Department of Health & Social Care

abpi

The 2019 Voluntary Scheme for Branded Medicines Pricing and Access - Annexes

January 2022

DHSC ID box
Title: The 2019 Voluntary Scheme for Branded Medicines Pricing and Access - Annexes
Author: Community Care/Medicines and Pharmacy/Medicines Pricing and Supply/Cost Centre No. 17080
Document Purpose: Transparency
Publication date: December 2018, Amended January 2022
Target audience: Department of Health and Social Care, NHS England and the Association of the British Pharmaceutical Industry and its members
Contact details: michael.vidal@dhsc.gov.uk

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright 2022

Published to gov.uk, in PDF format only.

www.gov.uk/dhsc

Contents

Annex 1: Membership Forms

FORM A

JOINING THE VOLUNTARY SCHEME

SECTION 261(2) AND SECTION 261(6) OF THE NATIONAL HEALTH SERVICE ACT 2006 AND THE HEALTH SERVICE MEDICINES (CONSENT TO THE SCHEME) REGULATIONS 1999
CERTIFICATE OF CONSENT FOR THE SCHEME TO BE TREATED AS APPLYING

Name...
[name of company, partnership etc.]

Address ....

....

....

1. I .... [name of person signing & capacity in which signing, (e.g. director, partner or other)] certify that the above named company/partnership/person[1] hereby consents to the scheme made between the Association of the British Pharmaceutical Industry and the Secretary of State [to which there are modifications/and additions made between [the company/partnership/name] and the Secretary of State on..............................[2])] being treated as applying to it/him[3].

2. I am duly authorised to sign this certificate.

Signed ....

Date ....

[1] Delete as appropriate
[2] Only insert date where a modification to the Scheme has been agreed
[3] Delete as appropriate

FORM A1

JOINING OTHER GROUP COMPANIES TO THE VOLUNTARY SCHEME AS "OTHER COMPANIES"

THIS FORM IS APPLICABLE TO COMPANIES WHO HAVE COMPLETED "FORM A - JOINING THE VOLUNTARY SCHEME" AND BY VIRTUE OF PARAGRAPH 2.26 OF THE VOLUNTARY SCHEME ELECT TO JOIN THE VOLUNTARY SCHEME WITH OTHER COMPANIES IN THE SAME GROUP

LEAD COMPANY

Name...
[name of company, partnership etc.]

Address ....

....

....

Date signed Form A

....

Name of person who signed Form A & capacity in which signed, (e.g. director, partner or other)

....

I .... [name of person signing & capacity in which signing, (e.g. director, partner or other)] certify that, in accordance with paragraph [ ] of the Voluntary Scheme , the below named companies/partnerships/persons[1] who are members of the [name of group] group of companies hereby consent to the scheme made between the Association of the British Pharmaceutical Industry and the Secretary of State [to which there are modifications/and additions made between [the companies/partnerships/names] and the Secretary of State on..............................[2])] being treated as applying to it/him[3].

OTHER COMPANIES

a) Name...
[name of company, partnership etc.]

Address ....

....

b) Name..
[name of company, partnership etc.]

Address ....

....

....[5]

I also certify that [name of company, partnership etc.] hereby consents to act as the “Lead Company”, as defined in paragraph [ ] of the Voluntary Scheme, in relation to these companies/partnerships/persons[4].

I am duly authorised to sign this certificate.

Signed ....

Date ....

[1] Delete as appropriate
[2] Only insert date where a modification to the Scheme has been agreed
[3] Delete as appropriate
[4] Delete as appropriate
[5] Add or delete as appropriate

FORM B

LEAVING THE VOLUNTARY SCHEME

SECTION 261(2) AND SECTION 261(6) OF THE NATIONAL HEALTH SERVICE ACT 2006 AND THE HEALTH SERVICE MEDICINES (CONSENT TO THE SCHEME) REGULATIONS 1999

CERTIFICATE OF NOTICE OF WITHDRAWAL OF CONSENT FOR THE SCHEME TO BE TREATED AS APPLYING

Name ....
[name of company/partnership etc.]

Address ....

....

....

Date on which the consent now being withdrawn was given

....

1. I .... [name of person signing & capacity in which signing (e.g. director/partner/other)] certify that the above named company/partnership/person[1] hereby withdraws its/his consent to the voluntary scheme made by the Secretary of State and the Association of British Pharmaceutical Industry being treated as applying to it/him.

2. I am duly authorised to sign this certificate.

Signed ....

Date ....

[1] Delete as appropriate

Annex 2: Powers of the Secretary of State Deriving from the National Health Service Act 2006

A summary of the provisions contained in sections 261 to 266

1. Section 261 enables the Secretary of State, after making a "voluntary scheme" with the industry body (in practice the ABPI), to make regulations or issue directions to secure compliance with certain key elements of that scheme. This Voluntary Scheme (which can be amended in accordance with paragraph 2.7) would apply only to those companies that consent to partake in it (subsection (2)). Subsections (4) and (5) provide for the Secretary of State to give notice to a manufacturer or supplier that the Voluntary Scheme no longer applies to them. This can be done where the acts or omissions of the manufacturer or supplier have shown that the Voluntary Scheme is ineffective in their case.

2. Section 261(8) read with section 266 enables the Secretary of State by regulations or directions to prohibit any manufacturer or supplier to whom the Voluntary Scheme applies from increasing the prices of medicines provided to the health service without the Secretary of State's approval and, where this is breached, provides for payment of any excesses representing the increase to the Secretary of State within a specified period.

3. The Health Service Medical Supplies (Costs) Act 2017 (Costs Act 2017) added to section 261 new subsections (9) and (10) which increase the Secretary of State's enforcement power under a voluntary scheme. Additionally to the aforementioned subsection (8), subsection (9) means that the Secretary of State can now provide for "any amount payable in accordance with a voluntary scheme" be paid to him within a specified period. Subsection (10) provides that a manufacturer or supplier leaving a voluntary scheme will not affect any liability to make payments to the Secretary of State, with respect to that scheme, under this section.

4. In addition to powers to secure compliance with a voluntary scheme, the Act provides powers to control maximum prices of health service medicines in other circumstances and to provide for a statutory scheme.

5. Section 262 read with section 266 provides for the Secretary of State, after consultation with the industry body, by regulations or directions, to limit any price that may be charged by any manufacturer or supplier and for payment of the excess to the Secretary of State within a specified period. This power is exercisable only in relation to the health service medicines of manufacturers and suppliers which are not covered by a voluntary scheme.

6. Section 263 read with section 266 enables the Secretary of State, after consultation with the industry body, by regulations or directions to make a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines, or for the purpose of providing for any manufacturer or supplier of any health service medicines to pay

to the Secretary of State an amount calculated by reference to sales or estimated sales of those medicines. Section 263(1A) holds that, in setting up such a scheme, consultation must include consideration of (a) the economic consequences for the life sciences industry in the United Kingdom, (b) the consequences for the economy of the United Kingdom, and (c) the consequences for patients to whom any health service medicines are to be supplied and for other health service patients. Section 263(5) provides for payment to the Secretary of State of profits in excess of the limits determined under the statutory scheme. The new Section 263(5A), added by the Costs Act 2017, increases the Secretary of State's enforcement power under the statutory scheme more generally. The statutory scheme may now provide for "any amount payable in accordance with the scheme" to be paid to the Secretary of State within a specified period. Section 263(6) enables the Secretary of State to prohibit any manufacturer to whom the scheme applies from increasing prices without his approval and to require a sum representing the amount of any excess to be paid to him. Section 263(7) states that section 263 does not apply in relation to the health service medicines of manufacturers and suppliers that are covered by a voluntary scheme.

7. Section 264 read with section 266 gives the Secretary of State power after consultation with the industry body to make supplementary regulations or directions enabling or facilitating the introduction of a statutory scheme.

8. The Costs Act 2017 also added new sections 264A, 264B and 264C. Section 264A replaces the information provisions previously in sections 261 (7), 263(3) and 264(2), and allows the Secretary of State to make regulations to require any person who manufactures, distributes or supplies health service medicines, medical supplies or other related products required for the purpose of the health service to record, keep and provide information to the Secretary of State for specified purposes. Section 264B allows the Secretary of State to disclose the information obtained from manufacturers, distributors and suppliers by virtue of new section 264A in specified circumstances. Section 264C supplements sections 264A and 264B. In particular, it requires the Secretary of State to consult any body which appears to the Secretary of State to represent manufacturers, distributors and suppliers of health service medicines, medical supplies or other related products required for the purposes of the health service in the United Kingdom before making any regulations under section 264A or 264B.

9. Section 265 provides for enforcement. Section 265(1) enables the Secretary of State to make regulations providing for the payment of penalties by a person who contravenes any provision of orders, regulations or directions made under sections 260 to 264A. Section 265(2) provides that the maximum single penalty for which provision can be made is £100,000 and the maximum daily penalty is £10,000. Section 265(3) provides that amounts payable to the Secretary of State in respect of excessive prices can be increased by up to 50%. Section 265(4) enables the Secretary of State to provide for interest at a rate specified or referred to in the regulations. Sums payable to the Secretary of State are recoverable through the civil courts.

10. Section 265(5) enables provision to be made by regulations conferring on suppliers and manufacturers a right of appeal against enforcement decisions. Section 265(5A) states that provision must be made by regulations for conferring on UK producers a right of appeal against enforcement decisions taken in respect of them in pursuance of section 264A and section 265 if the enforcement decisions relate to information notices. Section 265(7) lists the enforcement decisions against which a supplier or manufacturer may appeal. The decisions are those made by the Secretary of State to (a) require a specific manufacturer or supplier to provide information to him, (b) limit, in respect of any specific manufacturer or supplier, any price or profit, (c) refuse to give his approval to a price increase made by a specific manufacturer or supplier, or (d) require a specific manufacturer or supplier to pay any amount (including an amount by way of penalty) to him.

11. Section 265(8) provides that any requirement, prohibition or limit under sections 260 to 264A may only be enforced under this section and not relied on in any other proceedings. Section 265(9) requires the Secretary of State to consult the industry body and any other body which appears to the Secretary of State appropriate to represent UK producers before making regulations under section 265. Section 265(10) provides for the maximum amounts set out in section 265(2) to be increased by order, subject to the affirmative resolution procedures as provided for in section 272.

12. Section 266 deals with supplementary matters. In particular section 266(1) provides for how the powers in sections 261(6) to (9) and 262 to 264 may be exercised, namely by regulations or, in the case of a particular manufacturer or supplier, by directions. More generally, section 266 provides that the power to control prices and profits may be exercised only with a view to limiting them to what is fair and reasonable and for the purposes of the health service. When exercising powers the Secretary of State and any other person must bear in mind the need for medicinal products to be available to the health service on reasonable terms and the costs of R&D.

13. The provisions in sections 261 to 266 enable the Secretary of State to make regulations in respect of England, Scotland, Wales and Northern Ireland.

Annex 3: Forecasts, Allowed Growth Rates and Initial Profile of Payment Percentages

1. The table below sets out, for each year of the Voluntary Scheme, the initial values for the Voluntary Scheme:

Table 1: Key parameters

	2018	2019	2020	2021	2022	2023
Initial forecast growth rate of Voluntary Scheme Measured Sales ($F_{VS}\%_t$)		5.91%	7.16%	8.90%	9.53%	9.12%
Initial forecast growth rate of Statutory Scheme Measured Sales ($F_{SS}\%_t$)		5.82%	6.96%	8.73%	9.37%	8.86%
Initial forecast growth rate of Parallel Import Sales ($F_{PI}\%_t$)		1.80%	0.17%	1.25%	1.51%	-0.68%
Initial forecast growth rate of Measured Sales ($F_T\%_t$)		5.72%	6.84%	8.57%	9.21%	8.76%
Initial forecast 2018 baseline Voluntary Scheme Measured Sales (F_{VS0})	9,381					
Initial forecast 2019 – 2023 Voluntary Scheme Measured Sales (F_{VSt})		9,936	10,647	11,594	12,699	13,857
Initial forecast 2018 baseline Statutory Scheme Measured Sales (F_{SS0})	987					

Initial forecast 2019 – 2023 Statutory Scheme Measured Sales (F_{SSt})		1,044	1,117	1,214	1,328	1,446
Initial forecast 2018 baseline Parallel Import Sales (F_{PI0})	483					
Initial forecast 2019 – 2023 Parallel Import Sales (F_{PIt})		492	493	499	506	503
Allowed Growth Rate ($AGR\%_t$);		2.0%	2.0%	2.0%	2.0%	2.0%
Initial expected 2018 Repayments, F_{PAY0}	660					
Initial forecast 2018 baseline Allowed Sales (AS_0);	10,191					
Initial forecast Allowed Sales (AS_t);		10,395	10,602	10,814	11,031	11,251
Initial forecast Voluntary Scheme Measured Sales as a % of Measured Sales ($VS\%_t$)		86.6%	86.9%	87.1%	87.4%	87.7%
Initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales ($F_{EX}\%_t$);		2.6%	5.2%	6.8%	7.0%	7.3%
Initial Payment Percentage for Scheme Members ($P\%_1$);		9.6%				
Estimated 2020 future Payment Percentage for Scheme Members ($FP\%_2$)			14.2%			

2. The forecast growth rate of Measured Sales is composed of three component forecasts to reflect the fact that Measured Sales includes sales made by Scheme Members, Statutory Scheme Members, and Parallel Imports:

    a. Forecast growth rate of Voluntary Scheme Measured Sales;

    b. Forecast growth rate of Statutory Scheme Measured Sales;

    c. Forecast growth rate of Parallel Import Sales.

3. The Allowed Growth Rate will remain fixed as above for the whole period of the Voluntary Scheme and will not be revised.

4. The initial value of baseline Allowed Sales in 2018 reflects a net position whereby the initial 2018 baseline Measured Sales have been adjusted to account for expected payments made in 2018 by members of the 2014 PPRS and members of the Statutory Scheme.

$$\begin{aligned} &\textit{Initial baseline Allowed Sales} \\ &\qquad = \textit{Measured Sales in } 2018 - \textit{Payments made in respect of } 2018 \textit{ under the } 2014\ \textit{PPRS} \\ &\qquad - \textit{Payments made in respect of } 2018 \textit{ under the Statutory Scheme} \end{aligned}$$

5. The Payment Percentage applies to Eligible Sales.

6. The first Payment Percentage ($P\%_1$) will be 9.6% of Eligible Sales in 2019. This is based on the initial forecast growth rate of Measured Sales for 2019 and an Allowed Growth Rate of 2.0% for those sales in 2019. All subsequent payment percentages ($P\%_2$, $P\%_3$, $P\%_4$ and $P\%_5$) will be adjusted on an annual basis, as explained in Annexes 4 and 5.

7. The second Payment Percentage ($FP\%_2$) is currently forecasted at 14.2% of Eligible Sales in 2020 based on the initial forecast. The actual Payment Percentage ($P\%_2$) will depend on how outturn sales compare to the initial forecast and the final 2018 baseline values for Measured Sales and Allowed Sales.

8. Annex 5 sets out the methodology in more detail and the calculation formulae which will be used.

Annex 4: Calculation and Adjustments to Profile of Payments

Establishing the 2018 Baseline

1. The initial 2018 baseline Measured Sales will be captured in the following way:

a) **Scheme Members:** Scheme Members will complete a Sales Report breaking down 2018 Measured Sales and corresponding exemptions into quarters and submit this to the Department by 31 March 2019. This will be independently Audited, and the outcome submitted to the Department, within 9 months following each Scheme member's 2018 financial year end, which for those Scheme Members with financial years that correspond with the calendar year will be September 2019. Scheme Members will use the Sales Report pro-formas at Annex 6 for both the quarterly and annual reports of sales in the baseline year. The annual baseline year sales report will be Audited according to the requirements set out at paragraphs 4.26 – 4.31 of Chapter 4 as if this sales report was the Audited Annual Sales Report referred to in those paragraphs.

b) Members of the Statutory Scheme:

- **Who were members of the 2014 PPRS in 2018:** 2014 PPRS returns relating to 2018 received by the Department under the 2014 PPRS will be adjusted to reflect Exemptions from Measured Sales. This will involve the addition of Sales of Products sold under Brand Equalisation deals as defined by the 2014 PPRS[1] and removal of sales of low value sales using best available data[2]. This will be updated when companies provide Audited 2014 PPRS returns relating to 2018 in accordance with the 2014 PPRS.
- **Who were not members of the 2014 PPRS in 2018:** Statutory Scheme quarterly returns received by the Department for the 9 months from 01/04/2018 to 31/12/2018 will be proportionally scaled to estimate sales by Statutory Scheme members in 2018 for 12 months ending 31/12/2018. This will be updated as the Department receives Audited returns as part of their Statutory Scheme obligations from 2018.

c) **Parallel Import Sales:** 2018 Parallel Import Sales will be calculated based on IQVIA data for that period adjusted for discounts on list prices. Sales of Parallel Imports by brand at list price is provided by IQVIA. This is then adjusted to account for discounts offered on the list price to reach sales of Parallel Imports at net price. Brand level discount rates are calculated from historical PPRS returns, and applied to the IQVIA Parallel Imports data. Where no brand level discount is available, the weighted average discount is applied.

---

[1] Clarified by the Department in the note issued to companies dated 2nd May 2017.

[2] The Department anticipates that the adjustment of brand equalisation sales will be made on the basis of 2018 PPRS sales reports, which identify the quantum of brand equalisation sales made in that quarter. With respect to the removal of sales of low value sales, this will be done on the basis of the latest version of that company's presentation level reports. Where no presentation level report has been supplied to the Department, this adjustment will be made on the basis of the average proportion of sales with a list price below £2.

Derivation of the Payment Percentage

2. The first Payment Percentage ($P\%_1$) is set based on the initial forecast Measured Sales for 2019 (Table 1: Key parameters), and an Allowed Growth Rate of 2% for those sales (less payments made in respect of 2018 under the 2014 PPRS and under the Statutory Scheme) in 2019.

3. The calculation of all subsequent Payment Percentages will follow the same process. In November of each year of the Voluntary Scheme, the initial forecast growth rate of Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales, and Parallel Import Sales will be adjusted to take account of the outturn for previous years. This updated forecast is then applied to the 2018 baseline Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales, and Parallel Import Sales (which may itself have been updated with new outturn data), to reach forecast Measured Sales in the next year, in addition to the forecast Voluntary Scheme Measured Sales.

4. Similarly, the initial forecast of Share of Voluntary Scheme Measured Sales exempt from Eligible Sales is adjusted to take into account prior year outturns to reach the updated forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales. This is then applied to forecast Voluntary Scheme Measured Sales to calculate forecast Eligible Sales.

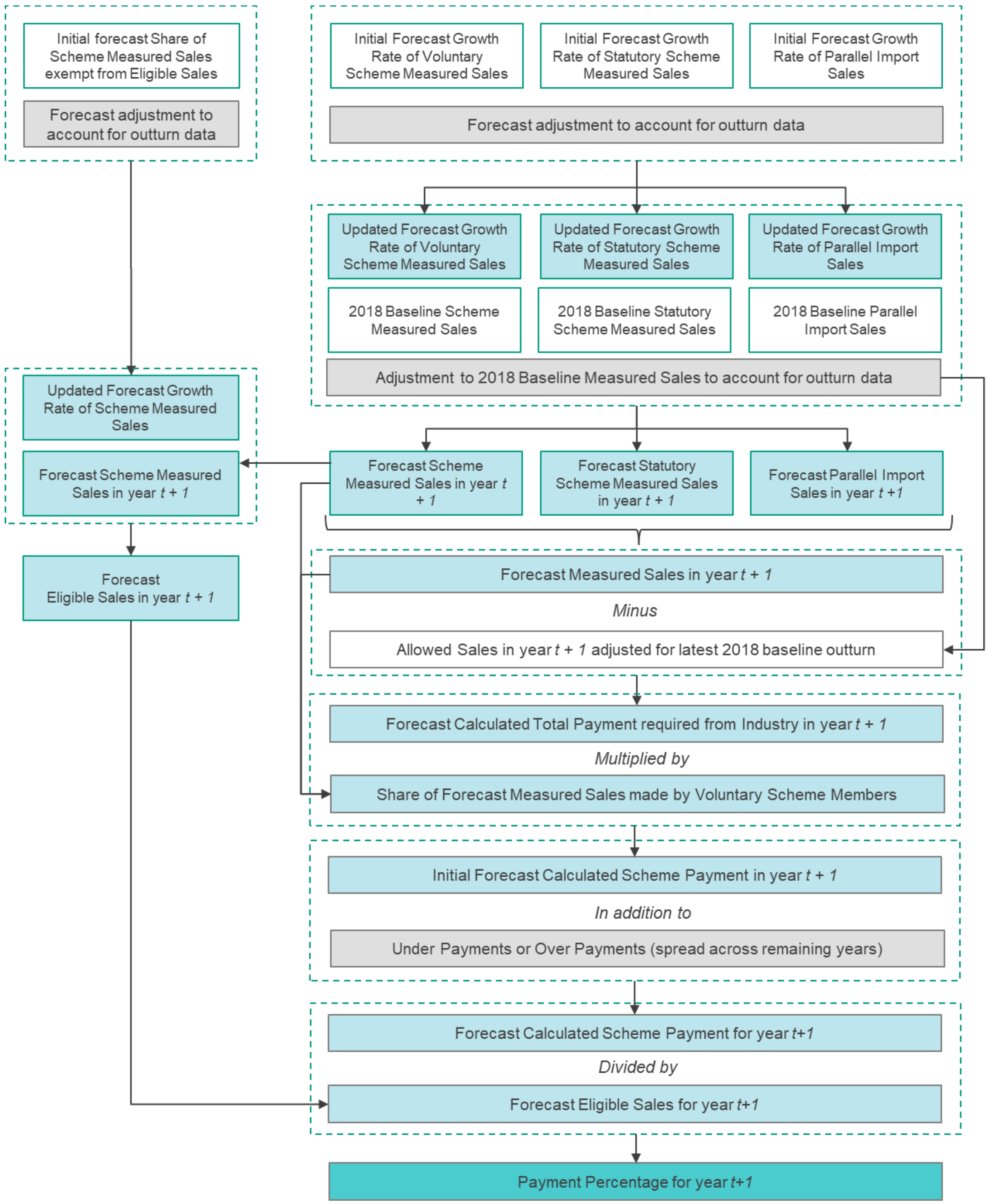
5. The Allowed Sales for the subsequent year is calculated by applying the Allowed Growth Rate, which will not change over the lifetime of the Voluntary Scheme, to 2018 baseline Allowed Sales. This 2018 baseline Allowed Sales number will be updated to reflect new outturn data for 2018 baseline Measured Sales and 2018 payments.

6. The difference between forecast Measured Sales for the subsequent year and Allowed Sales (where Measured Sales is greater than or equal to Allowed Sales) forms the Calculated Total Payment for that year. This value is then adjusted by forecast Voluntary Scheme Measured Sales as a share of Measured Sales to reach the initial Calculated Scheme Payment for that year. The initial Calculated Scheme Payment is adjusted for any Under Payments or Over Payments in prior years to reach the final forecast Calculated Scheme Payment for that year. This is divided by forecast Eligible Sales to reach the Payment Percentage for that year, which is then rounded to one decimal place, except under paragraph 29 in relation to the end scheme reconciliation.

7. In the event that forecast outturn Measured Sales is lower than Allowed Sales, incorporating any adjustments from Under Payments or Over Payments, the Payment Percentage applicable to Eligible Sales for that year is set at zero, however the Under Payments or Over Payments for that year will be taken into account in following years.

8. Further details on the algebra of the calculation of the Payment Percentage can be found in Annex 5. The remainder of this Annex will set out the adjustments process in greater detail.

Figure 1: Calculation of the payment percentage in year *t+1* (carried out in in Q4 year *t*)



9. The calculation of the Payment Percentage for years 2-5 of the Voluntary Scheme incorporates a number of adjustments:

   - **Adjustment of 2018 baseline Measured Sales and Allowed Sales baseline:** The initial forecast 2018 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales will be updated with outturn data, as will the initial forecast 2018 repayments from the 2014 PPRS and Statutory Scheme.
   - **Adjustment of forecast growth rates:** The initial forecast growth rate of Measured Sales is adjusted to take into account of outturn Measured Sales in previous years of the Voluntary Scheme.
   - **Adjustment of Calculated Scheme Payment to account for prior year payments**: The Calculated Scheme Payment used to calculate the Payment Percentage is adjusted for any Under Payments or Over Payments in previous years of the Voluntary Scheme due to differences in forecast and outturn Measured Sales.
   - **Adjustment of forecast Share of Measured Sales exempt from Eligible Sales:** The initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales is adjusted to take into account outturn Share of Voluntary Scheme Measured Sales exempt from Eligible Sales in previous years of the Voluntary Scheme.

10. In addition to the setting of each subsequent year’s Payment Percentage in 2019-2022, there will be an end-scheme reconciliation to account for the fact that all final Audited Sales returns will not be received until 2025 and to account for any residual rounding impact. This process will recalculate the year 5 Payment Percentage on the basis of updated data, and will take place in 2024 and 2025. Any resulting under or over payment as a result of the revised payment percentage will be settled between the Department and Scheme Members in 2025.

11. In the event that the parties agree on an alternative method of recovery for Under Payments or Over Payments arising from the end-scheme reconciliation, this will replace the repayment processes set out in paragraph 10.

Adjustment of 2018 Measured Sales baseline and Allowed Sales

12. The Payment Percentage for the first year of the Voluntary Scheme is set based on the agreed forecast of 2018 baseline Measured Sales and 2018 baseline Allowed Sales. These will both be updated through the lifetime of the Voluntary Scheme as the Department receives outturn data for:

   - Sales made by members of the Statutory Scheme in 2018;
   - Sales made by members of the 2014 PPRS in 2018;
   - Parallel Import Sales made in 2018; and
   - Payments made in respect of the year 2018 under the Statutory Scheme and the 2014 PPRS.

13. As 2018 baseline Measured Sales and Allowed Sales are updated, this will in turn update both Allowed Sales and forecast Measured Sales for each year of the Voluntary Scheme (even with no change in forecast growth rates or the Allowed Growth Rate).

Adjustment of forecast growth rates

14. In each year of the Voluntary Scheme, the forecast growth rate of Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales, and Parallel Import Sales (and hence the overall forecast Measured Sales growth rate) will be adjusted to account for the difference between forecast and outturn Measured Sales in prior years of the Voluntary Scheme. This will impact the difference between forecast Measured Sales and Allowed Sales for each subsequent year, and will therefore affect the Calculated Scheme Payment and corresponding Payment Percentage.

15. For each component forecast (Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales, Parallel Import Sales), this adjustment will be based on the difference between the outturn growth rate and forecast growth rate of Measured Sales rather than the difference for that individual component. For example, the initial forecast growth rate of Statutory Scheme Measured Sales will be adjusted by the difference between forecast and outturn Measured Sales. This is to prevent adjustments to forecasts driven purely by inter-scheme switching.

16. In order to avoid volatility, and only for the first adjustment of the forecasts in year two, the correction of the initial forecast growth rates will be half of the difference between the outturn growth rate of Measured Sales for year one and the initial forecast growth rate for Measured Sales in year one. This could be a positive or negative figure. This adjustment is then expressed as a percentage of the initial forecast Measured Sales growth rate for year 1, and used to multiplicatively adjust the initial component forecasts to produce updated forecast growth rates for subsequent years. Annex 5 sets out the methodology in more detail and the calculation formulae which will be used.

17. For years three and following, the forecast correction is the difference between the outturn cumulative growth rate of Measured Sales and forecast cumulative growth rate of Measured Sales from the start of the Voluntary Scheme to the prior year of the Voluntary Scheme. In each year, this difference is expressed as a percentage of the initial forecast cumulative growth rate of Measured Sales from the start of the Voluntary Scheme and used to multiplicatively adjust the initial component forecast growth rates in subsequent years. Annex 5 sets out the methodology in more detail and the calculation formulae which will be used.

18. The timing of these adjustments are outlined in Table 2: Timing of adjustments. Annex 5 sets out the methodology in more detail and the calculation formulae which will be used in each year of the Voluntary Scheme.

19. Due to end year dates for statutory accounts, it is possible that Audited Annual Sales Reports will not cover the full calendar year for the year in question. How differing end year statutory accounts are dealt with is covered in paragraph 35 of this Annex.

20. In the event that both parties agree on new forecasts during the lifetime of the Voluntary Scheme, these new forecasts will replace the initial forecasts by mutual agreement. These new forecasts will then be subject to the same process of annual mechanistic adjustments in subsequent years of the Voluntary Scheme.

Adjustment of Calculated Scheme Payment to account for prior year payments

21. The Under Payments or Over Payments in a given year is the difference between the forecast Calculated Scheme Payment and the Calculated Scheme Payment that would have been derived had the forecast been accurate for that year. This figure could be either positive or negative.

22. For each year there is an initial Under Payments or Over Payments figure calculated on the basis of unaudited outturn data, and a revised Under Payments or Over Payments figure calculated on the basis of updated outturn data following the submission of Scheme Members' Audited or de-facto Audited Sales Reports (described in paragraph 35). This is illustrated in Table 2: Timing of adjustments. Where Scheme Members are delayed in providing updated outturn data, or additional information comes to light which requires adjustments to Measured Sales, this will be used to calculate an updated Under Payments or Over Payments figure.

23. The Under Payments or Over Payments for a given year is spread equally over the remaining Voluntary Scheme years, and along with the updated forecast growth rate of Measured Sales, is taken into account when calculating future year Payment Percentages.

Adjustment of forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales

24. Forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales will be updated to account for outturn data each year. This adjustment will update the value of forecast Eligible Sales for each subsequent year and therefore the corresponding Payment Percentage.

25. The first adjustment to the Share of Voluntary Scheme Measured Sales exempt from Eligible Sales will be in Year 1 (2019), and will affect the forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales (and subsequently Eligible Sales) for 2020. The initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales will be adjusted in a multiplicative way based on the difference between the original forecast share and the outturn share in 2019. The outturn share will be based on company reported sales for exempt sales for the 6 months ending 30/09/19 multiplied by two, which is used as a first estimate for the exempt sales for 2019.

26. In year 2 (November 2020), the forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales for 2021 will be adjusted in the same way based on the average difference between forecast and outturn in 2019 (based on best available data for 12 months ending 31/12/2019), and 2020 (based on 6 months ending 30/09/20 multiplied by two).

27. For subsequent years of the Voluntary Scheme, the forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales will be adjusted in the same way, with the initial forecast being multiplicatively adjusted on the basis of the average difference between the initial forecast and outturn for all prior years (including the current year).

End scheme reconciliation

28. To reflect the fact that all final Audited and de-facto Audited Annual Sales Reports (as explained in paragraph 35 of this Annex) will not be received until 2025 at the earliest, and to account for any remaining rounding impact, there will be a two phase scheme-end reconciliation in 2024 and 2025 to account for any remaining Under Payments or Over Payments arising from the receipt of Audited and de-facto Audited reports after 2022.

29. Following the close of the third quarter of 2024, the Department should have received Audited or de-facto audited returns for Measured Sales made in 2022, and updated data for Measured Sales made in 2023 (this may be a mix of Audited returns for Scheme Members with a calendar year, and unaudited returns for Scheme Members whose financial year end date differs from the calendar end data, or who have been delayed in providing their Audited returns). This data is used to calculate a revised Payment Percentage and corresponding payment for 2023. The revised Payment Percentage will be calculated to two decimal places. Any change arising in the payment due from Scheme Members following the revision of the 2023 Payment Percentage will be payable (or refundable) in the first quarter of 2025.

30. Similarly, following the close of the third quarter of 2025, the Department should have received Audited and de-facto audited returns for Measured Sales made in 2023. This will be used to calculate a re-revised Payment Percentage and corresponding payment for 2023, which will be calculated to two decimal places. Any change arising in the payment due from Scheme Members in 2023, taking into account the scheme-end reconciliation in 2024, will be payable (or refundable) in the first quarter of 2026.

Timing of the adjustments

31. 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.

32. Following the independent Audit of the accounts after the end of each year (expected to be completed by 9 months following financial year end) any corrections necessary to the aggregated outturns are then fed into the calculation of the adjustment of the Payment Percentage for the year after.

33. So for year one (2019) any corrections to the outturn following the Audited accounts received by September 2020 in year two will be fed into the adjustment calculations for the Payment Percentage for years three and following (2021, 2022 and 2023). Where additional updates to 2019 outturns are received in 2020 and onwards, for example receipt of de-facto Audited returns for non-calendar year Scheme Members, this will be used in the adjustment calculations for Payment Percentages in subsequent years, and where applicable, the end scheme reconciliation exercise.

34. Each time a Scheme Member or member of the Statutory Scheme's sales exceed £5 million, the outturn figures used to calculate the growth rate in that year will be adjusted to include outturn sales for all members of the Voluntary Scheme and the Statutory Scheme counted as part of Measured Sales in both the current and the prior year, and only those members. For example, should such a member's sales grow to exceed £5 million in 2020 and remain above 2020 for the remainder of the Scheme, these sales will not be included in the growth rate calculation for 2020. They will however be included in the growth rate calculation for 2021.

35. All Scheme Members will be required to submit their Audited Annual Sales Report within nine months of the end of the Scheme Member's financial year. Where the financial year end date differs from the end of the calendar year (31 December) the best available data will be used at each point that adjustments are made (this could include part year Audited and part year unaudited data). When Audited data becomes available this will be used to make further corrections as necessary. Where Scheme Members have a financial year that differs from the calendar year, Scheme Members will be required to update their unaudited calendar quarterly returns to reflect their Audited returns as requested, referred to as 'de-facto Audited returns'.

36. This also covers data relating to the baseline period (2018). It is also possible that information may come to light that means that additional adjustments are required to the Measured Sales and therefore the component forecasts and Payment Percentages. This will be agreed with the Auditors on the basis of how to best represent Measured Sales historically and for future adjustments.

37. Where the Auditors recommended approach for accounting for Sales covered by the Scheme Payment differs from the approach adopted by the Scheme Member, the Scheme Member will adopt the methods recommended by the Auditors for future Sales Reports.

38. The calculation of Under Payments or Over Payments, and adjustment to the component forecasts are adjusted each year to the attached timetable. Additional adjustments that may be required over the course of the Voluntary Scheme, for example if new information comes to light, have not be captured in the table below.

Table 2: Timing of adjustments

Outturn year	Components			Calculated when	Payment percentage profile adjusted for Years
	Voluntary Scheme Measured Sales	**Statutory Scheme Measured Sales**	**Parallel Import Sales**		
Year 0 i.e. Baseline (2018)	Best available[1] 12 months ending 31/12/18	Calculated 2018 sales based on company returns received by the Department.	Outturn PI sales for 12 months ending 31/12/18 from IQVIA, adjusted to net prices	Sep 2019	Year 2-5
Year 0 i.e. Baseline (2018)	Audited/de-facto audited sales 12 months ending 31/12/18.	Calculated 2018 sales based on Audited/de-facto audited data received by the Department.	Revised Outturn PI sales for 12 months ending 31/12/18 from IQVIA, adjusted to net prices	Sep 2020	Year 3-5
Year 1 (2019)	Unaudited 9 months ending 30/9/19	Unaudited 9 months ending 30/9/19	Outturn PI sales for 9 months ending 30/9/19 from IQVIA, adjusted to net prices	Nov 2019	Years 2-5
Year 1 (2019)	Best available[1] 12 months ending 31/12/19	Best available[1] 12 months ending 31/12/19	Revised Outturn PI sales for 12 months ending	Nov 2020	Years 3-5

[1] This will consist of a mix of Audited returns (for those companies with a calendar financial year who have submitted their Audited returns), and unaudited (for those companies with a non-calendar financial year, or companies with a calendar financial year where audited returns have not been received).

			31/12/19 from IQVIA, adjusted to net prices		
Year 1 (2019)	Audited/de-facto audited 12 months ending 31/12/19	Audited/de-facto audited 12 months ending 31/12/19	Revised Outturn PI sales for 12 months ending 31/12/19 from IQVIA, adjusted to net prices	Nov 2021	Years 4-5
Year 2 (2020)	Unaudited 12 months ending 30/9/20	Unaudited 12 months ending 30/9/20	Outturn PI sales for 12 months ending 30/9/20 from IQVIA, adjusted to net prices	Nov 2020	Years 3-5
Year 2 (2020)	Best available[1] 12 months ending 31/12/20	Best available[1] 12 months ending 31/12/20	Revised Outturn PI sales for 12 months ending 31/12/20 from IQVIA, adjusted to net prices	Nov 2021	Years 4-5
Year 2 (2020)	Audited/de-facto audited 12 months ending 31/12/20	Audited/de-facto audited 12 months ending 31/12/20	Revised Outturn PI sales for 12 months ending 31/12/20 from IQVIA, adjusted to net prices	Nov 2022	Year 5
Year 3 (2021)	Unaudited 9 months ending 30/9/21	Unaudited 9 months ending 30/9/21	Outturn PI sales for 9 months ending 30/9/21 from IQVIA, adjusted to net prices	Nov 2021	Years 4-5
Year 3 (2021)	Best available[1] 12 months ending 31/12/21	Best available[1] 12 months ending 31/12/21	Revised Outturn PI sales for 12 months ending 31/12/21 from IQVIA, adjusted to net prices	Nov 2022	Year 5

Year 3 (2021)	Audited/de-facto audited 12 months ending 31/12/21	Audited/de-facto audited 12 months ending 31/12/21	Revised Outturn PI sales for 12 months ending 31/12/21 from IQVIA, adjusted to net prices	Nov 2023	End scheme reconciliation
Year 4 (2022)	Unaudited 9 months ending 30/9/22	Unaudited 9 months ending 30/9/22	Outturn PI sales for 9 months ending 30/9/22 from IQVIA, adjusted to net prices	Nov 2022	Year 5
Year 4 (2022)	Best available[1] 12 months ending 31/12/22	Best available[1] 12 months ending 31/12/22	Revised Outturn PI sales for 12 months ending 31/12/22 from IQVIA, adjusted to net prices	Nov 2023	End scheme reconciliation
Year 4 (2022)	Audited/de-facto audited12 months ending 31/12/22	Audited/de-facto audited 12 months ending 31/12/22	Revised Outturn PI sales for 12 months ending 31/12/22 from IQVIA, adjusted to net prices	Nov 2024	End scheme reconciliation
Year 5 (2023)	Unaudited 9 months ending 30/9/23	Unaudited 9 months ending 30/9/23	Outturn PI sales for 9 months ending 30/9/23 from IQVIA, adjusted to net prices	Nov 2023	End scheme reconciliation
Year 5 (2023)	Best available[1] 12 months ending 31/12/23	Best available[1] 12 months ending 31/12/23	Revised Outturn PI sales for 12 months ending 31/12/23 from IQVIA, adjusted to net prices	Nov 2024	End scheme reconciliation
Year 5 (2023)	Audited/de-facto audited 12 months ending 31/12/23	Audited/de-facto audited 12 months ending 31/12/23	Revised Outturn PI sales for 12 months ending 31/12/23 from IQVIA, adjusted to net prices	Nov 2025	End scheme reconciliation

Data Sources

39. The initial forecast for growth rate of Measured Sales (F_T%) and the forecast of Share of Voluntary Scheme Measured Sales exempt from Eligible Sales (F_{EX}%) are based on the initial forecast. These can be found in Annex 3.

40. Individual payments by Scheme Members will be based on data on sales of Branded Health Service Medicines provided by Scheme Members, which will be independently Audited at Financial year end. Sales data should be net of all discounts. Scheme Members will report their sales data for the Calculated Scheme Payment using the Quarterly Sales Reports and the Audited Annual Sales Reports as described at Annex 6.

41. The Department will use the Audited Annual Sales Reports (and in the case of Scheme Members with a non-calendar year financial year, de-facto Audited Sales Reports) in order to calculate the:

- Outturn Voluntary Scheme Measured Sales (including exempt sales) in the base year (2018) and in each subsequent year of the Voluntary Scheme;
- Outturn Exemptions from Eligible Sales in the base year (2018) and in each subsequent year of the Voluntary Scheme.

42. The outturn sales figures will be calculated gross of the Calculated Scheme Payment actually paid (i.e. including the value of the Calculated Scheme Payment paid) but net of (i.e. after subtracting) any Historic Cash Payments (i.e. payments in lieu of price cuts under the 2009 PPRS which Scheme Members are still paying).

43. Scheme Members' Quarterly and Audited Annual Sales Reports will need to include Exemptions from Measured Sales so that the outturn Measured Sales can be calculated. Sales of exempt products will be excluded from the sales used to calculate the Calculated Scheme Payment payable by each Scheme Member.

44. Statutory Scheme Sales will be calculated on the basis of best available data. For companies with a year end in December, annual sales reports will be used in the calculation.

45. Parallel Import Sales will be estimated on the basis of monthly sales data obtained from IQVIA up to September in each year. Prices will be adjusted for discounts observed in 2014 PPRS company returns, in respect of the year 2015 aggregated at the brand level. If newer discount data of sufficient quality becomes available during the Scheme, this could be used in place of the 2015 discounts by mutual agreement.

Annex 5: Payment Scheme Calculation Formulae

Scheme calculation formulae

1. The following formulae and tables outline the inputs and methodology used to calculate the Voluntary Scheme payment percentages. The first year's Payment Percentage is based on the initial forecasts, which can be seen in Annex 3. All subsequent Payment Percentage calculations are based on latest outturns from previous years including the 2018 baseline, Under Payments and Over Payments, adjustments to the forecasts of Measured Sales and the adjustments to the forecast of Share of Voluntary Scheme Measured Sales exempt from Eligible Sales.

2. The initial forecast Measured Sales is an aggregate forecast of Voluntary Scheme Measured Sales in 2018, Statutory Scheme Measured Sales in 2018 and Parallel Import Sales in 2018 (year 0) grown in line with the initial forecasts.

3. The initial Allowed Sales is calculated by growing the forecast 2018 baseline (Measured Sales in 2018 less payments made in respect of 2018 under the 2014 PPRS and the Statutory Scheme) by the Allowed Growth Rate.

4. Please note that any reference to latest outturn data refers to the latest estimate of outturn that will be available when the Payment Percentage is calculated for a particular year. The latest estimate of outturn may be based on Audited and de-facto audited company returns or unaudited company returns and will vary from year to year.

5. This can be seen in the notation, where a numerical subscript refers to the year of the Scheme the data applies to, and an alphabetical subscript refers to the year in which the data has been received. For example, L_{OT1a} is the Latest outturn Measured Sales for year 1 of the scheme (2019), which will be received in 2019. Conversely, L_{OT1b}, whilst still the Latest outturn Measured Sales for year 1 of the scheme (2019), will be received in 2020.

6. Payment Percentages can only take positive values. In the event that the formulae would result in a Payment Percentage taking a negative value (for example, where Allowed Sales are greater than Measured Sales), the Payment Percentage will be set at 0%. Under Payments and Over Payments will then be taken into consideration in the remainder years of the Scheme.

7. In the tables below, cells highlighted green are used or defined in the subsequent formulae.

2019 Payment Percentage calculation

8. The Voluntary Scheme requires an initial Payment Percentage, agreed to be 9.6% in 2019 ($P\%_1$ below). Data used in the 2019 payment percentage calculation are:

2018	2019	2020	2021	2022	2023
Forecast data	Forecast data	Not used	Not used	Not used	Not used

In year 1 the following inputs are required for calculation of the Payment Percentage: ($P\%_1$)

	Year 0
Initial forecast payments made in respect of 2018 under the 2014 PPRS and under the Statutory Scheme, F_{PAY}	F_{PAY0}
Initial forecast 2018 Voluntary Scheme Measured Sales, F_{VS}	F_{VS0}
Initial forecast 2018 Statutory Scheme Measured Sales, F_{SS}	F_{SS0}
Initial forecast 2018 Parallel Import Sales, F_{PI}	F_{PI0}
Initial forecast 2018 Measured Sales, F_T	F_{T0}

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Initial forecast of growth rate of Voluntary Scheme Measured Sales, $F_{VS}\%$	$F_{VS}\%_1$	$F_{VS}\%_2$	$F_{VS}\%_3$	$F_{VS}\%_4$	$F_{VS}\%_5$
Initial forecast of growth rate of Statutory Scheme Measured Sales, $F_{SS}\%$	$F_{SS}\%_1$	$F_{SS}\%_2$	$F_{SS}\%_3$	$F_{SS}\%_4$	$F_{SS}\%_5$
Initial forecast of growth rate of Parallel Import Sales, $F_{PI}\%$	$F_{PI}\%_1$	$F_{PI}\%_2$	$F_{PI}\%_3$	$F_{PI}\%_4$	$F_{PI}\%_5$
Initial forecast Voluntary Scheme Measured Sales, F_{VS}	F_{VS1}	F_{VS2}	F_{VS3}	F_{VS4}	F_{VS5}

	Year 1	Year 2	Year 3	Year 4	Year 5
Initial forecast Statutory Scheme Measured Sales, F_{SS}	F_{SS1}	F_{SS2}	F_{SS3}	F_{SS4}	F_{SS5}
Initial forecast Parallel Import Sales, F_{PI}	F_{PI1}	F_{PI2}	F_{PI3}	F_{PI4}	F_{PI5}
Initial forecast Measured Sales, F_T	F_{T1}	F_{T2}	F_{T3}	F_{T4}	F_{T5}

Initial forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales, VS%	$VS\%_1$	$VS\%_2$	$VS\%_3$	$VS\%_4$	$VS\%_5$
Initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $F_{EX}\%$	$F_{EX}\%_1$	$F_{EX}\%_2$	$F_{EX}\%_3$	$F_{EX}\%_4$	$F_{EX}\%_5$
Forecast Eligible Sales, F_{VSE}	F_{VSE1}	F_{VSE2}	F_{VSE3}	F_{VSE4}	F_{VSE5}
Forecast Calculated Total Payment, IR	IR_1	IR_2	IR_3	IR_4	IR_5
Forecast Calculated Scheme Payment, VSR	VSR_1	VSR_2	VSR_3	VSR_4	VSR_5
Allowed Sales based on initial forecast baseline, AS	**AS_1**	**AS_2**	**AS_3**	**AS_4**	**AS_5**
Payment Percentage, P%	**$P\%_1$**				

Calculation of the year 1 Payment Percentage

9. Calculation of forecast Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$$F_{VS1} = F_{VS0} * (1 + F_{VS}\%_1)$$

$$F_{SS1} = F_{SS0} * (1 + F_{SS}\%_1)$$

$$F_{PI1} = F_{PI0} * (1 + F_{PI}\%_1)$$

10. Calculation of the Measured Sales for year 0 and year 1:

$F_{T0} = F_{VS0} + F_{SS0} + F_{PI0}$

$F_{T1} = F_{VS1} + F_{SS1} + F_{PI1}$

11. Calculation of Allowed Sales:

$AS_1 = (F_{T0} – F_{PAY0}) * (1 + AGR\%_1)$

12. Calculation of Calculated Total Payment:

$IR_1 = F_{T1} – AS_1$

13. Calculation of initial forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$VS\%_1 = F_{VS1} / F_{T1}$

14. Calculation of Calculated Scheme Payment:

$VSR_1 = IR_1 * VS\%_1$

15. Calculation of initial forecast Eligible Sales:

$F_{VSE1} = F_{VS1} * (1 – F_{EX}\%_1)$

16. Calculation of the year 1 Payment Percentage:

$P\%_1 = VSR_1 / F_{VSE1}$

The results from these equations, taken with initial values given in Annex 3, give an agreed value for $P\%_1$ of 9.6% as above.

2020 Payment Percentage calculation

17. The calculation of the year 2 payment percentage reflects the availability of Audited/de-facto Audited outturn data for year 0 and indicative outturn for year 1.

2018	2019	2020	2021	2022	2023
Latest Outturn Data as of Q3 2019	Latest Outturn Data as of Q3 2019	Forecast data	Not used	Not used	Not used

	Year 0
Latest outturn payments made in respect of 2018 under the 2014 PPRS and under the Statutory Scheme, L_{OPAY}	L_{OPAY0a}

	Year 0
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS0a}
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS0a}
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI0a}
Latest outturn Measured Sales, L_{OT}	L_{OT0a}

	Year 1	Year 2
Initial forecast of growth rate of Voluntary Scheme Measured Sales, $F_{VS}\%$	$F_{VS}\%_1$	$F_{VS}\%_2$
Initial forecast of growth rate of Statutory Scheme Measured Sales, $F_{SS}\%$	$F_{SS}\%_1$	$F_{SS}\%_2$
Initial forecast of growth rate of Parallel Import Sales, $F_{PI}\%$	$F_{PI}\%_1$	$F_{PI}\%_2$
Reweighted forecast Measured Sales growth rate (adjusted for latest baseline outturns), $RF_T\%$	$RF_T\%_{1a}$	$RF_T\%_{2a}$
Latest outturn Voluntary Scheme Measured Sales growth rate, $L_{OVSGR}\%$	$L_{OVSGR}\%_{1a}$	
Latest outturn Statutory Scheme Measured Sales growth rate, $L_{OSSGR}\%$	$L_{OSSGR}\%_{1a}$	
Latest outturn Parallel Import Sales growth rate, $L_{OPIGR}\%$	$L_{OPIGR}\%_{1a}$	
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS1a}	
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS1a}	
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI1a}	
Latest outturn Measured Sales, L_{OT}	L_{OT1a}	

Latest outturn of Voluntary Scheme Measured Sales as a percentage of Measured Sales, $L_{OVS}\%$	$L_{OVS}\%_{1a}$	
Initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $F_{EX}\%$	$F_{EX}\%_{1}$	$F_{EX}\%_{2}$
Latest outturn of Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $L_{OFEX}\%$	$L_{OFEX}\%_{1a}$	
Latest outturn of Eligible Sales, L_{OFVSE}	$L_{OFVSE1a}$	
Latest outturn of Calculated Total Payment, L_{OIR}	L_{OIR1a}	
Latest outturn of Calculated Scheme Payment, L_{OVSR}	L_{OVSR1a}	
Allowed Sales, based on latest outturn baseline, AS	**AS_{1a}**	**AS_{2a}**
Under Payments or Over Payments of Calculated Scheme Payment, OU	**OU_{1}**	
Adjusted forecast of the growth rate of Voluntary Scheme Measured Sales, $Fa_{VS}\%$		$Fa_{VS}\%_{2}$
Adjusted forecast of the growth rate of Statutory Scheme Measured Sales, $Fa_{SS}\%$		$Fa_{SS}\%_{2}$
Adjusted forecast of the growth rate of Parallel Import Sales, $Fa_{PI}\%$		$Fa_{PI}\%_{2}$
Adjusted forecast Voluntary Scheme Measured Sales, Fa_{VS}		Fa_{VS2}
Adjusted forecast Statutory Scheme Measured Sales, Fa_{SS}		Fa_{SS2}
Adjusted forecast Parallel Import Sales, Fa_{PI}		Fa_{PI2}
Adjusted forecast Measured Sales, Fa_{T}		Fa_{T2}
Adjusted forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $Fa_{EX}\%$		$Fa_{EX}\%_{2}$
Adjusted forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales, VSa%		$VSa\%_{2}$
Adjusted forecast Eligible Sales, Fa_{VSE}		Fa_{VSE2}
Adjusted forecast Calculated Total Payment, IRa		IRa_{2}
Adjusted forecast Calculated Scheme Payment, VSRa		$VSRa_{2}$

Payment Percentage, P%	**$P\%_1$**	**$P\%_2$**

Calculation of the Under Payments or Over Payments in year 1 given latest outturn data

18. Calculation of latest outturn Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$$L_{OVS1a} = L_{OVS0a} * (1 + L_{OVSGR\%1a})$$

$$L_{OSS1a} = L_{OSS0a} * (1 + L_{OSSGR\%1a})$$

$$L_{OPI1a} = L_{OPI0a} * (1 + L_{OPIGR\%1a})$$

19. Calculation of the latest outturn Measured Sales for year 1:

$$L_{OT1a} = L_{OVS1a} + L_{OSS1a} + L_{OPI1a}$$

20. Calculation of Allowed Sales adjusted for latest 2018 baseline outturn data:

$$AS_{1a} = (L_{OT0a} – L_{OPAY0a}) * (1 + AGR\%_1)$$

$$AS_{2a} = AS_{1a} * (1 + AGR\%_2)$$

21. Calculation of the latest outturn Calculated Total Payment in year 1:

$$L_{OIR1a} = L_{OT1a} – AS_{1a}$$

22. Calculation of the latest outturn Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$$L_{OVS\%1a} = L_{OVS1a} / L_{OT1a}$$

23. Calculation of latest outturn Calculated Scheme Payment:

$$L_{OVSR1a} = L_{OIR1a} * L_{OVS\%1a}$$

24. Calculation of the latest outturn Eligible Sales in year 1:

$$L_{OFVSE1a} = L_{OVS1a} * (1 - L_{OFEX\%1a})$$

25. Calculation of the Under Payments or Over Payments of Calculated Scheme Payment in year 1, amortised to remaining years of Voluntary Scheme:

$$OU_1 = \frac{1}{4}(L_{OVSR1a} - (L_{OFVSE1a} * P\%_1))$$

The division by a factor of 4 matches the number of years left in the Voluntary Scheme.

Calculation of the year 2 Payment Percentage

26. Calculation of the reweighted initial forecast using latest outturn data:

$RF_T\%$ represents the initial forecast Measured Sales growth rate. This must be separately defined because it is liable to change with updated year 0 baseline values even where the component forecast growth rates do not change. It is affected by the relative proportions of the components that make up the total. To calculate the reweighted initial forecast, the cumulative forecasts are required to apply to the year 0 component sales baselines.

27. Calculation of cumulative initial forecasts:

$$CF_{VS}\%_1 = (1 + F_{VS}\%_1)$$

$$CF_{SS}\%_1 = (1 + F_{SS}\%_1)$$

$$CF_{PI}\%_1 = (1 + F_{PI}\%_1)$$

28. Calculation of reweighted initial forecast Measured Sales growth rate:

$$RF_T\%_{1a} = \frac{CF_{VS}\%_1 * L_{OVS0a} + CF_{SS}\%_1 * L_{OSS0a} + CF_{PI}\%_1 * L_{OPI0a}}{L_{OT0a}} - 1$$

29. Calculation of the adjusted forecast growth rates to account for forecast error:

$$Fa_{VS}\%_2 = F_{VS}\%_2 * \left[1+\frac{1}{2}\left(\frac{L_{OT}\%_{1a}}{RF_T\%_{1a}}-1\right)\right]$$

$$Fa_{SS}\%_2 = F_{SS}\%_2 * \left[1+\frac{1}{2}\left(\frac{L_{OT}\%_{1a}}{RF_T\%_{1a}}-1\right)\right]$$

$$Fa_{PI}\%_2 = F_{PI}\%_2 * \left[1+\frac{1}{2}\left(\frac{L_{OT}\%_{1a}}{RF_T\%_{1a}}-1\right)\right]$$

The division by the factor of 2 is a dampening factor to allow the fact that only one year's worth of latest outturn data is available at the time of adjustment. The effect of the adjustment is reduced to reflect the uncertainty.

30. Calculation of the adjusted forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales to account for forecast error:

$$Fa_{EX}\%_2 = F_{EX}\%_2 * \left[\frac{L_{OFEX}\%_{1a}}{F_{EX}\%_1}\right]$$

31. Calculation of the adjusted forecast Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales using the adjusted forecast growth rate:

$Fa_{VS2} = Lo_{VS1a} * (1 + Fa_{VS}\%_{2})$

$Fa_{SS2} = Lo_{SS1a} * (1 + Fa_{SS}\%_{2})$

$Fa_{PI2} = Lo_{PI1a} * (1 + Fa_{PI}\%_{2})$

32. Calculation of the adjusted forecast Measured Sales for year 2:

$Fa_{T2} = Fa_{VS2} + Fa_{SS2} + Fa_{PI2}$

33. Calculation of adjusted forecast Calculated Total Payment:

$IRa_{2} = Fa_{T2} – AS_{2a}$

34. Calculation of the adjusted forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$VSa\%_{2}= Fa_{VS2} / Fa_{T2}$

35. Calculation of adjusted forecast Calculated Scheme Payment:

$VSRa_{2} = IRa_{2} * VSa\%_{2}$

36. Calculation of the adjusted forecast Eligible Sales:

$Fa_{VSE2} = Fa_{VS2} * (1 – Fa_{EX}\%_{2})$

37. Calculation of the year 2 Payment Percentage:

$P\%_{2} = (VSRa_{2} + OU_{1})/ Fa_{VSE2}$

2021 Payment Percentage calculation

38. Calculation of the year 3 payment percentage reflects the availability of Audited/de-facto Audited and indicative outturn data.

2018	2019	2020	2021	2022	2023
Latest Outturn Data as of Q3 2020	Latest Outturn Data as of Q3 2020	Latest Outturn Data as of Q3 2020	Forecast data	Not used	Not used

	Year 0
Latest outturn payments made in respect of 2018 under the 2014 PPRS and under the Statutory Scheme, L_{OPAY}	L_{OPAY0b}
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS0b}
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS0b}
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI0b}
Latest outturn Measured Sales, L_{OT}	L_{OT0b}

	Year 1	Year 2	Year 3
Initial forecast of growth rate of Voluntary Scheme Measured Sales, $F_{VS}\%$	$F_{VS}\%_1$	$F_{VS}\%_2$	$F_{VS}\%_3$
Initial forecast of growth rate of Statutory Scheme Measured Sales, $F_{SS}\%$	$F_{SS}\%_1$	$F_{SS}\%_2$	$F_{SS}\%_3$
Initial forecast of growth rate of Parallel Import Sales, $F_{PI}\%$	$F_{PI}\%_1$	$F_{PI}\%_2$	$F_{PI}\%_3$
Reweighted initial forecast Measured Sales growth rate (adjusted for latest baseline outturns), $RF_T\%$	$RF_T\%_{1b}$	$RF_T\%_{2b}$	$RF_T\%_{3b}$
Latest outturn Voluntary Scheme Measured Sales growth rate, $L_{OVSGR}\%$	$L_{OVSGR}\%_{1b}$	$L_{OVSGR}\%_{2b}$	
Latest outturn Statutory Scheme Measured Sales growth rate, $L_{OSSGR}\%$	$L_{OSSGR}\%_{1b}$	$L_{OSSGR}\%_{2b}$	
Latest outturn Parallel Import Sales growth rate, $L_{OPIGR}\%$	$L_{OPIGR}\%_{1b}$	$L_{OPIGR}\%_{2b}$	
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS1b}	L_{OVS2b}	
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS1b}	L_{OSS2b}	

	Year 1	Year 2	Year 3
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI1b}	L_{OPI2b}	
Latest outturn Measured Sales, L_{OT}	L_{OT1b}	L_{OT2b}	

Latest outturn of Voluntary Scheme Measured Sales as a percentage of Measured Sales, $L_{OVS}\%$	$L_{OVS}\%_{1b}$	$L_{OVS}\%_{2b}$	
Initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $F_{EX}\%$	$F_{EX}\%_{1}$	$F_{EX}\%_{2}$	$F_{EX}\%_{3}$
Latest outturn of Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $L_{OFEX}\%$	$L_{OFEX}\%_{1b}$	$L_{OFEX}\%_{2b}$	
Latest outturn of Eligible Sales, L_{OFVSE}	$L_{OFVSE1b}$	$L_{OFVSE2b}$	
Latest outturn of Calculated Total Payment, L_{OIR}	L_{OIR1b}	L_{OIR2b}	
Latest outturn of Calculated Scheme Payment, L_{OVSR}	L_{OVSR1b}	L_{OVSR2b}	
Allowed Sales, based on latest outturn baseline, AS	$\mathbf{AS_{1b}}$	$\mathbf{AS_{2b}}$	$\mathbf{AS_{3b}}$
Under Payments or Over Payments of Calculated Scheme Payment, OU	$\mathbf{OU_{1}}$	$\mathbf{OU_{1-2}}$	
Adjusted forecast of the growth rate of Voluntary Scheme Measured Sales, $Fa_{VS}\%$			$Fa_{VS}\%_{3}$
Adjusted forecast of the growth rate of Statutory Scheme Measured Sales, $Fa_{SS}\%$			$Fa_{SS}\%_{3}$
Adjusted forecast of the growth rate of Parallel Import Sales, $Fa_{PI}\%$			$Fa_{PI}\%_{3}$
Adjusted forecast Voluntary Scheme Measured Sales, Fa_{VS}			Fa_{VS3}
Adjusted forecast Statutory Scheme Measured Sales, Fa_{SS}			Fa_{SS3}
Adjusted forecast Parallel Import Sales, Fa_{PI}			Fa_{PI3}
Adjusted forecast Measured Sales, Fa_{T}			Fa_{T3}

Adjusted forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $Fa_{EX}\%$			$Fa_{EX}\%_3$
Adjusted forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales, $VSa\%$			$VSa\%_3$
Adjusted forecast Eligible Sales, Fa_{VSE}			Fa_{VSE3}
Adjusted forecast Calculated Total Payment, IRa			IRa_3
Adjusted forecast Calculated Scheme Payment, VSRa			$VSRa_3$
Payment Percentage, P%	**$P\%_1$**	**$P\%_2$**	**$P\%_3$**

Calculation of the Under Payments or Over Payments in year 2 given latest outturn data

39. Calculation of Latest outturn Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

For year 1 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS1b} = L_{OVS0b} * (1 + L_O\%_{VS1b})$

$L_{OSS1b} = L_{OSS0b} * (1 + L_O\%_{SS1b})$

$L_{OPI1b} = L_{OPI0b} * (1 + L_O\%_{PI1b})$

For year 2 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS2b} = L_{OVS1b} * (1 + L_{OVS}\%_{2b})$

$L_{OSS2b} = L_{OSS1b} * (1 + L_{OSS}\%_{2b})$

$L_{OPI2b} = L_{OPI1b} * (1 + L_{OPI}\%_{2b})$

40. Calculation of the latest outturn Measured Sales for year 1 and year 2:

$L_{OT1b} = L_{OVS1b} + L_{OSS1b} + L_{OPI1b}$

$L_{OT2b} = L_{OVS2b} + L_{OSS2b} + L_{OPI2b}$

41. Calculation of Allowed Sales adjusted for latest 2018 baseline outturn data:

$AS_{1b} = (L_{OT0b} – L_{OPAY0b}) * (1 + AGR\%_1)$

$AS_{2b} = AS_{1b} * (1 + AGR\%_2)$

$AS_{3b}= AS_{2b} * (1 + AGR\%_3)$

42. Calculation of the latest outturn of Calculated Total Payment:

$L_{OIR1b} = L_{OT1b} – AS_{1b}$

$L_{OIR2b} = L_{OT2b} – AS_{2b}$

43. Calculation of the latest outturn Voluntary Scheme Measured Sales as a percentage of Measured Sales

$L_{OVS\%1b} = L_{OVS1b} / L_{OT1b}$

$L_{OVS\%2b} = L_{OVS2b} / L_{OT2b}$

44. Calculation of latest outturn of Calculated Scheme Payment:

$L_{OVSR1b} = L_{OIR1b} * L_{OVS\%1b}$

$L_{OVSR2b} = L_{OIR2b} * L_{OVS\%2b}$

45. Calculation of the latest outturn of Eligible Sales:

$L_{OFVSE1b} = L_{OVS1b} * (1 - L_{OFEX\%1b})$

$L_{OFVSE2b} = L_{OVS2b} * (1 - L_{OFEX\%2b})$

46. Calculation of the Under Payments or Over Payments of Calculated Scheme Payments, amortised to remaining years of Voluntary Scheme:

$$OU_{1-2} = \frac{1}{3} * [L_{OVSR1b} - (L_{OFVSE1b} * P\%_1) + L_{OVSR2b} – (L_{OFVSE2b} * P\%_2)]$$

The division by a factor of 3 matches the number of years left in the Voluntary Scheme.

Calculation of the year 3 Payment Percentage

47. Calculation of cumulative initial forecasts:

$CF_{VS\%2} = (1 + F_{VS\%1}) * (1 + F_{VS\%2})$

$CF_{SS\%2} = (1 + F_{SS\%1}) * (1 + F_{SS\%2})$

$CF_{PI\%2} = (1 + F_{PI\%1}) * (1 + F_{PI\%2})$

48. Calculation of reweighted initial forecast Measured Sales growth rate:

$$RF_T\%_{1b} = \frac{CF_{VS}\%_1 * L_{OVS0b} + CF_{SS}\%_1 * L_{OSS0b} + CF_{PI}\%_1 * L_{OPI0b}}{L_{OT0b}} - 1$$

$$RF_T\%_{2b} = \frac{CF_{VS}\%_2 * L_{OVS0b} + CF_{SS}\%_2 * L_{OSS0b} + CF_{PI}\%_2 * L_{OPI0b}}{CF_{VS}\%_1 * L_{OVS0b} + CF_{SS}\%_1 * L_{OSS0b} + CF_{PI}\%_1 * L_{OPI0b}} - 1$$

49. Calculation of the adjusted forecast growth rates to account for forecast error:

$$Fa_{VS}\%_3 = F_{VS}\%_3 * \left[\frac{(1 + L_{OT}\%_{1b}) * (1 + L_{OT}\%_{2b}) -1}{(1 + RF_T\%_{1b}) * (1 + RF_T\%_{2b}) -1}\right]$$

$$Fa_{SS}\%_3 = F_{SS}\%_3 * \left[\frac{(1 + L_{OT}\%_{1b}) * (1 + L_{OT}\%_{2b}) -1}{(1 + RF_T\%_{1b}) * (1 + RF_T\%_{2b}) -1}\right]$$

$$Fa_{PI}\%_3 = F_{PI}\%_3 * \left[\frac{(1 + L_{OT}\%_{1b}) * (1 + L_{OT}\%_{2b}) -1}{(1 + RF_T\%_{1b}) * (1 + RF_T\%_{2b}) -1}\right]$$

50. Calculation of the adjusted forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales to account for forecast error:

$$Fa_{EX}\%_3 = F_{EX}\%_3 * \frac{1}{2} * \left[\frac{L_{OFEX}\%_{1b}}{F_{EX}\%_1} + \frac{L_{OFEX}\%_{2b}}{F_{EX}\%_2}\right]$$

The adjustment for forecast error of percentage Share of Voluntary Scheme Measured Sales exempt from Eligible Sales is an average of all years. As such it is divided by two when calculating the year 3 adjusted forecast as there are two years of outturn data available.

51. Calculation of the adjusted forecast of Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales using the adjusted forecast growth rate:

$$Fa_{VS3} = L_{OVS2b} * (1 + Fa_{VS}\%_3)$$

$$Fa_{SS3} = L_{OSS2b} * (1 + Fa_{SS}\%_3)$$

$$Fa_{PI3} = L_{OPI2b} * (1 + Fa_{PI}\%_3)$$

52. Calculation of the adjusted forecast of Measured Sales for year 3:

$$Fa_{T3} = Fa_{VS3} + Fa_{SS3} + Fa_{PI3}$$

53. Calculation of adjusted forecast of Calculated Total Payment:

$$IRa_3 = Fa_{T3} - AS_{3b}$$

54. Calculation of the adjusted forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$$VSa\%_3 = Fa_{VS3} / Fa_{T3}$$

55. Calculation of adjusted forecast Calculated Scheme Payment:

$$VSRa_3 = IRa_3 * VSa\%_3$$

56. Calculation of the adjusted forecast Eligible Sales:

$$Fa_{VSE3} = Fa_{VS3} * (1 – Fa_{EX}\%_3)$$

57. Calculation of the year 3 Payment Percentage:

$$P\%_3 = (VSRa_3 + OU_{1-2})/ Fa_{VSE3}$$

2022 Payment Percentage calculation

58. 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.

2018	2019	2020	2021	2022	2023
Latest Outturn Data as of Q3 2021	Latest Outturn Data as of Q3 2021	Latest Outturn Data as of Q3 2021	Latest Outturn Data as of Q3 2021	Forecast data	Not used

	Year 0
Latest outturn payments made in respect of 2018 under the 2014 PPRS and under the Statutory Scheme, L_{OPAY}	L_{OPAY0c}
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS0c}
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS0c}
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI0c}
Latest outturn Measured Sales, L_{OT}	L_{OT0c}

	Year 1	Year 2	Year 3	Year 4
Initial forecast of growth rate of Voluntary Scheme Measured Sales, $F_{VS}\%$	$F_{VS}\%_1$	$F_{VS}\%_2$	$F_{VS}\%_3$	$F_{VS}\%_4$
Initial forecast of growth rate of Statutory Scheme Measured Sales, $F_{SS}\%$	$F_{SS}\%_1$	$F_{SS}\%_2$	$F_{SS}\%_3$	$F_{SS}\%_4$
Initial forecast of growth rate of Parallel Import Sales, $F_{PI}\%$	$F_{PI}\%_1$	$F_{PI}\%_2$	$F_{PI}\%_3$	$F_{PI}\%_4$
Reweighted initial forecast Measured Sales growth rate (adjusted for latest baseline outturns), $RF_T\%$	$RF_T\%_{1c}$	$RF_T\%_{2c}$	$RF_T\%_{3c}$	$RF_T\%_{4c}$
Latest outturn Voluntary Scheme Measured Sales growth rate, $L_{OVSGR}\%$	$L_{OVSGR}\%_{1c}$	$L_{OVSGR}\%_{2c}$	$L_{OVSGR}\%_{3c}$	
Latest outturn Statutory Scheme Measured Sales growth rate, $L_{OSSGR}\%$	$L_{OSSGR}\%_{1c}$	$L_{OSSGR}\%_{2c}$	$L_{OSSGR}\%_{3c}$	
Latest outturn Parallel Import Sales estimate growth rate, $L_{OPIGR}\%$	$L_{OPIGR}\%_{1c}$	$L_{OPIGR}\%_{2c}$	$L_{OPIGR}\%_{3c}$	
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS1c}	L_{OVS2c}	L_{OVS3c}	
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS1c}	L_{OSS2c}	L_{OSS3c}	
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI1c}	L_{OPI2c}	L_{OPI3c}	
Latest outturn Measured Sales, L_{OT}	L_{OT1c}	L_{OT2c}	L_{OT3c}	

Latest outturn of Voluntary Scheme Measured Sales as a percentage of Measured Sales, $L_{OVS}\%$	$L_{OVS}\%_{1c}$	$L_{OVS}\%_{2c}$	$L_{OVS}\%_{3c}$	

Initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $F_{EX}\%$	$F_{EX}\%_1$	$F_{EX}\%_2$	$F_{EX}\%_3$	$F_{EX}\%_4$
Latest outturn of Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $L_{OFEX}\%$	$L_{OFEX}\%_{1c}$	$L_{OFEX}\%_{2c}$	$L_{OFEX}\%_{3c}$	
Latest outturn Eligible Sales, L_{OFVSE}	$L_{OFVSE1c}$	$L_{OFVSE2c}$	$L_{OFVSE3c}$	
Latest outturn of Calculated Total Payment, L_{OIR}	L_{OIR1c}	L_{OIR2c}	L_{OIR3c}	
Latest outturn of Calculated Scheme Payment, L_{OVSR}	L_{OVSR1c}	L_{OVSR2c}	L_{OVSR3c}	
Allowed Sales, based on latest outturn baseline, AS	**AS_{1c}**	**AS_{2c}**	**AS_{3c}**	**AS_{4c}**
Under Payments or Over Payments of Calculated Scheme Payment, OU	**OU_1**	**$OU_{1\text{-}2}$**	**$OU_{1\text{-}3}$**	
Adjusted forecast of growth rate of Voluntary Scheme Measured Sales, $Fa_{VS}\%$				$Fa_{VS}\%_4$
Adjusted forecast of growth rate of Statutory Scheme Measured Sales, $Fa_{SS}\%$				$Fa_{SS}\%_4$
Adjusted forecast of growth rate of Parallel Import Sales, $Fa_{PI}\%$				$Fa_{PI}\%_4$
Adjusted forecast Voluntary Scheme Measured Sales, Fa_{VS}				Fa_{VS4}
Adjusted forecast Statutory Scheme Measured Sales, Fa_{SS}				Fa_{SS4}
Adjusted forecast Parallel Import Sales, Fa_{PI}				Fa_{PI4}
Adjusted forecast Measured Sales, Fa_T				Fa_{T4}
Adjusted forecast Share of Measured Sales exempt from Eligible Sales, $Fa_{EX}\%$				$Fa_{EX}\%_4$

Adjusted forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales, VSa%				$VSa\%_4$
Adjusted forecast of Eligible Sales, Fa_{VSE}				Fa_{VSE4}
Adjusted forecast Calculated Total Payment, IRa				IRa_4
Adjusted forecast Calculated Scheme Payment, VSRa				$VSRa_4$
Payment Percentage, P%	**$P\%_1$**	**$P\%_2$**	**$P\%_3$**	**$P\%_4$**

Calculation of the Under Payments or Over Payments in year 3 given latest outturn data

59. Calculation of Latest outturn Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

For year 1 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS1c} = L_{OVS0c} * (1 + L_{OVS}\%_{1c})$

$L_{OSS1c} = L_{OSS0c} * (1 + L_{OSS}\%_{1c})$

$L_{OPI1c} = L_{OPI0c} * (1 + L_{OPI}\%_{1c})$

For year 2 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS2c} = L_{OVS1c} * (1 + L_{OVS}\%_{2c})$

$L_{OSS2c} = L_{OSS1c} * (1 + L_{OSS}\%_{2c})$

$L_{OPI2c} = L_{OPI1c} * (1 + L_{OPI}\%_{2c})$

For year 3 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS3c} = L_{OVS2c} * (1 + L_{OVS}\%_{3c})$

$L_{OSS3c} = L_{OSS2c} * (1 + L_{OSS}\%_{3c})$

$L_{OPI3c} = L_{OPI2c} * (1 + L_{OPI}\%_{3c})$

60. Calculation of the latest outturn Measured Sales for year 1, year 2 and year 3:

$$L_{OT1c} = L_{OVS1c} + L_{OSS1c} + L_{OPI1c}$$

$$L_{OT2c} = L_{OVS2c} + L_{OSS2c} + L_{OPI2c}$$

$$L_{OT3c} = L_{OVS3c} + L_{OSS3c} + L_{OPI3c}$$

61. Calculation of Allowed Sales adjusted for latest 2018 baseline outturn data:

$$AS_{1c} = (L_{OT0c} – L_{OPAY0c}) * (1 + AGR\%_{1})$$

$$AS_{2c} = AS_{1c} * (1 + AGR\%_{2})$$

$$AS_{3c}= AS_{2c} * (1 + AGR\%_{3})$$

$$AS_{4c} = AS_{3c} * (1 + AGR\%_{4})$$

62. Calculation of the latest outturn of Calculated Total Payment:

$$L_{OIR1c} = L_{OT1c} – AS_{1c}$$

$$L_{OIR2c} = L_{OT2c} – AS_{2c}$$

$$L_{OIR3c} = L_{OT3c} – AS_{3c}$$

63. Calculation of the latest outturn Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$$L_{OVS}\%_{1c} = L_{OVS1c} / L_{OT1c}$$

$$L_{OVS}\%_{2c} = L_{OVS2c} / L_{OT2c}$$

$$L_{OVS}\%_{3c} = L_{OVS3c} / L_{OT3c}$$

64. Calculation of latest outturn of Calculated Scheme Payment:

$$L_{OVSR1c} = L_{OIR1c} * L_{OVS}\%_{1c}$$

$$L_{OVSR2c} = L_{OIR2c} * L_{OVS}\%_{2c}$$

$$L_{OVSR3c} = L_{OIR3c} * L_{OVS}\%_{3c}$$

65. Calculation of the latest outturn of Eligible Sales:

$$L_{OFVSE1c} = L_{OVS1c} * (1 - L_{OFEX}\%_{1c})$$

$$L_{OFVSE2c} = L_{OVS2c} * (1 - L_{OFEX}\%_{2c})$$

$$L_{OFVSE3c} = L_{OVS3c} * (1 - L_{OFEX}\%_{3c})$$

66. Calculation of the Under Payments or Over Payments of Calculated Scheme Payments, amortised to remaining years of Voluntary Scheme:

$$OU_{1\text{-}3} = \frac{1}{2} * [L_{OVSR1c} - (L_{OFVSE1c} * P\%_1) + L_{OVSR2c} - (L_{OFVSE2c} * P\%_2) + L_{OVSR3c} - (L_{OFVSE3c} * P\%_3)]$$

The division by a factor of 2 matches the number of years left in the Voluntary Scheme.

Calculation of the year 4 Payment Percentage

67. Calculation of cumulative initial forecasts:

$$CF_{VS}\%_3 = (1 + F_{VS}\%_1) * (1 + F_{VS}\%_2) * (1 + F_{VS}\%_3)$$

$$CF_{SS}\%_3 = (1 + F_{SS}\%_1) * (1 + F_{SS}\%_2) * (1 + F_{SS}\%_3)$$

$$CF_{PI}\%_3 = (1 + F_{PI}\%_1) * (1 + F_{PI}\%_2) * (1 + F_{PI}\%_3)$$

68. Calculation of reweighted initial forecast Measured Sales growth rate:

$$RF_T\%_{1c} = \frac{CF_{VS}\%_1 * L_{OVS0c} + CF_{SS}\%_1 * L_{OSS0c} + CF_{PI}\%_1 * L_{OPI0c}}{L_{OT0c}} - 1$$

$$RF_T\%_{2c} = \frac{CF_{VS}\%_2 * L_{OVS0c} + CF_{SS}\%_2 * L_{OSS0c} + CF_{PI}\%_2 * L_{OPI0c}}{CF_{VS}\%_1 * L_{OVS0c} + CF_{SS}\%_1 * L_{OSS0c} + CF_{PI}\%_1 * L_{OPI0c}} - 1$$

$$RF_T\%_{3c} = \frac{CF_{VS}\%_3 * L_{OVS0c} + CF_{SS}\%_3 * L_{OSS0c} + CF_{PI}\%_3 * L_{OPI0c}}{CF_{VS}\%_2 * L_{OVS0c} + CF_{SS}\%_2 * L_{OSS0c} + CF_{PI}\%_2 * L_{OPI0c}} - 1$$

69. Calculation of the adjusted forecast growth rates to account for forecast error:

$$Fa_{VS}\%_4 = F_{VS}\%_4 * \left[\frac{(1 + L_{OT}\%_{1c}) * (1 + L_{OT}\%_{2c}) * (1 + L_{OT}\%_{3c}) - 1}{(1 + RF_T\%_{1c}) * (1 + RF_T\%_{2c}) * (1 + RF_T\%_{3c}) - 1}\right]$$

$$Fa_{SS}\%_4 = F_{SS}\%_4 * \left[\frac{(1 + L_{OT}\%_{1c}) * (1 + L_{OT}\%_{2c}) * (1 + L_{OT}\%_{3c}) - 1}{(1 + RF_T\%_{1c}) * (1 + RF_T\%_{2c}) * (1 + RF_T\%_{3c}) - 1}\right]$$

$$Fa_{PI}\%_4 = F_{PI}\%_4 * \left[\frac{(1 + L_{OT}\%_{1c}) * (1 + L_{OT}\%_{2c}) * (1 + L_{OT}\%_{3c}) - 1}{(1 + RF_T\%_{1c}) * (1 + RF_T\%_{2c}) * (1 + RF_T\%_{3c}) - 1}\right]$$

70. Calculation of the adjusted forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales to account for forecast error:

$$Fa_{EX}\%_4 = F_{EX}\%_4 * \frac{1}{3} * \left[\frac{L_{OFEX}\%_{1c}}{F_{EX}\%_1} + \frac{L_{OFEX}\%_{2c}}{F_{EX}\%_2} + \frac{L_{OFEX}\%_{3c}}{F_{EX}\%_3}\right]$$

The adjustment for forecast error of percentage Share of Voluntary Scheme Measured Sales exempt from Eligible Sales is an average of all years. As such it is divided by three when calculating the year 4 adjusted forecast as there are three years of outturn data available.

71. Calculation of the adjusted forecast Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales using the adjusted forecast growth rate:

$Fa_{VS4} = Lo_{VS3c} * (1 + Fa_{VS}\%_4)$

$Fa_{SS4} = Lo_{SS3c} * (1 + Fa_{SS}\%_4)$

$Fa_{PI4} = Lo_{PI3c} * (1 + Fa_{PI}\%_4)$

72. Calculation of the adjusted forecast of Measured Sales for year 4:

$Fa_{T4} = Fa_{VS4} + Fa_{SS4} + Fa_{PI4}$

73. Calculation of adjusted forecast of Calculated Total Payment:

$IRa_4 = Fa_{T4} – AS_{4c}$

74. Calculation of the adjusted forecast of Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$VSa\%_4 = Fa_{VS4} / Fa_{T4}$

75. Calculation of adjusted forecast Calculated Scheme Payment:

$VSRa_4 = IRa_4 * VSa\%_4$

76. Calculation of the adjusted forecast of Eligible Sales:

$Fa_{VSE4} = Fa_{VS4} * (1 – Fa_{EX}\%_4)$

77. Setting the year 4 Payment Percentage:

$P\%_4 = 15\%$

2023 Payment Percentage calculation

78. Calculation of the 2023 payment percentage reflects the availability of Audited/de-facto Audited and indicative outturn data.

2018	2019	2020	2021	2022	2023

Latest Outturn Data as of Q3 2022	Latest Outturn Data as of Q3 2022	Latest Outturn Data as of Q3 2022	Latest Outturn Data as of Q3 2022	Latest Outturn Data as of Q3 2022	Forecast data

	Year 0
Latest outturn payments made in respect of 2018 under the 2014 PPRS and under the Statutory Scheme, L_{OPAY}	L_{OPAY0d}
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS0d}
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS0d}
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI0d}
Latest outturn Measured Sales, L_{OT}	L_{OT0d}

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Initial forecast of growth rate of Sales of Voluntary Scheme Products, $F_{VS}\%$	$F_{VS}\%_1$	$F_{VS}\%_2$	$F_{VS}\%_3$	$F_{VS}\%_4$	$F_{VS}\%_5$
Initial forecast of growth rate of Statutory Scheme Measured Sales, $F_{SS}\%$	$F_{SS}\%_1$	$F_{SS}\%_2$	$F_{SS}\%_3$	$F_{SS}\%_4$	$F_{SS}\%_5$
Initial forecast of growth rate of Parallel Import Sales, $F_{PI}\%$	$F_{PI}\%_1$	$F_{PI}\%_2$	$F_{PI}\%_3$	$F_{PI}\%_4$	$F_{PI}\%_5$

	Year 1	Year 2	Year 3	Year 4	Year 5
Reweighted initial forecast Measured Sales growth rate (adjusted for latest baseline outturns), $RF_T\%$	$RF_T\%_{1d}$	$RF_T\%_{2d}$	$RF_T\%_{3d}$	$RF_T\%_{4d}$	$RF_T\%_{5d}$
Latest outturn Voluntary Scheme Measured Sales growth rate, $L_{OVSGR}\%$	$L_{OVSGR}\%_{1d}$	$L_{OVSGR}\%_{2d}$	$L_{OVSGR}\%_{3d}$	$L_{OVSGR}\%_{4d}$	
Latest outturn Statutory Scheme Measured Sales growth rate, $L_{OSSGR}\%$	$L_{OSSGR}\%_{1d}$	$L_{OSSGR}\%_{2d}$	$L_{OSSGR}\%_{3d}$	$L_{OSSGR}\%_{4d}$	
Latest outturn Parallel Import Sales growth rate, $L_{OPIGR}\%$	$L_{OPIGR}\%_{1d}$	$L_{OPIGR}\%_{2d}$	$L_{OPIGR}\%_{3d}$	$L_{OPIGR}\%_{4d}$	
Latest outturn Voluntary Scheme Measured Sales, L_{OVS}	L_{OVS1d}	L_{OVS2d}	L_{OVS3d}	L_{OVS4d}	
Latest outturn Statutory Scheme Measured Sales, L_{OSS}	L_{OSS1d}	L_{OSS2d}	L_{OSS3d}	L_{OSS4d}	
Latest outturn Parallel Import Sales, L_{OPI}	L_{OPI1d}	L_{OPI2d}	L_{OPI3d}	L_{OPI4d}	
Latest outturn Measured Sales, L_{OT}	L_{OT1d}	L_{OT2d}	L_{OT3d}	L_{OT4d}	

Latest outturn of Voluntary Scheme Measured Sales as a percentage of Measured Sales, $L_{OVS}\%$	$L_{OVS}\%_{1d}$	$L_{OVS}\%_{2d}$	$L_{OVS}\%_{3d}$	$L_{OVS}\%_{4d}$	
Initial forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $F_{EX}\%$	$F_{EX}\%_1$	$F_{EX}\%_2$	$F_{EX}\%_3$	$F_{EX}\%_4$	$F_{EX}\%_5$

Latest outturn of Share of Voluntary Scheme Measured Sales exempt from Eligible Sales, $L_{OFEX}\%$	$L_{OFEX}\%_{1d}$	$L_{OFEX}\%_{2d}$	$L_{OFEX}\%_{3d}$	$L_{OFEX}\%_{4d}$	
Latest outturn of Eligible Sales, L_{OFVSE}	$L_{OFVSE1d}$	$L_{OFVSE2d}$	$L_{OFVSE3d}$	$L_{OFVSE4d}$	
Latest outturn of Calculated Total Payment, L_{OIR}	L_{OIR1d}	L_{OIR2d}	L_{OIR3d}	L_{OIR4d}	
Latest outturn of Calculated Scheme Payment, L_{OVSR}	L_{OVSR1d}	L_{OVSR2d}	L_{OVSR3d}	L_{OVSR4d}	
Allowed Sales, based on latest outrun baseline, AS	**AS_{1d}**	**AS_{2d}**	**AS_{3d}**	**AS_{4d}**	**AS_{5d}**
Under Payments or Over Payments of Calculated Scheme Payment, OU	**OU_{1}**	**OU_{1-2}**	**OU_{1-3}**	**OU_{1-4}**	
Adjusted forecast of the growth rate of Voluntary Scheme Measured Sales, $Fa_{VS}\%$					$Fa_{VS}\%_{5}$
Adjusted forecast of the growth rate of Statutory Scheme Measured Sales, $Fa_{SS}\%$					$Fa_{SS}\%_{5}$
Adjusted forecast of the growth rate of Parallel Import Sales, $Fa_{PI}\%$					$Fa_{PI}\%_{5}$
Adjusted forecast Voluntary Scheme Measured Sales, Fa_{VS}					Fa_{VS5}
Adjusted forecast Statutory Scheme Measured Sales, Fa_{SS}					Fa_{SS5}
Adjusted forecast Parallel Import Sales, Fa_{PI}					Fa_{PI5}

Adjusted forecast Measured Sales, Fa_T					Fa_{T5}
Adjusted forecast Share of Measured Sales exempt from Eligible Sales, $Fa_{EX}\%$					$Fa_{EX}\%_5$
Adjusted forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales, VSa%					$VSa\%_5$
Adjusted forecast Eligible Sales, Fa_{VSE}					Fa_{VSE5}
Adjusted forecast Calculated Total Payment, IRa					IRa_5
Adjusted forecast Calculated Scheme Payment, VSRa					$VSRa_5$
Payment Percentage, P%	**$P\%_1$**	**$P\%_2$**	**$P\%_3$**	**$P\%_4$**	**$P\%_5$**

Calculation of the Under Payments or Over Payments in year 4 given latest outturn data

79. Calculation of the adjusted forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales to account for forecast error:

For year 1 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS1d} = L_{OVS0d} * (1 + L_{OVS}\%_{1d})$

$L_{OSS1d} = L_{OSS0d} * (1 + L_{OSS}\%_{1d})$

$L_{OPI1d} = L_{OPI0d} * (1 + L_{OPI}\%_{1d})$

For year 2 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS2d} = L_{OVS1d} * (1 + L_{OVS}\%_{2d})$

$L_{OSS2d} = L_{OSS1d} * (1 + L_{OSS}\%_{2d})$

$L_{OPI2d} = L_{OPI1d} * (1 + L_{OPI}\%_{2d})$

For year 3 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS3d} = L_{OVS2d} * (1 + L_{OVS}\%_{3d})$

$L_{OSS3d} = L_{OSS2d} * (1 + L_{OSS}\%_{3d})$

$L_{OPI3d} = L_{OPI2d} * (1 + L_{OPI}\%_{3d})$

For year 4 Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales:

$L_{OVS4d} = L_{OVS3d} * (1 + L_{OVS}\%_{4d})$

$L_{OSS4d} = L_{OSS3d} * (1 + L_{OSS}\%_{4d})$

$L_{OPI4d} = L_{OPI3d} * (1 + L_{OPI}\%_{4d})$

80. Calculation of the latest outturn Measured Sales for year 1, year 2, year 3 and year 4:

$L_{OT1d} = L_{OVS1d} + L_{OSS1d} + L_{OPI1d}$

$L_{OT2d} = L_{OVS2d} + L_{OSS2d} + L_{OPI2d}$

$L_{OT3d} = L_{OVS3d} + L_{OSS3d} + L_{OPI3d}$

$L_{OT4d} = L_{OVS4d} + L_{OSS4d} + L_{OPI4d}$

81. Calculation of Allowed Sales adjusted for latest 2018 baseline outturn data:

$AS_{1d} = (L_{OT0d} – L_{OPAY0d}) * (1 + AGR\%_{1})$

$AS_{2d} = AS_{1d} * (1 + AGR\%_{2})$

$AS_{3d}= AS_{2d} * (1 + AGR\%_{3})$

$AS_{4d} = AS_{3d} * (1 + AGR\%_{4})$

$AS_{5d} = AS_{4d} * (1 + AGR\%_{5})$

82. Calculation of the latest outturn of Calculated Total Payment:

$L_{OIR1d} = L_{OT1d} – AS_{1b}$

$L_{OIR2d} = L_{OT2d} – AS_{2b}$

$L_{OIR3d} = L_{OT3d} – AS_{3b}$

$L_{OIR4d} = L_{OT4d} – AS_{4b}$

83. Calculation of the latest outturn Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$$L_{OVS}\%_{1d} = L_{OVS1d} / L_{OT1d}$$

$$L_{OVS}\%_{2d} = L_{OVS2d} / L_{OT2d}$$

$$L_{OVS}\%_{3d} = L_{OVS3d} / L_{OT3d}$$

$$L_{OVS}\%_{4d} = L_{OVS4d} / L_{OT4d}$$

84. Calculation of the latest outturn of Calculated Scheme Payment:

$$L_{OVSR1d} = L_{OIR1d} * L_{OVS}\%_{1d}$$

$$L_{OVSR2d} = L_{OIR2d} * L_{OVS}\%_{2d}$$

$$L_{OVSR3d} = L_{OIR3d} * L_{OVS}\%_{3d}$$

$$L_{OVSR4d} = L_{OIR4d} * L_{OVS}\%_{4d}$$

85. Calculation of the latest outturn of Eligible Sales:

$$L_{OFVSE1d} = L_{OVS1d} * (1 - L_{OFEX}\%_{1d})$$

$$L_{OFVSE2d} = L_{OVS2d} * (1 - L_{OFEX}\%_{2d})$$

$$L_{OFVSE3d} = L_{OVS3d} * (1 - L_{OFEX}\%_{3d})$$

$$L_{OFVSE4d} = L_{OVS4d} * (1 - L_{OFEX}\%_{4d})$$

86. Calculation of the Under Payments or Over Payments of Calculated Scheme Payments, amortised to remaining years of the Voluntary Scheme:

$$OU_{1\text{-}4} = L_{OVSR1d} – (L_{OFVSE1d} * P\%_1) + L_{OVSR2d} – (L_{OFVSE2d} * P\%_2) + L_{OVSR3d} - (L_{OFVSE3d} * P\%_3) + L_{OVSR4d} - (L_{OFVSE4d} * P\%_4)$$

Calculation of the year 5 Payment Percentage

87. Calculation of cumulative initial forecasts:

$$CF_{VS}\%_4 = (1 + F_{VS}\%_1) * (1 + F_{VS}\%_2) * (1 + F_{VS}\%_3) * (1 + F_{VS}\%_4)$$

$$CF_{SS}\%_4 = (1 + F_{SS}\%_1) * (1 + F_{SS}\%_2) * (1 + F_{SS}\%_3) * (1 + F_{SS}\%_4)$$

$$CF_{PI}\%_4 = (1 + F_{PI}\%_1) * (1 + F_{PI}\%_2) * (1 + F_{PI}\%_3) * (1 + F_{PI}\%_4)$$

88. Calculation of reweighted initial forecast Measured Sales growth rate:

$$RF_T\%_{1d} = \frac{CF_{VS}\%_1 * L_{OVS0d} + CF_{SS}\%_1 * L_{OSS0d} + CF_{PI}\%_1 * L_{OPI0d}}{L_{OT0d}} - 1$$

$$RF_T\%_{2d} = \frac{CF_{VS}\%_2 * L_{OVS0d} + CF_{SS}\%_2 * L_{OSS0d} + CF_{PI}\%_2 * L_{OPI0d}}{CF_{VS}\%_1 * L_{OVS0d} + CF_{SS}\%_1 * L_{OSS0d} + CF_{PI}\%_1 * L_{OPI0d}} - 1$$

$$RF_T\%_{3d} = \frac{CF_{VS}\%_3 * L_{OVS0d} + CF_{SS}\%_3 * L_{OSS0d} + CF_{PI}\%_3 * L_{OPI0d}}{CF_{VS}\%_2 * L_{OVS0d} + CF_{SS}\%_2 * L_{OSS0d} + CF_{PI}\%_2 * L_{OPI0d}} - 1$$

$$RF_T\%_{4d} = \frac{CF_{VS}\%_4 * L_{OVS0d} + CF_{SS}\%_4 * L_{OSS0d} + CF_{PI}\%_4 * L_{OPI0d}}{CF_{VS}\%_3 * L_{OVS0d} + CF_{SS}\%_3 * L_{OSS0d} + CF_{PI}\%_3 * L_{OPI0d}} - 1$$

89. Calculation of the adjusted forecast growth rates to account for forecast error:

$$Fa_{VS}\%_5 = F_{VS}\%_5 * \left[\frac{(1 + L_{OT}\%_{1d}) * (1 + L_{OT}\%_{2d}) * (1 + L_{OT}\%_{3d}) * (1 + L_{OT}\%_{4d}) - 1}{(1 + RF_T\%_{1d}) * (1 + RF_T\%_{2d}) * (1 + RF_T\%_{3d}) * (1 + RF_T\%_{4d}) - 1}\right]$$

$$Fa_{SS}\%_5 = F_{SS}\%_5 * \left[\frac{(1 + L_{OT}\%_{1d}) * (1 + L_{OT}\%_{2d}) * (1 + L_{OT}\%_{3d}) * (1 + L_{OT}\%_{4d}) - 1}{(1 + RF_T\%_{1d}) * (1 + RF_T\%_{2d}) * (1 + RF_T\%_{3d}) * (1 + RF_T\%_{4d}) - 1}\right]$$

$$Fa_{PI}\%_5 = F_{PI}\%_5 * \left[\frac{(1 + L_{OT}\%_{1d}) * (1 + L_{OT}\%_{2d}) * (1 + L_{OT}\%_{3d}) * (1 + L_{OT}\%_{4d}) - 1}{(1 + RF_T\%_{1d}) * (1 + RF_T\%_{2d}) * (1 + RF_T\%_{3d}) * (1 + RF_T\%_{4d}) - 1}\right]$$

90. Calculation of the adjusted forecast Share of Voluntary Scheme Measured Sales exempt from Eligible Sales to account for forecast error:

$$Fa_{EX}\%_5 = F_{EX}\%_5 * \frac{1}{4} * \left[\frac{L_{OFEX}\%_{1d}}{F_{EX}\%_1} + \frac{L_{OFEX}\%_{2d}}{F_{EX}\%_2} + \frac{L_{OFEX}\%_{3d}}{F_{EX}\%_3} + \frac{L_{OFEX}\%_{4d}}{F_{EX}\%_4}\right]$$

The adjustment for forecast error of percentage Share of Voluntary Scheme Measured Sales exempt from Eligible Sales is an average of all years. As such it is divided by four when calculating the year 5 adjusted forecast as there are four years of outturn data available.

91. Calculation of the adjusted forecast Voluntary Scheme Measured Sales, Statutory Scheme Measured Sales and Parallel Import Sales is calculated from the adjusted forecast growth rate:

$$Fa_{VS5} = L_{OVS4d} * (1 + Fa_{VS}\%_5)$$

$$Fa_{SS5} = L_{OSS4d} * (1 + Fa_{SS}\%_5)$$

$$Fa_{PI5} = L_{OPI4d} * (1 + Fa_{PI}\%_5)$$

92. Calculation of the adjusted forecast of Measured Sales for year 5:

$$Fa_{T5} = Fa_{VS5} + Fa_{SS5} + Fa_{PI5}$$

93. Calculation of adjusted forecast of Calculated Total Payment:

$$IRa_5 = Fa_{T5} – AS_{5d}$$

94. Calculation of the adjusted forecast of Voluntary Scheme Measured Sales as a percentage of Measured Sales:

$$VSa\%_5 = Fa_{VS5} / Fa_{T5}$$

95. Calculation of adjusted forecast Calculated Scheme Payment:

$$VSRa_5 = IRa_5 * VSa\%_5$$

96. Calculation of the adjusted forecast of Eligible Sales:

$$Fa_{VSE5} = Fa_{VS5} * (1 – Fa_{EX}\%_5)$$

97. Calculation of the year 5 Payment Percentage:

$$P\%_5 = (VSRa_5 + OU_{1-4}) / Fa_{VSE5}$$

End of scheme reconciliation

98. When outturn data for the period of the Voluntary Scheme has been received in 2024, the Under Payments or Over Payments will be recalculated for each year, and a revised 2023 Payment Percentage calculated. This will be done using the same methodology for setting the original 2023 Payment Percentage – however it will be based solely on outturn data rather than a combination of outturn and adjusted forecast data, and will be to two decimal places rather than one decimal place.

99. Equally when the outturn data for the period of the Voluntary Scheme has been received in 2025, the above methodology will be repeated to arrive at a final 2023 Payment Percentage, and calculation of any required additional payments or refunds.

Annex 6: Guidance Notes on Completion of Quarterly Sales Reports, Annual Sales Reports and Auditing Requirements

General

1. This Annex 6 sets out guidance on the completion of Quarterly Sales Reports, unaudited Annual Sales Reports and Audited Annual Sales Reports.

2. The sales reports must show how the reported Sales, Sales of Scheme Products covered by the Scheme Payment, Measured Sales, Eligible Sales and any adjustments reported relate to turnover set out in the Scheme Member's statutory accounts submitted under the Companies Act 2006 (Audited Annual Sales Report) or underlying accounting records.

3. This guidance covers the Quarterly Sales Reports and Annual Sales Reports. It also includes the reporting requirements for Small Companies (paragraphs 26 to 28 of this Annex 6) and Medium Sized Companies (paragraphs 29 to 32 of this Annex 6).

Quarterly Sales Reports

4. The Quarterly Sales Reports should be used by Scheme Members to calculate the Scheme Payment for each Quarter. The Quarterly Sales Report will be available on-line through the Branded Medicines Portal (BMP) and separate guidance will be issued for use of the on-line system as well as elsewhere in this Annex 6. The structure of this report can be found at Appendix 1. The on-line report may look slightly different but the content is substantively the same. A payment (electronic transfer) should be completed at the same time as each Quarterly Sales Report is provided.

5. The Quarterly Sales Report should be accompanied by the Scheme Member's Declaration as set out in Appendix 2.

6. Scheme Members with Sales of Scheme Products below £5m are not required to complete a Quarterly Sales Report. Please see paragraphs 26 to 28 of this Annex 6 on reporting for Small Companies.

Annual Sales Reports

7. The structure of the Annual Sales Report can be found at Appendix 3. The on-line report may look slightly different but the content is substantively the same.

8. All Scheme Members with Sales of Scheme Products of more than £1m and less than £5m will be required to submit an unaudited Annual Sales Report (see paragraphs 26 to 28 of this Annex 6).

9. All Scheme Members with Sales of Scheme Products of £5m or more will be required to submit an Audited Annual Sales Report (see paragraphs 44 to 53 of this Annex 6) together with the Audit Report in accordance with the requirements for Audit (Appendix 4) and a Scheme Member's Declaration (Appendix 2).

10. The Audited Annual Sales Report must be submitted within nine (9) months of the end of the Scheme Member's Financial Year, following the Audit of the Scheme Member's statutory accounts.

Defining Sales of Scheme Products & Exclusions

11. The definition of Scheme Products is set out in Chapter 2 and the Glossary.

12. The Quarterly Sales Report and Annual Sales Report start with the total Scheme Member's turnover. The turnover figure at line 1 of the Sales Report is based on:

- Management accounts for Quarterly Sales Reports;
- Statutory accounts or supporting notes of the applicable UK company statutory accounts for Annual Sales Reports;
- The Sales Report then deducts the following exclusions and exemptions to arrive at a net sales value for calculating the Scheme Payment:
  - Customer Exclusions;
  - Product Exclusions;
  - Non-UK Sales of Branded Prescription Only Medicines;
  - Sales of Scheme Products by the Scheme Member relating to Exceptional Central Procurements (see Glossary);
  - Sales of Scheme Products by the Scheme Member relating to Centrally Procured Vaccines (see Glossary);
  - Low Value Sales (see Glossary);
  - NAS Sales (see Glossary);
  - Medium Sized Company exemption.

Pharmaceutical Turnover

13. The Scheme Member must report all Sales of Branded Health Service Medicines (calculated net of all discounts) as set out in Chapter 2 for the period being reported on.

14. The sales report (line 1) must reconcile to the turnover in the Scheme Member's accounts.

15. Line 2 of the Sales Report should state Sales of unlicensed medicines in the UK (specials), being Sales of Special Medicinal Products within the meaning of regulation 167 of The Human Medicines Regulations 2012. A licensed medicine used outside the terms of its licence (often referred to as 'off label use') does not fall within the meaning of regulation 167 of The Human Medicines Regulations 2012. Accordingly, Sales relating to 'off label use' of a licensed medicine should be included in line 14 and not included in line 2 of the Sales Report.

16. If the Scheme Payment is recognised in the statutory or management accounts as a reduction in turnover it needs to be added back into the sales report (line 4) to arrive at the net sales value that is used to calculate the Measured Sales and the Eligible Sales used to calculate the Scheme Payment.

Customer Exclusions (line 6)

17. The Voluntary Scheme does not apply to sales to non-NHS customers. For example:

    - Supply of medicines on private prescription or other use outside the NHS;
    - Private hospitals;
    - Over the Counter (OTC) sales;
    - Other private medicine sales – for example flu vaccines sold to retailers;
    - Ministry of Defence;
    - Clinical trial companies;
    - Contract manufacturers;
    - Other non-health service concerns such as cruise and holiday companies, occupational health practices or veterinary practices.

18. The category of non-health service customers does not apply where service is provided by private or third sector providers for the NHS or for public health functions e.g. homecare providers.

19. Where a Branded P&GSL Medicine is provided on an NHS prescription, the Department may exercise its discretion to exclude sales of such medicine from the

Voluntary Scheme where total NHS prescription sales of a Presentation in any calendar year within the duration of the Voluntary Scheme amount to less than £50,000.

Product Exclusions

20. Product exclusions cover other medicinal product categories as set out in Chapter 2 and including:

- Unbranded generic medicines/dental anaesthetics (line 8);
- Parallel Import Sales (line 9).

The MHRA or EMA marketing authorisation/SPC states the product category. Other sources of information to determine product category include the British National formulary (BNF), the Prescription Cost Analysis (PCA) and the prescription drugs database IQVIA.

Non-UK Sales of Branded POMs Exclusions (line 11)

21. Non-UK Sales include:

- Sales to markets outside of the UK, including the Channel Islands and the Isle of Man. The UK legal entity could cover a wider geographical area than the UK, for example the UK and Ireland, so non-UK sales need to be identified and excluded;
- Direct exports from the UK to third parties;
- Direct exports from the UK to affiliated companies;
- Parallel export sales which are sold by the UK entity but are not reimbursed by the NHS.

(see paragraphs 33 to 38 of this Annex 6 for more details).

Exemptions from Measured Sales (and Eligible Sales)

22. The following Sales are exempt from Measured Sales and therefore Eligible Sales:

- Sales of Scheme Products by a Scheme Member relating to Exceptional Central Procurements (line 15) (see Glossary);
- Sales of Scheme Products by a Scheme Member relating to Centrally Procured Vaccines (line 16) (see Glossary); and
- Low Value Sales (line 17) (see Glossary).

Exemptions from Eligible Sales

23. The following are exempt from Eligible Sales are deducted to arrive at a net sales value for calculating the Scheme Payment:

    - NAS Sales (line 20); and
    - Medium Sized Company exemption (line 21).

Deadlines

24. The Quarterly Sales Report for each Quarter will be required no later than one (1) month after the Quarter end and is therefore due as follows:

    - Q1: January-March is due no later than 30 April
    - Q2: April-June is due no later than 31 July
    - Q3: July-September is due no later than 31 October
    - Q4: October to December is due no later than 31 January of the following calendar year

25. Scheme Members with a Financial Year that does not end on the last calendar day of a Quarter will be required to provide two unaudited returns in place of the Quarterly Sales Report for the Quarter that overlaps the Scheme Member's Financial Year end. The unaudited returns must comply with the requirements of the Quarterly Sales Reports in terms of content and it is acknowledged that, while the content of each unaudited return may only cover a portion of the period of the relevant Quarter, together the two unaudited returns must cover the whole of the period of the relevant Quarter. (Scheme Members with a Financial Year that does not end on the last calendar day of a Quarter are still required to submit one Audited Annual Sales Return relating to the relevant calendar year). For example where a company has a Financial Year ending 30 November, it will be required to complete five unaudited sales reports for the calendar year due as follows:

    - Q1: January-March is due no later than 30 April
    - Q2: April-June is due no later than 31 July
    - Q3: July-September is due no later than 31 October
    - Q4: October – November, and

then December only. Both are due no later than 31 January of the following calendar year.

Reporting by Small Companies

26. Scheme Members with Sales of Scheme Products of more than £1m and less than £5m in the previous calendar year will be required to submit an unaudited Annual Sales Report for that calendar year as set out in the guidance above.

27. Scheme Members with Sales of Scheme Products of less than £1m must submit a Scheme Member's Declaration on the value of their Sales.

28. Refer to Chapter 4 for further information on Small Companies.

Reporting by Medium Sized Companies

29. Scheme Members with Sales of Scheme Products of £5m or over but under £25m will have their first £5m of Sales (excluding NAS Sales) exempt from the assessment of Eligible Sales. Refer to Chapter 4 for full details on the requirements for Medium Sized Companies.

30. Medium Sized Companies will have the first £5 million of their Measured Sales exempt from the Scheme Payment. Where Medium Sized Companies have NAS Sales, these will be excluded from Measured Sales before the Medium Sized Company exemption is applied.

31. The Audited Annual Sales Report will calculate the value of the exemption and apply it at line 21.

32. The Quarterly Sales Report uses a different approach. The first Quarter of the calendar year sets the exemption at its maximum level of £5 million. A company will receive up to the maximum level of the exemption depending on the level of its Measured Sales (excluding NAS Sales) in the first Quarter. Any remainder of the exemption will be carried over to the next Quarter and so on for subsequent Quarters until the exemption has been exhausted for that calendar year. The value of the exemption in each Quarter will appear at line 21 of the Quarterly Sales Report.

Methodology for Calculations

33. There are certain calculations that need to be made where reliance is placed on data sources other than the Scheme Member's underlying accounting records. The following methodologies are recommended to help ensure that sales reports are as accurate as possible and within the materiality levels outlined in paragraph 49 of this Annex 6.

34. Scheme Members may consider that they have a more precise methodology. If that is the case then an individual Scheme Member should agree an alternative methodology

with the Department in writing so that it can form part of the audit trail. The Auditor must confirm this methodology has been reviewed as part of the Audit.

35. Parallel exports – can be identified in several ways including IQVIA or PCA data versus ex-factory comparisons, irregular retail pharmacy ordering patterns and specific information from overseas affiliates. Depending on what distribution arrangements are in place companies may also have visibility of customer stock movements. Where possible parallel export units should be supported by the Scheme Member's accounting and supply chain records. Where IQVIA or PCA data is used Scheme Members should compare available year to date IQVIA or PCA units with ex-factory units for the same period. Given the time delay in receiving IQVIA and PCA data there will be a timing difference in Quarterly Sales Reports but this can be corrected for in the Audited Annual Sales Report which has a nine (9) month deadline. Scheme Members should ignore parallel export adjustments if they cannot provide a clear audit trail using company records and IQVIA or PCA data.

36. OTC prescription sales – if there is evidence that some OTC units are prescribed then companies should use either the latest available IQVIA or PCA data to calculate the percentage of OTC sales that are prescribed and therefore reimbursed by the NHS. This may result in an adjustment in the Audited Annual Sales Report versus the sum of the four Quarters if the amount is material.

37. Private medicine sales – if there is evidence that such sales are being sold privately and are therefore not reimbursed by the NHS, for example flu vaccines sold to retailers, then these sales should be excluded. Where possible private medicine sales should be supported by the Scheme Member's accounting and supply chain records. Alternatively, latest available IQVIA or PCA data should be compared with ex-factory data to calculate the value of non-NHS sales.

38. Adjustments that rely on third party information and an agreed methodology should be disclosed in the Scheme Member's accounting policies.

Procedures for Payment

39. The Quarterly Sales Report should be used by Scheme Members to calculate the Scheme Payment. Scheme Payments must be paid in Quarterly instalments by individual Scheme Members at the same time as the Quarterly Sales Reports are submitted. Payment and Quarterly Sales Reports will be due within one (1) month of the end of each Quarter.

40. To assist the Department's accounting procedures, Scheme Payments should be made separately from any other payments made to the Department (e.g. HCPs). For all payments to the Department, Scheme Members should include detailed remittance

information. This should include, but not be restricted to the invoice number, description and the payment reference found on the Sales report.

41. Any differences between the Scheme Payment made by an individual Scheme Member on account of the Quarterly Sales Reports and the actual Scheme Payment due following the submission of the Audited Annual Sales Report must be corrected. Any amounts owed by either the Department or the Scheme Member as a result will be settled as a separate payment and not set off against other Scheme Payments, whether past or future, unless otherwise agreed with the Department.

Other guidance

42. Co-promotions - Scheme Members should agree in advance who is going to report sales in any co-promotion arrangements and disclose in accounting policies.

43. These guidance notes may be updated from time to time by way of a supplementary note, if further information comes to light that would help improve the accuracy of the sales reports.

Audited Annual Sales Report

44. At the end of each Financial Year a Scheme Member must submit an Audited Annual Sales Report within nine (9) months of the end of the Scheme Member's Financial Year end. For companies with a Financial Year end of 31 December the deadline is therefore 30 September in the following year.

45. The “Turnover per audited Statutory Accounts” figure included in the Audited Annual Sales Report must be included in the primary statements or supporting notes of the applicable Scheme Member’s statutory accounts. The Scheme Member’s statutory accounts should be submitted with the Audited Annual Sales Report.

46. The Audited Annual Sales Report (line 1) must reconcile to the turnover in the Scheme Member’s statutory accounts. The Auditor of the statutory accounts should also Audit the Audited Annual Sales Report unless it has been agreed otherwise with the Department.

47. The Audited Annual Sales Report must be accompanied by an Audit Report as set out below in Appendix 4. This Audit Report must provide a Reasonable Assurance opinion in an agreed form (below) and reported for each calendar year of sales applicable to the Voluntary Scheme including the baseline calendar year sales (2018).

48. The Audit must confirm how the reported Sales, Sales of Scheme Products covered by the Scheme Payment, Measured Sales and Eligible Sales and any adjustments align

with the Audited Annual Sales Report and reconcile to the sales figures set out in the Scheme Member's statutory accounts submitted under the Companies Act 2006.

49. As part of the Audit contract with the Scheme Member, the Auditor must include the following terms in relation to the Audit engagement:

- Materiality as per statutory Audit, provided it is in the range of 0.5%-1.2% of turnover. In the event that:
  - Materiality used for the statutory Audit is in this range it can therefore be used;
  - Materiality used for the statutory Audit is above this range 1.2% of turnover is to be used (to ensure sufficient Auditing of the sales report);
  - Materiality used for the statutory Audit is below this range 0.5% of turnover is to be used (to avoid expensive over Auditing of the sales report);
- De minimis reporting threshold set at 10% of materiality;
- Each Scheme Member will pay all Audit fees in respect of any Audits undertaken as part of the Voluntary Scheme in order to comply with the requirements of the Voluntary Scheme and reasonable requests from the Department;
- Audit plan (including details of materiality and reporting timetable) and report to those charged with governance (including an update on the materiality used and any unadjusted errors) to be provided to the Department at the same time they are provided to the Scheme Member.

50. This guidance does not override applicable accounting or Auditing standards.

51. Any differences between the Scheme Payment by an individual Scheme Member derived from the Quarterly Sales Reports and Audited Annual Sales Report must be corrected following the Audit. Any amounts owed by either the Department or the Scheme Member as a result will be settled as a separate payment and not set off against other, whether past or future, Scheme Payments, unless otherwise agreed with the Department.

52. The Audited Annual Sales Report should be accompanied by an Audit Report as set out below. The format of this report should not be amended.

53. If an Auditor provides a qualified opinion, the Department may at its discretion use the administrative data available to define Sales of Scheme Products for that Scheme Member.

Submission on the Portal

54. Following the submission of the return on the relevant Portal, Scheme Members will also need to provide the following documents to the Department:

- Scheme Member's Declaration (Appendix 2);
- Audit Report – Audited Annual Sales Report (Appendix 4);
- Scanned version of the sales report verified by the Auditor at the foot of the report – downloadable from the portal;
- Scheme Member's Audited statutory accounts for the period, which also form the basis of the return.

Independent Third Party

55. All Quarterly Sales Reports and Annual Sales Reports should also be submitted by Scheme Members to BDO LLP, the independent third party appointed by the ABPI (or such other firm as the ABPI may appoint from time to time, subject to the Department's reasonable right of veto).

Appendix 1: Quarterly Sales Report

2019 Voluntary Scheme for Branded Medicines Pricing and Access

Sales Report — Unaudited Quarterly

Report Completion Date	
Accounting Period	
Payment Reference	

Company:	
Company Reference:	
Medium-Sized Company:	Yes/No
Medium-Company Exemption Carried-Forward:	£0

Payment Required [3]:	0.00%	£0

	Line No.	£'000
TURNOVER PER MANAGEMENT ACCOUNTS (Unaudited Return) (net of any Scheme Payments and Historic Cash Payments if appropriate)	1	0
Sales of unlicensed medicines (specials) in the UK [1]	2	0
Less non-pharmaceutical sales [2]	3	0
Add Back Scheme Payment (as appropriate) [3]	4	0
PHARMACEUTICAL TURNOVER (line 1 - line 2 - line 3 + line 4)	5	0

	Line No.	£'000
LESS EXCLUSIONS		
Customer Exclusions		
For example: private medicine sales [4]; sales to the MOD; sales used for clinical trials; non-prescription OTC sales	6	0
Total Customer Exclusions (line 6)	7	0
Product Exclusions		
Unbranded Generic Medicines; Dental Anaesthetics	8	0
Parallel Import Sales [5]	9	0
Total Product Exclusions (line 8 + line 9)	10	0
Non-UK Sales of Branded POMs		
For example: sales in markets outside of the UK via direct exports; parallel exports [4]	11	0
Total Non-UK Sales of Branded POMs (line 11)	12	0
TOTAL EXCLUSIONS (line 7 + line 10 + line 12)	13	0
TOTAL SALES OF SCHEME PRODUCTS (line 5 - line 13)	14	0

LESS EXEMPTIONS		
Exemptions from Voluntary Scheme Measured Sales (and Eligible Sales)		
Sales of Scheme Products relating to Exceptional Central Procurements [5]	15	0
Sales of Scheme Products relating to Centrally Procured Vaccines [5]	16	0
Low Value Sales [5]	17	0
Total Exemptions From Voluntary Scheme Measured Sales (and Eligible Sales) (line 15 + line 16 + line 17)	**18**	0
VOLUNTARY SCHEME MEASURED SALES (line 14 - line 18)	**19**	0
Exemptions from Eligible Sales		
New Active Substance Sales [5]	20	0
Medium-Sized Company Exemption	21	0
Total Exemptions From Eligible Sales (line 20 + line 21)	**22**	0
ELIGIBLE SALES (line 19 - line 22)	**23**	0
SCHEME PAYMENT REQUIRED ON ELIGIBLE SALES at Line 23	**24**	0
Department of Health and Social Care Adjustment	**25**	0
TOTAL SCHEME PAYMENT (Line 24 + Line 25)	**26**	0

Comments:

Notes:

[1] Sales of Special Medicinal Products (within the meaning of regulation 167 of The Human Medicines Regulations 2012) in the UK.
[2] Sales of products other than licensed medicines and specials sold in the UK.
[3] The Scheme Payment is rounded to the nearest £1,000. Where a Scheme Payment has been netted off of Turnover (line 1) in this period, only the netted off amount should be added back at line 3.
[4] Adjustments that rely on third party information and an agreed method to be disclosed separately.
[5] Definitions are contained in the Scheme Glossary.

Appendix 2: Scheme Member Declaration – Sales Report

Statement of directors' responsibilities

The directors are responsible for complying with the Voluntary Scheme and for designing, implementing and maintaining systems and controls which enable their preparing the [Quarterly Sales Report] OR [unaudited Annual Sales Report] OR [Audited Annual Sales Report] [*to delete as applicable*] in accordance with the basis of preparation and accounting policies in [note 1 below] and the guidance notes in Annex 6 of the Voluntary Scheme. The directors must not approve the [Quarterly Sales Report] OR [unaudited Annual Sales Report] OR [Audited Annual Sales Report] unless they are satisfied that they have been properly prepared, in all material respects, in accordance with the basis of preparation and accounting policies in [note 1] to this statement (Appendix 2: Scheme Member's Declaration).

In preparing the [Quarterly Sales Report] OR [unaudited Annual Sales Report] OR [Audited Annual Sales Report] the directors have:

- selected suitable accounting policies and then applied them consistently;
- made judgements and accounting estimates that are reasonable and prudent;
- stated the basis of preparation and accounting polices applied;
- prepared the [Quarterly Sales Report] OR [unaudited Annual Sales Report] OR [Audited Annual Sales Report] on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the company's transactions and disclose with reasonable accuracy at any time the financial position of the company. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

[Quarterly Sales Report sign off

The Quarterly Sales Report for the quarter ended [insert quarter-end] was approved by the board of directors on [insert date] and signed on their behalf by:

[Insert name] [Director]]

OR

[Unaudited Annual Sales Report] OR [Audited Annual Sales Report sign off]

The [unaudited Annual Sales Report] OR [Audited Annual Sales Report] for the year ended [insert year-end] was approved by the board of directors on [insert date] and signed on their behalf by:

[insert name] [Director]]

Note 1

Basis of preparation of the [Quarterly Sales Report] OR [unaudited Annual Sales Report] OR [Audited Annual Sales Report]

[insert details of the basis of preparation e.g. The schedule has been prepared in accordance with the Voluntary Scheme and the Guidance Notes in Annex 6 to the Voluntary Scheme.

Accounting policies

[insert details of accounting policies used in preparing the schedule, including details of any estimates and source data used in these estimates and confirmation that the revenue recognition policy is consistent with the statutory accounts].

Appendix 3: Annual Sales Report

2019 Voluntary Scheme for Branded Medicines Pricing and Access

Sales Report — Annual

Report Completion Date	
Accounting Period	
Payment Reference	

Company:	
Company Reference:	
Medium-Sized Company:	Yes/No

Payment Required[3]**:**	0.00%	£0

	Line No.	£'000
TURNOVER PER STATUTORY ACCOUNTS (net of any Scheme Payments and Historic Cash Payments if appropriate)	1	0
Sales of unlicensed medicines (specials) sold in the UK [1]	2	0
Less non-pharmaceutical sales [2]	3	0
Add Back Scheme Payment (as appropriate) [3]	4	0
PHARMACEUTICAL TURNOVER (line 1 - line 2 - line 3 + line 4)	5	0
LESS EXCLUSIONS		
Customer Exclusions For example: private medicine sales [4]; sales to the MOD; sales used for clinical trials; non-prescription OTC sales	6	0
Total Customer Exclusions (line 6)	7	0
Product Exclusions Unbranded Generic Medicines; Dental Anaesthetics	8	0
Parallel Import Sales [5]	9	0
Total Product Exclusions (line 8 + line 9)	10	0
Non-UK Sales of Branded POMs For example: sales in markets outside of the UK via direct exports; parallel exports [4]	11	0
Total Non-UK Sales of Branded POMs (line 11)	12	0
TOTAL EXCLUSIONS (line 7 + line 10 + line 12)	13	0
TOTAL SALES OF SCHEME PRODUCTS (line 5 - line 13)	14	0
LESS EXEMPTIONS		
Exemptions from Voluntary Scheme Measured Sales (and Eligible Sales) Sales of Scheme Products relating to Exceptional Central Procurements [5]	15	0
Sales of Scheme Products relating to Centrally Procured Vaccines [5]	16	0
Low Value Sales [5]	17	0
Total Exemptions From Voluntary Scheme Measured Sales (and Eligible Sales) (line 15 + line 16 + line 17)	18	0
VOLUNTARY SCHEME MEASURED SALES (line 14 - line 18)	19	0

Exemptions from Eligible Sales		
New Active Substance Sales [5]	20	0
Medium-Sized Company Exemption	21	0
Total Exemptions From Eligible Sales (line 20 + line 21)	22	0
ELIGIBLE SALES (line 19 - line 22)	23	0
SCHEME PAYMENT REQUIRED ON ELIGIBLE SALES at Line 23	24	0
Department of Health and Social Care Adjustment	25	0
TOTAL SCHEME PAYMENT (Line 24 + Line 25)	26	0

Comments:

Notes:

[1] Sales of Special Medicinal Products (within the meaning of regulation 167 of The Human Medicines Regulations 2012).
[2] Sales of products other than licensed medicines and specials sold in the UK.
[3] The Scheme Payment is rounded to the nearest £1,000. Where a Scheme Payment has been netted off of Turnover (line 1) in this period, only the netted off amount should be added back at line 3.
[4] Adjustments that rely on third party information and an agreed method to be disclosed separately.
[5] Definitions are contained in the Scheme Glossary.

Appendix 4: Audit Report – Audited Annual Sales Report

We, (state name of the Audit firm) have Audited the 2019 Voluntary Scheme for Branded Medicines Pricing and Access Audited Annual Sales Report, of (name of entity) for the [year/period] ended [period end date] which comprise the [state the primary financial statements] and the related notes. The financial reporting framework that has been applied in its preparation is the basis of preparation and accounting policies in note 1 of the Scheme Member's Declaration.

Directors' responsibilities for the special purpose financial information

As explained more fully in the Scheme Member's Declaration, the directors are responsible for the preparation of the special purpose financial information in accordance with the basis of preparation and accounting policies in [note 1] of the Scheme Member's Declaration. This includes determining that the basis of accounting is an acceptable basis for the preparation of the Audited Annual Sales Report and for such internal control as management determines is necessary to enable the preparation of the Audited Annual Sales Report that is free from material misstatement, whether due to fraud or error.

Auditor's responsibilities

Our responsibility is to express an opinion on the Audited Annual Sales Report based on our Audit. We conducted our Audit in accordance with International Standards on Auditing. Those standards require us to comply with the ethical requirements and plan and perform the Audit to obtain reasonable assurance about whether the special purpose financial information is free from material misstatement.

An Audit involves performing procedures to obtain Audit evidence about the amounts and disclosures in the special purpose financial information. The procedures selected depend on the Auditor's judgment, including the assessment of the risks of material misstatement of the Audited Annual Sales Report, whether due to fraud or error. In making those risk assessments, the Auditor considers internal control relevant to the entity's preparation and fair presentation of the Audited Annual Sales Report in order to design Audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An Audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates, if any, made by management, as well as evaluating the overall presentation of the special purpose financial information.

We believe that the Audit evidence we have obtained is sufficient and appropriate to provide a basis for our Audit opinion.

This report, including the opinion, has been prepared for and only for the directors and the Secretary of State for Heath in respect of the Audited Annual Sales Report. This report, including opinion, should not be given to any other party or referred to without our prior written consent. We do not, in giving this opinion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come including without limitation under any contractual obligations of the company, save where expressly agreed by our prior consent in writing.

Scope of our Audit

We have conducted our Audit in accordance with International Standards on Auditing issued by the International Auditing and Assurance Standards Board ("IAASB") and ethical requirements. This will include reporting in accordance with ISA 805 – 'Special considerations – audits of single financial statements and specific elements, accounts or items of a financial statement'. An Audit involves obtaining evidence about the amounts and disclosures in the Audited Annual Sales Report sufficient to give reasonable assurance that the Audited Annual Sales Report is free from material misstatement, whether caused by fraud or error. This includes an assessment of the appropriateness of the accounting policies applied in the context of Annex 6 of the Voluntary Scheme, whether they have been consistently applied and adequately disclosed, the reasonableness of significant accounting estimates made by the directors, and the overall presentation of the Audited Annual Sales Report.

The level of materiality applied in the Audit of the Audited Annual Sales Report has been determined as follows:

(i) If the materiality applied in the Audit of the company's financial statements is less than 0.5% of turnover, then materiality applied in the Audit of the Audited Annual Sales Report will be 0.5% of turnover.

(ii) If the materiality applied in the Audit of the company's financial statements is in the range 0.5%-1.2% of turnover, then that same level of materiality will be applied in the Audit of the Audited Annual Sales Report.

(iii) If the materiality applied in the Audit of the company's financial statements is greater than 1.2% of turnover, then materiality applied in the Audit of the Audited Annual Sales Report will be 1.2% of turnover.

We will report uncorrected misstatements in excess of 10% of the level of materiality applied in the Audit of the Audited Annual Sales Report to the directors of the Scheme Member.

We will provide the Department with copies of our Audit plan (including details of materiality and the reporting timetable) and our report to the directors of Scheme Member including an update on the materiality used and any unadjusted misstatements) at the same time as they are provided to the directors of Scheme Member.

Subsequent events

Once we have issued our Auditors' report we have no further obligation to perform any Audit procedures in relation to the Audited Annual Sales Report for that financial year. However, in accordance with ISA 560 'Subsequent events', if afterwards we become aware of a fact that may have caused us to amend our Auditors' report had we known it before we signed it, we shall discuss the matter with management and the Department, who shall, together, consider whether the Audited Annual Sales Report needs revision. The directors of Scheme Member agree to inform us of any material event occurring after the date of our Auditors' report which may affect the Audited Annual Sales Report.

Opinion

In our opinion the Audited Annual Sales Report for the year ended [period end date] has been properly prepared, in all material respects, in accordance with the basis of preparation and accounting policies in [note 1] to the Scheme Member's Declaration.

[Auditor[1]]

[Chartered Accountants]

[Location]

[Date]

[1] The report is signed in the firm's name.

Annex 7: Unaudited Annual Presentation Level Sales Report

Scheme Member or Lead Company (as applicable):													
Calendar Year:													
Reference[1]:													
								PRIMARY CARE SALES		HOMECARE SALES (sales direct to homecare providers)		ALL OTHER CUSTOMERS (e.g. Secondary Care)	
Code Number	Presentation	Pack Size	Form	NHS List Price (£)	Payment ¦ Exclusion ¦ Exemption	Date From	Date To	Quantity	Net Sales (£)	Quantity	Net Sales (£)	Quantity	Net Sales (£)

Note:

1. Reference —Scheme Member's or Lead Company's (as applicable) reference number.

Annex 8: Company Declaration for the unaudited Annual Presentation Level Sales Report

Scheme Member or Lead Company (as applicable):	....

Calendar Year ended:	....

We can confirm that:

i. the figures set out in the Schedules have been accurately extracted from the records of:

a. the Scheme Member; or

b. where the Scheme Member has elected to join the Voluntary Scheme with others in the same Group pursuant to Chapter 2, the Lead Company and Other Companies;

ii. in compiling the schedules:

a. the Scheme Member has complied with the requirements of the Voluntary Scheme; or

b. where the Scheme Member has elected to join the Voluntary Scheme with others in the same Group pursuant to Chapter 2, the Lead Company has, and each of the Other Companies have, complied with the requirements of the Voluntary Scheme.

Signature.. Date.......................................

Name…………………... *(Managing Director/Chief Executive)*

Signature.. Date……………………………..

Name... *(Finance Director/senior financial executive)*

Annex 9: Company Declaration covering Sales of Scheme Products of less than £1m

Scheme Member or Lead Company (as applicable):	....

Calendar Year ended:	....

We can confirm that our Sales of Scheme Products or (where the Scheme Member has elected to join the Voluntary Scheme with others in the same Group pursuant to Chapter 2) the Sales of Scheme Products for the Lead Company and all of the Other Companies for the above period amount to the total sum of:

£................

Signature.. Date..

Name.. *(Managing Director/Chief Executive)*

Signature.. Date..

Name.. *(Finance Director/senior financial executive)*

Annex 10: Company Declaration covering (unaudited) Annual Sales Report for Sales of Scheme Products of £1m or more and less than £5m

Scheme Member or Lead Company (as applicable):	....

Calendar Year ended:	....

We can confirm that:

i. the figures set out in the Schedules have been accurately extracted from the records of:

a. the Scheme Member; or

b. where the Scheme Member has elected to join the Voluntary Scheme with others in the same Group pursuant to Chapter 2, the Lead Company and Other Companies;

ii. in compiling the Schedules:

a. the Scheme Member has complied with the requirements of the Voluntary Scheme; or

b. where the Scheme Member has elected to join the Voluntary Scheme with others in the same Group pursuant to Chapter 2, the Lead Company has, and each of the Other Companies have, complied with the requirements of the Voluntary Scheme.

Signature.. Date..

Name.. *(Managing Director/Chief Executive)*

Signature.. Date..

Name... *(Finance Director/senior financial executive)*

Annex 11: Historic Case Payment Form

Box 1

Scheme Member or Lead Company (as applicable):

Calendar Year:

Scheme Reference:

HCP Percentage:

HCP Box

Total Annual Historic Cash Payment Sales

Annual Historic Cash Payment

Code Number	Product Description	Strength	Pack Size	NHS List Price (£) at 31 December 2018	Date From	Date To	SECONDARY CARE (Including Homecare) Quantity	PRIMARY CARE Quantity

Annex 12: Independent Audit Report Covering Historic Cash Payments

[headed paper]

The Directors
Company Address

Scheme Member or Lead Company (as applicable): ....

Calendar Year ended: ....

We have examined the attached schedules (which we have initialed for the purposes of identification) that set out the information relating to Historic Cash Payments for the period .... as required under the 2019 Voluntary Scheme for Branded Medicines Pricing and Access.

In our opinion (and subject to the reservations mentioned below) we have concluded that the information contained in the schedules has been accurately extracted from the records of the Scheme Member or, as applicable, the Lead Company and Other Companies, in that we have:

i. agreed the extraction of the quantity figures in primary and secondary care set out in the HCP schedule from the Scheme Member or, as applicable, the Lead Company and Other Companies', underlying accounting records;

ii. agreed the reference price figures set out in the HCP schedule to the Scheme Member or, as applicable, the Lead Company and Other Companies', price list that was in effect at 31 December 2018;

iii. agreed the extraction of the HCP price figures to the Scheme Member or, as applicable, the Lead Company and Other Companies', published price list and to the underlying records of the Scheme Member or, as applicable, the Lead Company and Other Companies.

This engagement is separate from, and unrelated to, our audit work on the financial statements of the Scheme Member or, as applicable, the Lead Company and Other Companies, which was carried out solely for the purposes of *Section 235 of the Companies Act 1985/Sections 495/and 496 and 497 of the Companies Act 2006* and nothing herein creates any additional obligations or liabilities regarding our statutory audit work, our statutory audit report or the opinions we have formed in respect of that statutory audit, which would not otherwise exist.[1] [Delete italics as appropriate]

Signature.. **Date** ....

Name...

Address..

Professional qualification..

[1] This paragraph should be included only where the same audit firm provides both statutory audit and services related to the Voluntary Scheme.

Annex 13: Company Declaration Covering Historic Cash Payments

Scheme Member or Lead Company (as applicable):	…………………………………………………………

Calendar Year ended:	…………………………………………………………

We can confirm that:

i. the figures set out in the Schedules have been accurately extracted from the records of:

a. the Scheme Member; or

b. where the Scheme Member has elected to join the Voluntary Scheme with others in the same Group pursuant to Chapter 2, the Lead Company and Other Companies;

ii. in compiling the schedules:

a. the Scheme Member has complied with the requirements of the Voluntary Scheme; or

b. where the Scheme Member has elected to join the Voluntary Scheme with others in the same Group pursuant to Chapter 2, the Lead Company has, and each of the Other Companies have, complied with the requirements of the Voluntary Scheme.

Signature…………………………………………… Date……………………………

Name…………………………………………… *(Managing Director/Chief Executive)*

Signature…………………………………………… Date……………………………

Name…………………………………………… *(Finance Director/senior financial executive)*

Annex 14: Guidance on the Completion of PIFRs and AFRs

Introduction

1. This Annex 14 contains further detail relating to the completion of PIFRs and AFRs and the calculation of ROS/ROC and allowances.

2. It is not intended to be comprehensive in its approach and does not cover all the issues that may arise in the assessment of PIFRs or AFRs. The Department will continue to discuss with Scheme Members bilaterally and may limit costs and capital to a level that is reasonable in its analysis of the Scheme Member's figures as provided below.

3. The PIFR or AFR should relate to business organisations that manufacture and supply Branded Health Service Medicines that ultimately are charged to the NHS. The PIFR or AFR should cover, on a consolidated basis, the company and its subsidiaries, and should include business done through branches or divisions. Where, however, with the group organisation, audited accounts are prepared for a sub-group which embraces all the group pharmaceutical business carried on in the UK (though not necessarily confined to such business), the PIFR or AFR should comprise consolidated figures for this sub-group. In such circumstances, references in the PIFR or AFR to affiliated concerns should be regarded as extending to such excluded units as overseas subsidiaries, and non-pharmaceutical UK subsidiaries, branches or divisions. Where NHS sales occur in more than one company under the same ultimate common ownership (whether part of a UK group or not) e.g. sales of branded OTC prescription medicines by a consumer healthcare company within the group, these sales should be added together.

4. It is recognised that the availability of consolidated and/or audited accounts will be a matter of corporate organisation and will not necessarily coincide with the requirements of the AFR. It is not intended that Scheme Members should produce additional audited accounts especially for the purpose of the PIFR or AFR and where the accounting arrangements of the group are such that some other basis for the completion of the PIFR or AFR is more appropriate, such other basis may be adopted by agreement between the Scheme Member and the Department. Nevertheless, the Department requires a reconciliation to the audited accounts

5. It is accepted that the accounting system employed by the Scheme Members will result in some variation in the nature of expenses included under the various headings of the PIFR or AFR. The purpose of these notes is to identify the main areas of consistency that are sought from all companies.

6. For the purpose of the PIFR or AFR:

   - all figures should be reported to the nearest £1,000;

- all figures for sales and costs should be stated net of UK Value Added Tax. Where a Scheme Member has been unable to recover input tax or a proportion of it, thus making it a cost to the business, it should be treated as such.

7. The Appendices to be completed as necessary:

   - Appendix 1 - PIFRs and AFRS
   - Appendix 1a - AFRs only
   - Appendix 2 - AFR only (for ROC)
   - Appendix 2a - AFR only (for ROC)

Small Companies

8. In assessing the AFR or other financial information provided by a Scheme Member whose total Sales of Scheme Products are less than £5m in the relevant calendar year, the Department may exercise a degree of discretion in relation to such matters as the levels of costs or capital employed allowed. In particular, the levels of allowances for R&D, marketing and information, set out at paragraph 47 of this Annex 14, are not necessarily applicable to Small Companies. The Department will continue to look at these flexibly with regard to the circumstances of the individual Scheme Member, including the level of its NHS turnover.

Apportionment

9. The Department recognises that Scheme Members cannot always allocate costs and capital directly to its NHS Home, NHS Exports and Other Products businesses and that various apportionment techniques have to be used to attribute shared costs and capital to the three businesses. Scheme Members are required to make such apportionments on the most realistic and reasonable basis possible, striking an equitable balance between the separate interests of the Scheme Member in reporting the lowest possible profitability/ROC employed on its NHS home business and that of the taxpayer in reporting the highest possible profitability/ROC employed. Where the Department requests an Audited AFR (at the Department's discretion), it is expected that the Auditor will use their professional judgement to ensure that the bases adopted are adequately explained in the accompanying notes and to qualify their report in those cases where they are not satisfied that this has been the case.

10. The Scheme Member will include with the PIFR or AFR, notes identifying, with amounts, those items that have been specifically allocated against each cost and capital heading and those that have been apportioned. For those items that have been apportioned, Scheme Members should give the amounts involved and explain the reasons for that allocation. The Scheme Member should ensure that when sales are allocated between AFR headings (NHS Home, NHS Export and Other Products), all relevant costs are considered and

apportioned in an appropriate and consistent manner. The Department may ask for additional information on the method of apportionment/allocation if this is unclear.

Allocation of Costs and Capital

11. The Department expects manufacturers and suppliers to achieve all reasonable economies in the costs of pharmaceutical production and supply, and related overheads.

12. Costs, capital employed and any related receipts or income, claimed in any PIFR or AFR submission (Return) must be those included in the Scheme Member's UK audited accounts, except where otherwise specified in the Return with supporting justification and reconciliation to the most recent audited accounts.

13. The Department may specify other arrangements where the supply of NHS medicines in the UK arises from overseas sources and comprehensive financial information is not available in the accounts of the UK trading entity. In particular, it is expected that, where trade in the UK is conducted on a principal-commissionaire basis, the Return will be based on the audited accounts of the overseas entity, provided that those accounts have been audited in accordance with generally accepted international accounting standards.

14. Any Scheme Member must be able to demonstrate that costs or capital included in its Return are appropriate to the supply of Branded Health Service Medicines in accordance with the Voluntary Scheme. Overhead costs and shared assets utilised in both NHS medicines and other products must be reasonably apportioned. Scheme Members will provide reasonable details of costs and capital either directly allocated or apportioned to Branded Health Service Medicines, together with explanations supporting any apportionment.

15. Scheme Members accept that the Voluntary Scheme is not a cost plus scheme and that the Department is entitled to satisfy itself that costs and capital claimed for medicines supplied to the NHS are properly incurred in accordance with the Voluntary Scheme and they are reasonable in the light of accepted commercial practice. Excess costs and capital will be disallowed from the assessment.

16. In its examination of the reasonableness of a Scheme Member's costs and capital the Department will have regard to factors such as the following:

    - the trends in the data reported by the Scheme Member over a number of calendar years, including those for exports and other products;

    - any special features of the Scheme Member's operation;

    - ratios inferred from the Return for the Scheme Member's business outside the Voluntary Scheme;

- each Scheme Member’s reported figures and the average of other similar Scheme Members; and/or

- data from external sources that relate to the pharmaceutical industry across companies.

17. Where the Department does not receive an adequate explanation of costs and capital claimed in a Scheme Member’s Return, it may limit the costs and capital to a level that is reasonable in the light of its analysis of the Scheme Member's figures as set out in paragraph 19 of this Annex 14. The Department may discuss the basis of any limitations with the Scheme Member.

Rates of Return

18. For Scheme Members whose UK sales exceed their average assessed capital employed in the UK (excluding any capital imputation from the transfer price) by a factor of 3.5 or more, return on sales (ROS), rather than return on capital (ROC), will be used to determine the Scheme Member’s relevant profit for the purposes of the target. Otherwise, ROC will be used to determine the Scheme Member’s relevant profit. The assessment of the returns of Scheme Members that are subject to the ROS measure will take account of the transfer price profit and the MOT on transfer price profit.

19. Scheme Members will be able to include capital employed in their Return on the basis of its inclusion in UK statutory accounts. Scheme Members will be allowed to inject costs or capital on the condition that they provide Audited evidence that these injections are appropriate and are not duplicated in any way by other entries in the Return.

20. Where a Scheme Member is satisfied that its profitability should be assessed on the basis of return on sales in accordance with paragraph 18, Appendix 2 of the relevant Return is not required to be submitted.

Completion of Appendix 1 - Sales, Costs and Profit

Sales

21. Sales should be shown net after deduction of all trade and other discounts (whether allowed to wholesalers, NHS authorities, trusts or others) and all rebates, return allowances, Scheme Payments (where these are netted off against sales) and sales taxes. Discounts include settlement discounts where these are allowed as part of the normal wholesalers’ discount. NHS medicines should include only those products covered by the Voluntary Scheme as set out in Chapter 2.

22. Other Products sales include all products that are not specifically NHS products including contract manufacture for third parties, sales of intermediates and sales of bulk chemicals (whether in the form of tablets or not).

23. Columns are provided for separate information on home and export trade in NHS medicines. Sales of products not falling within the definition of NHS medicines should be shown under Other Products. This information is required to assist the Department in forming an independent judgement on the reasonableness of any methods of apportionment used in preparing the NHS figures and to reduce to a minimum the requests for additional information in individual cases.

Cost of goods sold

24. Materials purchased from affiliates and independents should be on a materials consumed basis. Manufacturing process costs should include all direct and indirect labour costs, depreciation of manufacturing fixed assets and other related manufacturing overhead expenses. Costs should not include any one-off costs (line 19) or other expenses that would be better included elsewhere in Appendix 1.

25. In all cases where there are products being licensed in or out, or contract manufacturing is being undertaken for either other independent companies or for affiliated companies, which impact in a material way on the sales of NHS medicines, all costs and revenue shall be included in the PIFR/AFR, together with a brief description of the arrangement and of how expenditure and income has been treated in the PIFR/AFR. Where a company manufactures a product for marketing by another, the relevant costs should be shown under ‘Other Products’ in the PIFR/AFR of the producing company and the purchase price recorded under ‘NHS Medicines’ in the PIFR/AFR of the marketing company.

Transfer Pricing

26. Where possible, Scheme Members should seek to provide a breakdown of their transfer prices (purchases from companies in the same Group, lines 4 and 7 of Appendix 1).

27. Where a Scheme Member does not provide a breakdown of transfer price costs, it will be required to demonstrate that its transfer prices are at arm’s length, to indicate the basis on which such arm’s-length prices are set, and to confirm that the transfer prices reported in the Return are as will be reported in the Scheme Member’s corporation tax computation. In such cases, the Department will assume that transfer prices comprise 59% manufacturing, 21% R&D and 20% profit, subject to paragraphs 28 to 31 of this Annex 14.

28. The maximum permitted transfer price profit allowed in the assessment is 25% of accepted costs. ‘Accepted costs’ means the reasonable costs allowed by the Department after discussion with the Scheme Member. In the case of a Scheme Member assessed on a ROC basis, the allowed profit will be converted to an equivalent amount of assets, using the Voluntary Scheme ROC target, and added to the Scheme Member’s total capital employed. In the case of a Scheme Member assessed on a ROS basis, the allowed profit will be added to the Scheme Member’s ROS profit target.

29. In a Financial Year in which a Scheme Member is subject to the default transfer price breakdown and 20% or more of claimed NHS UK manufacturing costs i.e. total cost of

goods sold (line 11, Appendix 1) is derived from the transfer price, the maximum acceptable manufacturing costs i.e. total cost of goods sold (line 11) will be restricted to 45% of UK NHS sales in the assessment (after re-assignment of costs to take account of the transfer price analysis).

30. Where a Scheme Member's manufacturing costs, i.e. total cost of goods sold, are restricted to 45%, the excess will first be disallowed from the transfer price component, thus reducing accepted transfer price costs and consequently the transfer price profit allowed.

31. If, in the assessment of a Return, a Scheme Member's claimed total R&D costs, including the R&D component from the transfer price, exceeds its R&D allowance for the calendar year, any R&D costs derived from the transfer price will be allowed first, unless the Scheme Member indicates otherwise when submitting the AFR.

32. Where significant currency movements occur, the Department may seek clarification from Scheme Members on the effects of these movements on transfer prices, including information on the sources of transfers. The Department may also look at the consistency of transfer prices from one calendar year to another.

Distribution costs

33. Distribution costs should normally cover only those costs directly associated with the physical warehousing of finished products and their distribution to wholesalers, hospitals etc.

Information Allowance

34. Information expenses should include the costs of the provision and dissemination of factual information on a Scheme Member's Branded Health Service Medicines. This includes information whether or not required by statute or regulation or requested by a public body, the provision of non-product-specific information, support for the development, implementation or monitoring of protocols, guidelines, service standards or frameworks, and the provision to patients of support and information as required or permitted by law and the relevant Code of Practice. Information expenses will also include the costs of samples for identification purposes, summaries of product characteristics and medical symposia. The information allowances are allowable only where a Scheme Member can demonstrate within the Return that the amount claimed relates to expenditure actually incurred and provide relevant supporting documentation.

Marketing Allowance

35. In addition to all costs associated with the operation of marketing departments, marketing expenditure should include the cost of all advertising, selling and promotion of a Scheme Member's Branded Health Service Medicines as well as the administrative support to such

activities. Costs and activities that are expected to fall within marketing include market research and marketing strategy.

36. The following expenditure is not allowable as a charge in NHS prices and must be excluded from the Return:

- samples (other than samples for identification purposes);
- gifts;
- hospitality (other than that provided for eligible medical symposia).

The marketing allowances are allowable only where a Scheme Member can demonstrate within the Return that the amount claimed relates to expenditure actually incurred and provide relevant supporting documentation.

General & Administrative (G&A) costs

37. G&A expenses include the administrative costs of running a business including the salaries and employment costs of administrative staff, accommodation costs and the associated costs of general management. When completing a PIFR or AFR a Scheme Member can include Scheme Payments as a cost in G&A where such costs are not netted off against the sales value for calculating the Scheme Payment(s) (this does not apply to financial information provided for a product launch).

Research and Development (R&D)

38. The Department confirms its commitment to recognising the cost of R&D within the prices paid for Branded Health Service Medicines. The amount allowed reflects both a contribution to the worldwide cost of R&D undertaken by companies developing human medicines and a desire to reward and provide an incentive for success in R&D. The Department expects this allowance to contribute towards the R&D of new and improved medicines.

39. R&D allowances are allowable only where a Scheme Member can demonstrate within the Return that the amount claimed relates to expenditure actually incurred and provide relevant supporting documentation.

One off costs

40. One off costs (line 19) by their very nature will not occur every calendar year. This heading should be used for any large but infrequent costs that would distort other cost heads if they were included within them

AFRs

41. The AFR should be accompanied by a copy of the audited accounts of the company, group or sub-group whose figures form the basis of the AFR and by a statement setting out the names of the companies, branches and divisions whose figures are included in the AFR with a broad indication of the business activities of the major units. Published financial accounts of the ultimate holding company and of any relevant intermediate holding company should accompany the AFR.

42. The completed AFR should be signed by the Managing Director or Chief Executive and the Finance Director or appropriate senior financial executive of the Scheme Member (see company declaration at Appendix 3 of this Annex 14). Where the Department requests an Audited AFR , this should be accompanied by a report from the Auditor to the effect that (subject to such reservations as they consider necessary), in their opinion, and in accordance with the explanations given to them, the AFR has been prepared on the basis required, and fairly reflects for the relevant Financial Year the profit earned from home sales of NHS medicines and, where appropriate, the capital employed in relation to NHS home medicines (see the Auditor's report at Appendix 4 of this Annex 14).

43. The Department will acknowledge receipt within twenty eight (28) calendar days of receiving an AFR and will endeavour to advise Scheme Members in writing within eight weeks of receipt if it also wishes to make further enquiries into the information submitted. The Department may require that any supplementary information requested is Audited where information in the original submission is found to be incorrect or further explanations on such matters as apportionment are required and revised or additional information is submitted. Scheme Members must provide supplementary information within twenty eight (28) calendar days of the date of the request.

44. Appendix 1 and Appendix 1a (Sales, Costs and Profit) should be completed in respect of the reporting company’s Financial Year and Appendix 2 and Appendix 2a (Capital employed) should relate to the balance sheet date at the end of the same Financial Year. Where a Scheme Member is satisfied that it does not qualify to be assessed as a return on capital company owing to its home sales to capital ratio being greater than 3.5:1, there is no requirement to submit Appendices 2 or 2a.

45. The Department will only recognise that an AFR has been submitted by a Scheme Member when all components of the AFR including relevant supporting documents have been submitted (see paragraph 6.12 as appropriate). Below is a checklist of items to be submitted for a full AFR:

- Accounts:
    - Published accounts of UK company supplying medicines to NHS.
    - Published accounts of UK holding company (if applicable).
    - Published accounts of ultimate holding company.

- Appendices and Supporting Information:
    - Company declaration signed on behalf of company and including a list of companies, branches and divisions included in the AFR.
    - Auditor's report.
    - Appendices 1, 1A, 2 and 2A of this Annex 14. Companies assessed as return on sales may omit Appendices 2 and 2A.
    - Details of reallocations between cost headings (Appendices 1A and 2A).
    - Details of items in the accounts excluded from the AFR.
    - Details of items injected into the AFR.
    - Details of apportionments for all cost and capital headings either directly allocated or apportioned to NHS home medicines with explanations of the apportionments.
    - NHS medicines home costs and capital claimed columns completed.
    - Details of partnerships, joint ventures and other joint commercial arrangements relating to sales of an NHS medicine to the NHS included in this return.

- Product Information:
    - List of products included in NHS home medicines with sales over £100,000 (after discounts and rebates) for which PSA is claimed and indicating whether they are considered to be eligible for a variable rate (innovation and paediatrics) R&D allowance.
    - Date of expiry of the active substance patent for each product and any SPC, or where no patent exists, the date of grant of the first marketing authorisation for that new active substance.

46. Scheme Members must provide a list of the Branded Health Service Medicines that have been included within their AFR with Sales of Scheme Products of £100,000 or more (after discounts and rebates but gross of Scheme Payments) for which variable rate (innovation and paediatric) R&D allowances or marketing product servicing (Marketing Allowances) are sought. For each product, Scheme Members must indicate the date of expiry of the active substance patent and any supplementary protection certificate or where no patent exists, the date of grant of the first Marketing Authorisation for that new active substance. This will be used for:

- calculating allowable expenditure for R&D (see paragraphs 47 to 51 of this Annex 14);
- calculating allowable expenditure for marketing (see paragraphs 47 and 52 of this Annex 14);

47. The maximum allowances for the purposes of assessing ROS or ROC in relation to an AFR are:

Category of Cost	Maximum Percentage of Value of Sales of Scheme Products
Research and development	30%, consisting of: a fixed rate of up to 20%; and a variable rate of up to 10% as specified below
Marketing	A fixed rate of £1,000,000 pa and up to 4% plus a product servicing allowance as specified below
Information	Up to 4%

48. The variable rate allowance for R&D comprises a variable rate for innovation and a variable rate for paediatrics as set out in the paragraphs below.

49. In relation to a variable rate for innovation:

- an allowance for each in-patent active substance protected by a basic preparation patent (and Supplementary Protection Certificate (SPC) where one exists) with Sales of Scheme Products above a threshold of £100,000, up to a limit of 28 active substances.

- The allowance shall be 0.75% of Sales of Scheme Products for the first 4 qualifying products, 0.5% for the next 4 qualifying products, and 0.25% of Sales of Scheme Products for the next 20 qualifying products in excess of 8 and up to a maximum of 28.

- The maximum allowance for this component is, therefore, 10% of Sales of Scheme Products and is additional to the flat-rate allowance.

- Where no patent exists, the additional component may apply to each substance, which has been granted a New Active Substance Marketing Authorisation. The allowance will be given for a period of 10 calendar years after the grant of the first Marketing Authorisation for that New Active Substance. For clarification, this provision is intended to cover all Branded Health Service Medicines which are not patentable. This is subject to them being recognised by the Licensing Authority as a new active substance, in that a full (major) Marketing Authorisation is required.

50. In relation to a variable rate for paediatrics: 1% of Sales of Scheme Products in the calendar year in which a product is first generally available on prescription in the UK under the terms of a Marketing Authorisation that includes a paediatric indication, up to a limit of three products in any one calendar year. The combined maximum allowance for the variable rate for paediatrics and the variable rate for innovation is 10% of Sales of Scheme Products. This additional element for paediatric indications may not be utilised for applying for a price increase under the Voluntary Scheme.

51. The AFR should include the completion of the table below. A list of all products with sales in excess of £100,000 for which an innovation R&D allowance or paediatric allowance is claimed should be provided. For each product for which a variable rate innovation R&D allowance is claimed, the list should show the date of expiry of the active substance patent and any supplementary protection certificate or where no patent exists, the date of grant of the first Marketing Authorisation for that New Active Substance. This information is used to calculate the R&D and marketing allowances and might be submitted in the format below.

Company:

Product information

(calendar year)

		home sales >£100k	Qualifying for PSA	Qualifying for innovation allowance	Qualifying for paediatric allowance
PRODUCT	PATENT DETAILS				
A					
B					
C					
D					
E					
Etc					
Total		0	0	0	0

52. The product servicing allowance for marketing will apply to each active substance with sales to the NHS of £100,000 or more (in the calendar year to which the AFR relates). This will be set at £58,000 for each of the first three eligible products, £46,000 for each of the next three, £35,000 for each of the next three, and £23,000 each for all others

53. Scheme Members will be able to retain profits up to 150% of the relevant target. The MOT will not be available to a Scheme Member for any Financial Year in which it has implemented a price increase approved by the Department. Where a Scheme Member

exceeds the relevant ROS or ROC target for a Financial Year in which it has received a price increase, the Scheme Member must undertake one or more of the actions specified at paragraph 6.16. Where a price increase is agreed by the Department in the second half of a Financial Year, the MOT will not be available to a Scheme Member for the Financial Year following the increase.

54. Irrespective of the final date of settlement, any agreed price reductions will take effect from the date (the Effective Date) falling three (3) months after the Scheme Member's AFR is submitted. In the event of negotiations not being completed by the Effective Date, any price reductions resulting from the review will in any case be made effective as if they had been operative from the Effective Date, if necessary by payment or other adjustment having equivalent effect. The Department will specify the date on which a payment is to be made. That date will be no later than one (1) month after the date of settlement.

55. The Department will use reasonable endeavours to ensure the confidentiality of commercially sensitive information submitted by Scheme Members.

Completion of Appendix 1A - Reconciliation of Appendix 1 with audited accounts

56. Columns on Appendix 1A provide for a reconciliation of sales, costs and profit shown in Appendix 1 with the amounts disclosed in the audited accounts on which the AFR is based.

57. Figures from the accounts should be transferred directly into the first column 'Total per audited accounts'. If the cost headings used in the accounts are incompatible with the AFR, then sales, total costs and profit before interest and taxation should be shown.

58. The column headed 'Reallocations between cost headings' provides for cost reallocation where cost heads in the accounts are not the same as in the AFR. Details of costs reallocated should be explained, together with reasons for the reallocation, in notes accompanying the AFR.

59. The column headed 'Items in audited accounts excluded from AFR' is where costs that are not appropriate to the Voluntary Scheme should be shown. Home costs reported in Appendix 1 will exclude certain items of non-Voluntary Scheme income and expenditure that are normally recognised for published accounts purposes. It is expected that items which are omitted from the figures reported for NHS Home will also be excluded from NHS Exports and Other Products so that the three businesses may be compared on a basis which is as close as possible to like-with-like. Non-Voluntary Scheme items should be eliminated consistently and in their entirety on Appendix 1A. Examples of costs that should be excluded from Appendix 1 and shown in column 3 of Appendix 1A include amortisation of intangible assets, dividends and trade investment income received, interest paid and received and charitable and political donations.

60. The column of Appendix 1A headed ‘Items not in audited accounts included in AFR’ allows for costs that are not in the accounts that form the basis of the AFR to be brought in if they are dealt with through the accounts of other group companies but are directly relevant to the supply of medicines to the NHS. The usual cost that is brought in under this column is R&D that has been done by or has been recharged to affiliate companies.

61. Costs reported in this column at lines 22 and 23 will be subject to the Auditor's report (see Auditor's report Appendix 4). These will only be accepted where it can be reasonably determined that costs incurred in the Scheme Member’s accounts do not fully reflect the level of worldwide group services it receives and that appropriate bases of apportionment have been applied in calculating these costs.

62. The final column of Appendix 1A must agree with the total column on Appendix 1.

Completion of Appendix 2A – Reconciliation of Appendix 2 with audited accounts

63. Fixed assets should be presented at historical cost. Any difference between the figures included in the AFR and the balance sheet should be shown in Appendix 2A. Assets should not include investments the income from which has been excluded from Appendix 1.

64. The inclusion of intangible assets in the computation of capital employed is not permitted for the purposes of the Voluntary Scheme.

65. Any provision for corporate taxation, including deferred taxation, should be excluded from current liabilities. Also excluded from current liabilities are items which do not represent normal trading balances but are of a long-term nature representing, in reality, part of the reporting company’s capital structure (e.g. bank borrowing; advances from affiliated concerns). Such items should be entered in the column ‘Total per audited accounts’ to tie back to the accounts and then excluded in the column ‘Items in audited accounts excluded from AFR.

66. The amounts shown in lines 45 to 48 should be the proportion of fixed and current assets less current liabilities appropriate to the operations covered by the AFR but not included in the audited accounts of the Scheme Member. Injected capital reported at lines 45 to 48 is subject to the Auditor's report (see Auditor's report at Appendix 4) and will only be accepted where it can be reasonably determined that capital, as shown in the Scheme Member’s accounts, does not fully reflect the level of worldwide group services it receives and that appropriate bases of apportionment have been applied in calculating this capital. This net capital should generally correspond to the expenses shown at lines 22 and 24 of Appendix 1. Conversely, a deduction should, if appropriate, be shown in Appendix 2A, calculated on the same principles, when the Scheme Member shows amounts excluded from the AFR on Appendix 1A.

67. The strict apportionment or allocation of capital may result in home capital that is greater than the Department is likely to accept. This is most likely to occur where costs being claimed are less than initially allocated to home such as R&D, marketing or information. Scheme Members should include in the NHS Medicines home capital claimed column, only that capital that it is expected that the Department will accept.

68. If the average capital employed during the calendar year would not be fairly represented by averaging the capital employed at the beginning and at the end of the calendar year, a statement should be attached indicating the appropriate adjustment.

69. Appendix 2A should be used to reconcile items on Appendix 2 with the corresponding figures in the audited Balance Sheet. The columns are a mirror of Appendix 1A and comments above in respect of Appendix 1A also apply to Appendix 2A.

Appendix 1: Sales, Costs and Profit

COMPANY:					
AFR FOR YEAR ENDED:					
	Line number	NHS Medicines Home	NHS Medicines Exports	Other products	Total
		£0	£0	£0	£0
SALES		-	-	-	-
To affiliates	1				
To independents	2				
Total sales	3				
COSTS AND EXPENSES					
Finished goods bought in					
From affiliates	4				
From independents	5				
Total finished goods resold	6				
Own manufactured goods resold					
Materials purchased from affiliates	7				
Materials purchased from independents	8				
Manufacturing process costs	9				
Total MCOGS	10				
Total COGS	11				
Distribution costs	12				
Information expenses	13				
Marketing expenses	14				
General & administrative expenses	15				
Royalties payable - to affiliates	16				
Royalties payable - to Independents	17				
R & D expenses in accounts	18				
One-off costs and expenses	19				
Total costs and expenses	20				
TRADING PROFIT	21				
Supplementary items					
R & D expenses - injected - UK recharged	22				
R & D expenses - injected - overseas costs	23				
Other injected costs	24				
Other trading income less charges (-)	25				
Royalties received - affiliates (-)	26				
Royalties received - independents (-)	27				
Other income (-)/costs (+)	28				
PROFIT BEFORE INTEREST AND TAX	29				

Appendix 1A: Reconciliation of Appendix 1 with audited accounted

COMPANY:						
AFR FOR YEAR ENDED:						
	Line number	Total per audited accounts	Re-allocations between cost headings	Items in audited accounts excluded from AFR	Items not in audited accounts included in AFR	Total
		£0	£0	£0	£0	£0
SALES		-	-	-	-	-
To affiliates	1					
To independents	2					
Total sales	3					
COSTS AND EXPENSES						
Finished goods bought in						
From affiliates	4					
From independents	5					
Total finished goods resold	6					
Own manufactured goods resold						
Materials purchased from affiliates	7					
Materials purchased from independents	8					
Manufacturing process costs	9					
Total MCOGS	10					
Total COGS	11					
Distribution costs	12					
Information expenses	13					
Marketing expenses	14					
General & administrative expenses	15					
Royalties payable - to affiliates	16					
Royalties payable - to independents	17					
R & D expenses in accounts	18					
One-off costs and expenses	19					
Total costs and expenses	20					
TRADING PROFIT	21					
Supplementary items						
R & D expenses - injected - UK recharged	22					
R & D expenses - injected - overseas costs	23					
Other injected costs	24					
Other trading income less charges (-)	25					
Royalties received - affiliates (-)	26					
Royalties received - independents (-)	27					
Other income (-)/costs (+)	28					
PROFIT BEFORE INTEREST AND TAX	29					

Appendix 2: Capital Employed

COMPANY:					
AFR FOR YEAR ENDED:					
	Line number	**NHS Medicines Home**	**NHS Medicines Export**	**Other Products**	**Total**
		£0	£0	£0	£0
FIXED ASSETS (at historic cost)		-	-	-	-
Land & Buildings	30				
Plant & Machinery	31				
Other Fixed Assets	32				
Total Fixed Assets	33				
R & D Fixed Assets	34				
Non R & D Fixed Assets	35				
Total Fixed Assets (to agree with line 34)	36				
WORKING CAPITAL					
Current Assets					
Cash and bank balances	37				
Debtors - affiliates	38				
Debtors - other	39				
Stocks	40				
Other Current Assets	41				
Total Current Assets	42				
Current Liabilities	43				
Net Working Capital	44				
INJECTED CAPITAL					
R & D Fixed Assets – UK	45				
R & D Fixed Assets - overseas	46				
Non R & D Fixed Assets	47				
Other Capital	48				
Total Injected Capital	49				
CAPITAL EMPLOYED	50				

Appendix 2A: Reconciliation of Appendix 2 with audited accounts

COMPANY:						
AFR FOR YEAR ENDED:						
	Line number	**Total per audited accounts**	**Re- allocations between cost headings**	**Items in audited accounts excluded from AFR**	**Items not in audited accounts included in AFR**	**Total**
		£0	£0	£0	£0	£0
FIXED ASSETS (at historic cost)		-	-	-	-	-
Land & Buildings	30					
Plant & Machinery	31					
Other Fixed Assets	32					
Total Fixed Assets	33					
R & D Fixed Assets	34					
Non R & D Fixed Assets	35					
Total Fixed Assets	36					
WORKING CAPITAL						
Current Assets						
Cash and bank balances	37					
Debtors - affiliates	38					
Debtors - other	39					
Stocks	40					
Other Current Assets	41					
Total Current Assets	42					
Current Liabilities	43					
Net Working Capital	44					
INJECTED CAPITAL						
R & D Fixed Assets – UK	45					
R & D Fixed Assets - overseas	46					
Non R & D Fixed Assets	47					
Other Capital	48					
Total Injected Capital	49					
CAPITAL EMPLOYED	50					

Appendix 3: Company Declaration

AFR for the year ended:	....

Scheme Member or Lead Company (as applicable):	....

Other Companies consolidated in this Return:-

1...

2...

3...

4...

5...

We confirm that

i. the figures set out in the annexed appendices 1, 1A, 2 & 2A ("the Appendices"), together with the accompanying notes and reconciliations ("the AFR") have been reconciled to the audited accounts and have been compiled on the basis required for the purpose of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access agreed between the Department of Health and Social Care, NHS England and the Association of the British Pharmaceutical Industry;

ii. where apportionment of costs has been necessary, an appropriate method of apportionment has been selected and this has been adequately disclosed in the accompanying notes. Those bases of apportionment are fair and reasonable in the context of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access and the figures in the Appendices fairly reflect the income, costs and profits relating to home sales of NHS Medicines, exports sales of those products and the rest of the business as represented by other products for the financial year and the capital for each of those businesses at the close of the financial year.

iii. where injected costs and/or capital have been included, an appropriate method of apportionment has been selected in calculating the amounts of injected costs and/or capital attributed to NHS medicines, and has been adequately disclosed in the accompanying notes. To the best of our knowledge, the injected costs have not been included in the transfer price paid for goods or services received and exclude profit where the associated capital has been injected into AFR Appendix 2.

Signed.. *(Managing Director/Chief Executive)*

Date...

Signed.. *(Finance Director/senior financial executive)*

Date...

Appendix 4: Auditor's Report

[headed paper]

The Directors
Company
Address

Auditor's Report

AFR for the year ended:	....

Scheme Member or Lead Company (as applicable):	....

Other Companies consolidated in this Return:-

1...

2...

3...

4...

5...

I/we have examined the annexed appendices 1, 1A, 2 & 2A ("the Appendices"), together with the accompanying notes and reconciliations ("the AFR") which *I/we* have initialled for the purpose of identification.

On the basis of *my/our* examination and of the explanations give to *me/us*, *I/we* report that, in *my/our* opinion and subject to the reservations mentioned below:

i. the figures set out in the AFR have been reconciled to audited accounts and have been compiled on the basis required for the purpose of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access agreed between the Department of Health and Social Care, NHS England and the Association of the British Pharmaceutical Industry;

ii. where apportionment of costs has been necessary, the Appendices have been prepared in accordance with the basis of allocation set out in the accompanying notes;

iii. transfer prices in the AFR are on the same basis as those the company expects to include in its corporation tax return and are consistent with those used in the previous corporation tax return except as set out overleaf and are set on the following basis:

Basis adopted: ……………………………………………………………………

iv. *where injected costs and/or capital have been included I/we have seen acceptable evidence to support the inclusion in the Appendices of items dealt with in the accounts of Other Companies. The method of apportionment to NHS medicines has been adequately disclosed in the accompanying notes.*

This engagement is separate from, and unrelated to, our audit work on the financial statements of the Company which was carried out solely for the purposes of *Section 235 of the Companies Act 1985/Sections 495,/and 496 and 497 of the Companies Act 2006* as appropriate and nothing herein creates any additional obligations or liabilities regarding our statutory audit work, our statutory audit report or the opinions we have formed in respect of that statutory audit, which would not otherwise exist[1]. (Delete italics as appropriate)

Signature ………………………………………………………………… **Date** ……………

Name ……………………………………………………………………………………………

Address …………………………………………………………………………………………

……………………………………………………………………………………………………

Professional Qualification ……………………………………………………………………

[1] This paragraph should only be included where the same audit firm provides both statutory audit and services relating to the Voluntary Scheme.

Annex 15: Dispute Resolution

Secretariat to the DRP

1. The secretariat shall be provided jointly by the Department and the ABPI.

2. Communications to the secretariat shall be addressed to:

   The Secretariat

   Secretary of State for Health and Social Care

   Third Floor

   39 Victoria Street

   London SW1H 0EU

   Tel: 0207 210 4850

   and to:

   The Secretary to the Association of the British Pharmaceutical Industry

   7th Floor, Southside,

   105 Victoria Street,

   London SW1E 6QT

   Tel: 0207 930 3477

3. The cost of the secretariat shall be shared equally by the Department and the ABPI.

4. It shall be the duty of the secretariat to ensure that communications from one Party shall be made available to the other Party (and to the DRP).

5. Similarly, it shall be the duty of the secretariat to make available to the Parties communications from the DRP.

6. The duties described in paragraphs 4 and 5 of this Annex 15 shall be discharged as soon as possible after receipt of a communication and, in any event, not later than two (2) working days from receipt of the communication.

Dispute Resolution Procedure

7. If the Dispute is referred to the DRP in accordance with paragraph 7.8 the Parties hereby agree that:

- the panel shall comprise:
    - a chair appointed by the Department subject to the agreement of the ABPI (the Chair). A representative of the ABPI shall sit on the interview panel for the post of Chair. The Chair should ideally be a solicitor or barrister qualified to practise in England and Wales, Scotland or Northern Ireland of at least seven practice years' standing and/or a person who has at least seven practice years' experience of significant mediation or dispute resolution; and
    - two members; one appointed by the Department and the other by the ABPI from an agreed pool of pre-selected individuals.

  (together the DRP);

- within twenty eight (28) calendar days of the referral to the DRP, the referring party (the Referring Party) must provide the DRP with the following:
    - the material particulars of the Dispute;
    - the reasons why the Referring Party believes the Dispute has arisen; and
    - a detailed account of the Referring Party's position in relation to the Dispute

  (together the Referring Party Documents). Upon receipt of the Referring Party Documents from the Referring Party, (subject always to paragraph 7.14) the DRP shall promptly disclose the Referring Party Documents to the other Party (the Non Referring Party);

- within twenty eight (28) calendar days of receipt of the Referring Party Documents from the DRP, the Non Referring Party must provide the DRP with the following:
    - the material particulars of the Dispute to the extent that they differ from the Referring Party's account;
    - the reasons why the Non Referring Party believes the Dispute has arisen; and
    - a detailed account of the Non Referring Party's position in relation to the Dispute,

  (together the Non Referring Party Documents). Upon receipt of the Non Referring Party Documents from the Non Referring Party, (subject always to paragraph 7.14) the DRP shall promptly disclose the Non Referring Party Documents to the Referring Party;

- the DRP shall:
    - arrange the date of the hearing of the DRP (the Hearing) within twenty (20) calendar days of receipt of the Non Referring Party Documents from the Non Referring Party; and
    - hold the Hearing within thirty (30) calendar days of receipt of the Non Referring Party Documents from the Non Referring Party;

- the Chair may (but shall not be obliged to) offer the Parties a joint meeting with himself/herself (sitting alone) to explore the possibility of a compromise and settlement of the Dispute. Such process shall be considered independent of any Hearing;

- prior to, or at, the Hearing, the DRP may request supplementary written information from either Party where it considers this necessary to properly understand the issues. Following such request, the Party that has received the request shall be required to provide the supplementary written information within fifteen (15) calendar days of the request or such other period as the Parties and the DRP shall agree;

- a Party shall only provide information and/or materials to the DRP where it is not prohibited in doing so by any duties of confidentiality owed to a third party or other statutory obligations (including but not limited to the Data Protection Act 2018) and where information and/or materials are provided by a Party to the DRP, those information and/or materials shall (subject always to paragraph 7.14) be made available to the other Party;

- the DRP shall notify the Parties (and the ABPI) of its decision (the DRP Decision) within:
  - thirty (30) calendar days of the Hearing concluding; or
  - where it has been necessary to obtain additional written information from any Party, within forty five (45) calendar days of the Hearing concluding.
- the DRP Decision shall be final on the Parties. There shall be no right of appeal against the DRP Decision;

- following notification of the DRP Decision in accordance with the preceding sub-paragraph, each of the Department and the ABPI shall publish the DRP Decision on their respective websites following the redaction of any commercially sensitive information. In determining what is commercially sensitive for the purposes of publication of the DRP Decision, in relation to its own data, each Party shall have a right of veto in deciding which details of the DRP Decision are commercially sensitive. This shall not affect any legal obligation to publish information which either Party may be subject to;
  - the costs of the DRP in respect of the Dispute shall be shared equally by the Parties; and
  - except as otherwise provided at the preceding sub-paragraph, the Parties shall each bear their own costs and expenses incurred in respect of the Dispute Resolution Procedure.

8. At any time before the DRP Decision is made the Parties may agree to settle the Dispute and agree terms for the full and final settlement of the Dispute. In which event the Dispute Resolution Procedure shall cease with immediate effect and no DRP Decision shall be made.

9. At any time before the DRP Decision is made, either Party shall have the right to withdraw from the Dispute Resolution Procedure in which event:

- the Party that has withdrawn shall be deemed to have conceded the Dispute; and

- the Dispute Resolution Procedure shall cease with immediate effect and no DRP Decision shall be made.

10. Each Party agrees to use its best endeavours to procure that the DRP complies with the procedures and time limits specified in Chapter 7 and this Annex 15.

11. Each Party acknowledges that if, at any time, it fails to meet any time limit specified in paragraph 7 of this Annex 15, the Dispute Resolution Procedure may proceed in accordance with the procedures and time limits specified in paragraph 7 regardless.

Conduct of Hearings

12. At the Hearing, the DRP shall give each Party the opportunity to put forward its case on the issue(s) in dispute. Each Party shall be free to decide its own representation at the Hearing. Each Party shall be allowed a reasonable period (being no less than two (2) hours) at the Hearing to make oral representations.

13. In the event that the Chair is not legally qualified as described in paragraph 7 of this Annex 15 a solicitor or barrister qualified to practice in England and Wales, Scotland or Northern Ireland shall be appointed jointly by the Department and the ABPI (with both having the right of veto over such appointment) to advise the DRP on any aspects of its role and shall be entitled to be present throughout the Hearing.

14. All members of the DRP must all be in attendance in order for the Hearing to proceed. The Chair may not sit alone for any part of the Hearing.

15. Directions for the conduct of the Hearing shall be notified by the Chair to the Parties in writing at least fourteen (14) calendar days in advance of the Hearing.

16. Hearings shall be informal and shall not be bound by strict rules of evidence or legal procedure.

17. Hearings shall be held in private to protect matters of commercial confidentiality. The notes of proceedings kept by the secretariat shall be made available only to:

    - the members of the DRP;
    - the Scheme Member; and
    - the Department.

18. It is open to each Party to call such witnesses as it sees fit.

19. The conduct of the Hearing shall be for the Chair to decide in matters such as order of business, questions and evidence.

20. The ABPI shall be entitled to circulate the number and in broad terms, the nature of cases that have been referred to dispute resolution, to Scheme Members at regular intervals.

Powers of the DRP

21. The DRP may request any information from either Party that it considers necessary to determine any point of fact.

22. The DRP may call any expert witness whom it considers necessary to determine any point of fact.

23. The DRP may not, without the express consent of the Parties, extend any of the time limits specified in Chapter 7 or this Annex 15.

24. The DRP shall either refer a matter to the Department for reconsideration under direction or substitute its own decision in respect of that matter.

Disputes arising from the 2005, 2008 and 2009 Pharmaceutical Price Regulation Schemes and the 2014 PPRS

25. Any dispute between the Department and the Scheme Member arising out of or in connection with the 2005, 2008 or 2009 pharmaceutical price regulation schemes and the 2014 PPRS shall not be extinguished by virtue of expiry of the said schemes and shall continue to be dealt with under the dispute resolution arrangements pertinent to the scheme under which the dispute arises and paragraph 2.35 of the Voluntary Scheme.