	430	82	5
Initials – established meds IRP route A	56	11	100
Initials – NAS IRP route A	55	1	100
Work type	**Average assessment time in days**	**Numbers assessed**	**% assessed within statutory time**
PIQU	52	73	100
Compliance – national MAAs only	30	61	92

Work on hand	
Overdue individual Product Licences from backlog of 1167 at 9 Jan 2024 (past the 210 days) as at 30 April 2024****	805

- * 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