STATUTORY INSTRUMENTS

### 2023 No. 239

# NATIONAL HEALTH SERVICE, ENGLAND AND WALES NATIONAL HEALTH SERVICE, SCOTLAND HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Branded Health Service Medicines (Costs) (Amendment) Regulations 2023

Made	28th February 2023
Laid before Parliament	2nd March 2023
Coming into force	1st April 2023

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 263(1), 264(3), 266(1) and (4A) and 272(7) and (8) of the National Health Service Act 2006(1).

The Secretary of State has consulted in accordance with section 263(1) and (1A) of that Act.

#### Citation, commencement and extent

**1.**—(1) These Regulations may be cited as the Branded Health Service Medicines (Costs) (Amendment) Regulations 2023 and come into force on 1st April 2023.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

# Amendment of regulation 3 of the Branded Health Service Medicines (Costs) Regulations 2018

**2.**—(1) Regulation 3 (Payment scheme) of The Branded Health Service Medicines (Costs) Regulations 2018(**2**) is amended as follows.

<sup>(1) 2006</sup> c. 41; section 263 was amended by the Health Service Medical Supplies (Costs) Act (c. 23) ("the 2017 Act"), section 5 and 10(5). Section 266 was amended by the 2017 Act, section 6(5) to (9) and 7(6). See section 275(1) of the National Health Service Act 2006 for definition of "regulations" that are relevant to the powers being exercised.

<sup>(2)</sup> S.I 2018/345; relevant amending instruments are S.I. 2018/1255, S.I. 2020/258 and S.I. 2022/593.

(2) In paragraph (1), for the table substitute—

"Table

Applicable Period	Payment Percentage
1st April 2023 to the end of 2023	27.5%
2024 and any subsequent calendar year	27.5%".

- (3) In paragraph (1B)—
  - (a) for "1st July 2022 to the end of 2022" substitute "1st April 2023 to the end of 2023",
  - (b) for "17.7%" substitute "28.6%", and
  - (c) for "14.3%" substitute "27.5%".
- (4) In paragraph (1C)—
  - (a) for "1st July 2022 to the end of 2022" substitute "1st April 2023 to the end of 2023",
  - (b) in sub-paragraph (a)—
    - (i) for "1st January 2022" substitute "1st January 2023", and
    - (ii) for "30th June 2022" substitute "31st March 2023", and
  - (c) in sub-paragraph (b), for "10.9%" substitute "24.4%".

Signed by the authority of the Secretary of State for Health and Social Care

28th February 2023

*Will Quince* Minister of State, Department of Health and Social Care

### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations, which apply to the whole of the United Kingdom, amend regulation 3 of the Branded Health Service Medicines (Costs) Regulations 2018 (S.I. 2018/345) (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 the net sales income or estimated net sales income from supplies of such medicines.

Regulation 3(1) and (1B) of the Statutory Scheme Regulations specify the percentages of net sales income by which the 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 April 2023 increase these percentages: firstly, from 24.4% to 27.5% in the case of the percentage to be applied for the rest of 2023, in effect just to net sales income of new presentations of medicines (regulation 2(2)); and secondly, to 28.6% in the case of the percentage to be applied to net sales income of all presentations from the start of 2023 (regulations 2(3) and (4)).

Regulations 2(3) and (4) amend regulation 3(1B) and (1C) of the Statutory Scheme Regulations to make transitory provisions for manufacturers or suppliers who were required to make payments in relation to a supply of a presentation of a medicine under regulation 3(1) of the Statutory Scheme Regulations at the former rate, 24.4%, during the period beginning with 1st January 2023 and ending at the end of 31st March 2023, 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 28.6% on their supplies of those presentations for the period beginning 1st April 2023 to the end of 2023, compared to the 27.5% payment percentage applied to presentations that are newly on the market on or after 1st April 2023. However, the net effect of both the higher payment percentage applied in respect of such supplies on or after 1st April 2023 and the lower payment percentage applied before that date is that in a case where a presentation is available throughout the whole of 2023 and sales are constant, a payment percentage of 27.5% would apply in respect of the annual net sales income (or estimated net sales income) of that presentation in 2023.

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.