



Medicines & Healthcare products
Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

January 2023 – February 2024



February summary

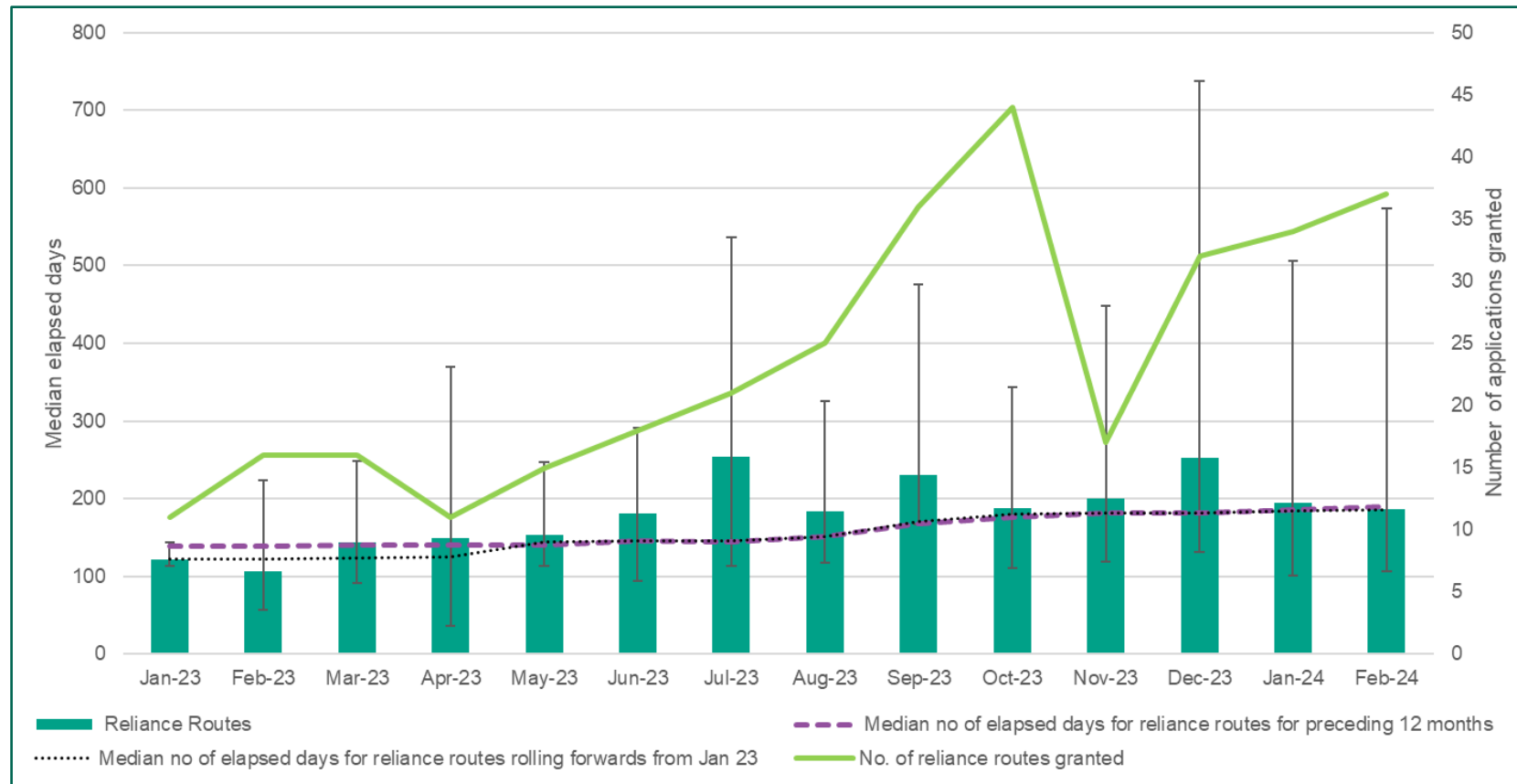
Work type	Median time in days*	Numbers granted	% within target time
Type IA variations – national	2	540	100%
Type IB variations – all submission routes**	18	983	70%
Type IB IRP variations	0	179	96%
Type II variations – all submission routes***	82	337	71%
Type II IRP variations	26	40	100%
Initials – established medicines national MAA	660	86	12%
Initials – established medicines MRDCRP/ ECDRP reliance MAA	187	36	14%
Initials – established meds IRP route A	30	1	100%
Initials – established meds IRP route B	0	0	-

Work on hand

Overdue individual Product Licences from backlog of 1167 at 9 Jan 2024 (past the 210 days) as at 29 Feb 2024****	933
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- *Median elapsed days from validation to determination.
- **Type IB variations – 690 of 981 granted in time 70%
- ***Type II variations – 240 of 337 granted in time 71%. This is a crude estimation of 90 days as there are different work types and different procedure types lumped together
- ****Overdue individual Product licences (past the 210) days shows all pending abridged (biologicals removed) national licences (which current clock on or off) over regulatory clock on days over 210

Figure 1. Established medicines reliance initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan 2023 – Feb 2024, median elapsed days for preceding 12 months, and median elapsed days rolling forwards from Jan 23



Key features

- Reliance routes include ECDRP and MRDC reliance
- This graph shows lines for the median elapsed days for reliance route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This includes applications which are being worked through from the queue, which is not truly able to be trended and median times are showing an extension.

Figure 2. Initial national established licences - median time to first RFI (total elapsed days from received) & number of applications with first RFI for Jan 2023 – Feb 2024



Key features

- This graph shows the median number of elapsed days from application received to first RFI.
- This includes applications which are being worked through from the queue, which is not truly able to be trended.

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