

## UNITED KINGDOM

### Recent and planned developments in pharmaceutical policies 2018

#### Special topic: national incentives and derogatory procedures for orphan medicines

##### CHANGES IN PRICING

The Statutory Pharmaceutical Price Scheme, which controls the cost of branded medicines where companies making sales are not part of the voluntary Pharmaceutical Price Regulation Scheme (PPRS), was amended in April 2018. The principal changes were:

- To reverse out the 15% price cut on the list price at which products were on sale as at 1 Dec 2013; and
- Replace the price cuts with a payment system, currently set at 7.8% of relevant sales income, aligning the scheme more closely to the PPRS.

Negotiations are underway with industry on a potential successor to the current, 2014 PPRS agreement. The 2014 scheme terminates on 31 Dec 2018.

Further changes to the statutory scheme have also been consulted on this year, principally to increase the levels of the required payment. New regulations are expected to come into force on 1 Jan 2019.

##### CHANGES IN REIMBURSEMENT

The NHS prescription charge in England increased from £8.60 to £8.80 on 1 April 2018.

##### OTHERS CHANGES

No new significant changes currently in train.

##### SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

The Medicines and Healthcare Products Regulatory Agency (MHRA) has made available an Early Access to Medicines Scheme (EAMS), which aims to give patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is clear unmet need. Under the scheme, the MHRA will give a scientific opinion on the benefit/risk balance of the medicine, based on the data available when the EAMS submission was made.

