
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the whole of the United Kingdom, amend the Branded Health Service Medicines (Costs) Regulations 2018 (the “Statutory Scheme Regulations”). The Statutory Scheme Regulations, amongst other matters, make a scheme for the purposes of requiring specific manufacturers and suppliers of medicines for NHS use to pay amounts to the Secretary of State. These amounts are calculated by reference to their net sales income or estimated net sales income from supplies of such medicines.

Regulation 3(1) of the Statutory Scheme Regulations specifies the percentages of net sales income by which these payable amounts are to be calculated, and the periods in relation to which those percentages are to be applied. The new arrangements in place from 1st July 2022 increase these percentages: firstly, from 10.9% to 14.3% in the case of the percentage to be applied for the rest of 2022, in effect just to net sales income of new presentations of medicines; and secondly, to 24.4% in the case of the percentage to be applied to net sales income of all presentation from the start of 2023 (regulation 2(2)(a)).

Regulation 2(2)(b) and (c) make transitory provisions for manufacturers or suppliers who were required to make a payment in relation to a supply of a presentation of a medicine under regulation 3(1) of the Statutory Scheme Regulations at the former rate, 10.9%, during the period beginning with 1st January 2022 and ending at the end of 30th June 2022- in effect because the presentation was on the market at that time. The effect of these amendments is that manufacturers and suppliers who made payments under the Statutory Scheme Regulations in relation to such presentations will be subject to a higher payment percentage of 17.7% on their supplies of those presentations for the period beginning 1st July 2022 to the end of 2022, compared to the 14.3% payment percentage applied to presentations that are newly on the market on or after 1st July 2022. However, the net effect of both the higher percentage payment applied in respect of such supplies on and after 1st July 2022 and the lower payment percentage applied before that date is that, in a case where a presentation is available throughout the whole of 2022 and sales are constant, a payment percentage of 14.3% would apply in respect of the annual net sales income (or estimated net sales income) of that presentation in 2022.

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU and is available on the www.legislation.gov.uk website.