HPR205

An International Mapping Review of Medicines Approvals and Access to Innovative Technologies for the United Kingdom (UK)- A Retrospective Analysis.

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BACKGROUND

On the 1st of January 2024, the MHRA implemented the International Recognition Procedure (IRP) by collaborating with global regulators to expedite the licensing of innovative medicines already licensed by the recognised regulators.[1]

This paper explores the regulation of innovative medicines in the UK and internationally, focusing on 5 of the IRP's Reference Regulators (RR).

The IRP can potentially disrupt the standard working practices of the health systems in the UK, as such, it is essential to understand the current landscape of UK medicines and patient access alongside the international landscape of regulation for medications .

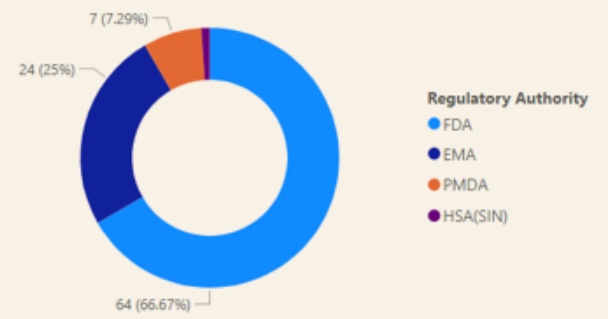
METHODS

A retrospective analysis of 154 technologies (medicine(s) + studied indication(s)) was conducted based on the National Institute for Health and Care Research (NIHR) Innovation Observatory (IO) technology briefings submitted to the National Institute for Health and Care Excellence (NICE) in 2020.

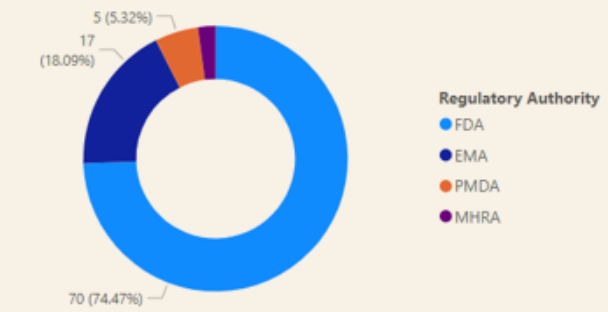
Data on technologies' submission and approval dates available as at 31st July 2023 were extracted across 5 IRP RRs, which are the regulators from the United States (FDA), European Union (EMA), Japan (PMDA), Australia (TGA), and Singapore (HSA). The dates were compared with data from the UK.

RESULTS

First submission to a Regulatory Authority

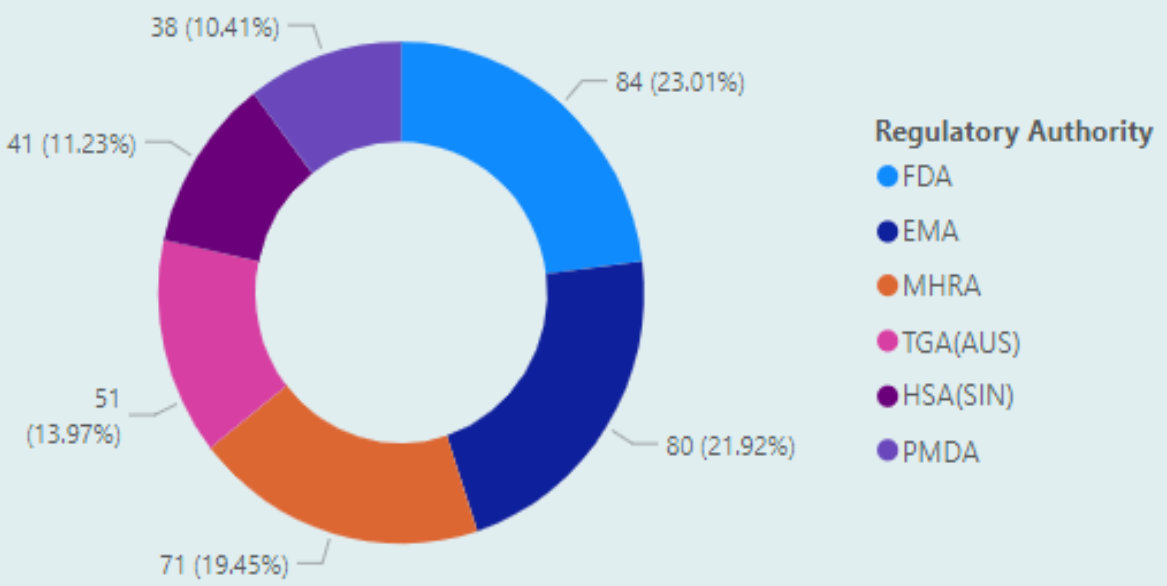


First approval by a Regulatory Authority



RESULTS

Approved technologies by Regulatory Authority



CONCLUSION

There were significant differences in market access timelines using approval dates across the 5 RRs, with the FDA and EMA taking the lead, with the highest number of approved technologies and first approvals compared to other RRs IRP applications with the FDA or EMA as RR may expedite access to innovative technologies in the UK by reducing the submission gap between the FDA/EMA and the MHRA. This understanding of the regulatory landscape would help inform future planning to accommodate the disruption that the IRP may cause

References

1. GOV.UK. MHRA's new International Recognition Procedure (IRP) goes live from 1 January 2024. 2024.

The average time difference between FDA and MHRA approvals was 360 days, and 86 days between EMA and MHRA, in favour of the FDA and EMA.

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