

This FIRST AMENDMENT to the 2019 VOLUNTARY SCHEME FOR BRANDED MEDICINES PRICING AND ACCESS is dated 19 January 2022 and made between

The Department of Health and Social Care (representing the UK Government, and the governments of Scotland, Wales and Northern Ireland) (hereinafter referred to as the “DHSC”)

and

The Association of the British Pharmaceutical Industry (hereinafter referred to as the “ABPI”).

WHEREAS

The 2019 VOLUNTARY SCHEME FOR BRANDED MEDICINES PRICING AND ACCESS (hereinafter referred to as the “VS”) came into force on 1 January 2019 between the DHSC, NHS England, legally referred to as the National Health Service Commissioning Board, the ABPI and manufacturers or suppliers of Branded Health Service Medicines that join the VS.

The above parties entered the VS so as to recognise the importance of collaboration between the public and private sectors in delivering improved health gains from medicines in the national health service across the United Kingdom and in supporting the pharmaceutical industry in the United Kingdom so that it can continue to innovate now and in the future.

The VS sets out a UK wide affordability mechanism under which scheme members make a financial contribution to the DHSC for sales of Branded Health Service Medicines above the agreed level of allowable sales.

Exceptional growth in total Measured Sales of branded medicines in 2021, resulting in part from demand related to the coronavirus (COVID-19) pandemic, has led to a sharp increase in the calculated payment percentage for 2022. Whilst this is evidence of the scheme adjusting for high growth as intended, the parties recognise the impact of this on scheme members as well as the current high levels of uncertainty around underlying sales growth. Accordingly, the parties have agreed to apply a payment percentage of 15% for 2022, rather than at the level calculated under the scheme’s affordability mechanism. In all other respects, the VS and its Annexes shall remain unchanged and in full force and effect.

When setting the Voluntary Scheme payment percentage according to the scheme mechanics, a payment percentage is calculated in December for the following year. In doing so, rolling 4-quarter growth is used as a proxy for the most recent year’s measured sales growth. In order that the proxy growth rate is not unduly impacted by movement of Scheme Members between the Voluntary Scheme and the Statutory Scheme, the DHSC and the ABPI have agreed that the above calculations should be modified by 3-quarter year-to-date (YTD) growth being used as a proxy for growth when setting the subsequent year’s Voluntary Scheme payment percentage.

By paragraph 2.7 of the VS, the provisions thereof may only be amended by the mutual written agreement of the DHSC and the ABPI.

The DHSC and the ABPI have therefore agreed that the provisions of the VS shall be amended as follows with effect from the date on which the last to sign of the DHSC and the ABPI signed this First Amendment:

Annex 4

1. Paragraph 31 of Annex 4 shall be deleted in its entirety and shall be replaced by the following:

“In each year of the Voluntary Scheme, initial outturn of Measured Sales is calculated following the close of the third quarter of that calendar year. The initial outturn consists of actual Measured Sales for the nine months ending in September versus the same period the previous year. This is in order that the adjustments can be calculated and set in advance of the following calendar year. The only exception to this is in setting the 2021 Payment Percentage in November 2020 which is based on October 2019 to September 2020 versus October 2018 to September 2019. For all years, once the Audited and de-facto Audited Annual Sales Reports have been received, the outturn growth rate of Measured Sales will be calculated by comparing the twelve months 1 January to 31 December with the twelve months in the year previous.”

2. The following changes shall be made to Table 2: Timing of Adjustments (hereinafter referred to as the “Table”) in paragraph 38 of Annex 4: Calculation of Adjustments to Profile of Payments to the VS:

- (a) In the first of the three rows in the Table in which the entry in the first column (“Outturn Year”) is “Year 3 (2021)”, in each of the second, third and fourth columns (headed respectively, “Voluntary Scheme Measured Sales”, “Statutory Scheme Measured Sales” and “Parallel Import Sales”) the figure “12” shall be replaced by the figure “9”.
- (b) In the first of the three rows in the Table in which the entry in the first column (“Outturn Year”) is “Year 4 (2022)”, in each of the second, third and fourth columns (headed respectively, “Voluntary Scheme Measured Sales”, “Statutory Scheme Measured Sales” and “Parallel Import Sales”) the figure “12” shall be replaced by the figure “9”.
- (c) In the first of the three rows in the Table in which the entry in the first column (“Outturn Year”) is “Year 5 (2023)”, in each of the second, third and fourth columns (headed respectively, “Voluntary Scheme Measured Sales”, “Statutory Scheme Measured Sales” and “Parallel Import Sales”) the figure “12” shall be replaced by the figure “9”.

3. In the first sentence of paragraph 45 of Annex 4, the words “,for the 12 months” shall be deleted.

Annex 5

4. The first sentence of Paragraph 58 of Annex 5 shall be deleted and replaced with:

“Calculation of the year 4 payment percentage reflects the availability of Audited/de-facto Audited and indicative outturn data. Notwithstanding any of the provisions of this paragraph or any other provisions of the VS and its annexes, the year 4 payment percentage will be set in accordance with Paragraph 77 for all purposes of the VS and its Annexes.

5. In Paragraph 77 of Annex 5, “Calculation of” shall be replaced with “Setting” and “ $(VSRa_4 + OU_{1-3}) / Fav_{SE4}$ ” shall be replaced with “15%”.

In all other respects, the VS and its Annexes shall remain unchanged and in full force and effect.

The DHSC and the ABPI hereby signify their agreement to this FIRST AMENDMENT to the 2019 VOLUNTARY SCHEME FOR BRANDED MEDICINES PRICING AND ACCESS by executing the same as follows:

Agreed by DHSC, 18/01/2022

Agreed by ABPI, 19/01/2022