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# UK MHRA's International Recognition Procedure Does Not Guarantee OTC Status

by David Ridley

Under its new International Recognition Procedure, approval by one of the MHRA's seven "reference regulators" – including the US FDA – as an OTC medicine does not necessarily mean the same status will be granted in post-Brexit UK, warns regulatory consultancy JensonR+.

As of 1 January 2024, manufacturers of OTC medicines approved by regulators in seven countries will be able to access a quicker approval process for these products in the UK.

However, OTC status granted by one of these "reference regulators" – Australia (TGA), Canada (Health Canada), Switzerland (SwissMedic), Singapore (HAS), Japan (PMDA), US (FDA), and EU (EMA and individual member states competent authorities) – does not guarantee OTC status in the UK, warns regulatory consultancy firm JensonR+.

"We anticipate that the legal status of the medicine in the UK (Rx or OTC) will be a national decision by the UK Medicines and Healthcare products Regulatory Agency based on current market and treatment pathways and will not be influenced significantly by the RR's opinion," Jenson R+ regulatory manager Ben Smith told HBW Insight.

"The MHRA did not provide a clear position on this," Smith added. "It would be recommended to seek advice on possible legal status prior to applying if OTC status is key to your commercial success."

## Streamlined

The MHRA's new International Recognition Procedure (IRP) will permit a quicker, streamlined review process for medicines approved by these regulators, Smith explained.

"The IRP is intended to increase speed to market for products and enhance the desirability of the UK market, whilst meanwhile providing predictability and reliability to IRP eligible marketing

applications," he commented.

Building on the European Commission Decision Reliance Procedure (ECDRP) – a temporary post-Brexit measure introduced by the MHRA to speed up UK access to new medicines recommended for EU-wide approval by the EMA – the IRP has two routes depending on how much assessment is required.

OTC products must be assessed via recognition route B, which has a 110-day timetable with one clock stop at day 70, allowing the applicant up to 60 days to respond to any issues identified.

The agency noted in its *recently published guidance* that if there are any outstanding major objections at Day 110, formal advice on approvability will be sought from the Commission on Human Medicines, and the timetable will revert to the national 210-day timetable.

## Good Advice

Smith welcomed the new guidance, particularly the information provided around eligibility criteria, which he said is "critical for strategic planning." However, "there is clearly more information that needs to be published."

"When considering utilizing the IRP, the applicant should ensure that they have factored in the UK specific requirements we have detailed above," Smith advised. "The application will need to be prepared by a team that is familiar with the UK medicines market and the documentation requirements needed for national applications."