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Brexit Could Open Up Rx-To-OTC Switch Opportunities In UK, Says MHRA

by Tom Gallen

The MHRA has told HBW Insight it is exploring how the UK's exit from the EU could create new opportunities to switch more medicines from prescription to OTC status. Separately, the UK government is reviewing how plans to require all opioids to carry on-pack addiction warnings will impact OTC medicines.

Brexit may spark a new wave of prescription-to-OTC switches in the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) has suggested.

In its "Business Plan" for the 2019-2020 period, the MHRA says it intends this year to evaluate the opportunities for "innovative reclassifications of medicines in the context of the UK's new relationship with the EU" following the country's expected withdrawal from the union. The agency will review its existing guidance to "streamline" the reclassification of medicines in the UK where they may safely be supplied without prescription, with the goal of increasing the range of medicines available for OTC sale.

Asked about the thinking behind these plans, a spokesperson for the MHRA said the agency wanted to explore whether Brexit would positively impact switching.

"Although the classification of a medicinal product is a national competence, working within the European legislative framework places some restrictions on a member state's national ability to reclassify medicines," the spokesperson pointed out. "If these restrictions no longer apply post Brexit, the MHRA may have more flexibility in its ability to widen access to medicines when it is safe to do so."

As an EU member state the UK is currently bound by Article 71 of Directive 2001/83/EC, which specifies the criteria by which member states should classify medicines into those subject to medical prescription and those not subject to prescription control. Furthermore, when applying

to switch a medicine in the UK, manufacturers must follow the EU Risk Management Plan (RMP) template, as well as ensure all labelling and patient information leaflets are compliant with the Directive.

Article 74a of the Directive also allows for one year's data protection for a manufacturer following the change of classification of a medicinal product. Post-Brexit, MHRA could in theory extend, or even shorten, this period.

UK Plans Opioid Warnings

Meanwhile, the UK government is reviewing how plans to require all opioid-containing medicines sold in the country to carry on-pack addiction warnings will impact OTC products.

Currently, OTC medicines containing the opioids codeine and dihydrocodeine already have the warning "can cause addition" on their packs. All prescription medicines will going forward also be required to carry this warning, plus "contains opioid."

Asked whether OTC products would also be required to display this additional message, the Department for Health and Social Care told *HBW Insight* that it was "considering what changes need to be made to individual packs."

The Department said it anticipated that packs including the warnings on product labelling would begin to be rolled out by the end of the year, adding that it would be seeking voluntary compliance from industry, and if necessary, the changes would be mandated.