Department of Health & Social Care

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Annexes to the 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth

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 in December 2023 (known as the 2024 Voluntary Scheme) [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.

Annex: 2024 Voluntary Scheme Members within the same Group

Listed below are all Scheme Members that have elected to or intend to elect to join the 2024 Voluntary Scheme as separate Scheme Members that are within the same Group as your parent undertaking or within the same Group as a subsidiary undertaking of your company.

(a) Name.....

[name of company, partnership etc.]

(b) Name.....

[name of company, partnership etc.]

(c) Name.....

[name of company, partnership etc.]

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 2.25 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 .....

.....

.....

1. I ..... [name of person signing and capacity in which signing, (e.g. director, partner or other)] certify that the below names companies/partnerships/persons[4] 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 in December 2023 (known as the 2024 Voluntary Scheme) [to which there are modifications/and additions made between [the company/partnership/name] and the Secretary of State on.....[5]] being treated as applying to it/him[6].

Other companies

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

Address .....

.....

.....

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

[4] Delete as appropriate.
[5] Only insert date where a modification to the Scheme has been agreed.
[6] Delete as appropriate.

Address .....

.....

.....[7]

2. I also certify [name of company, partnership etc.] hereby consents to act as the “Lead Company”, as defined in paragraph 2.25 of the 2024 Voluntary Scheme, in relation to these companies/partnerships/persons[8].

2024 Voluntary Scheme Members within the same Group

3. List below all Scheme Members that have elected to or intend to elect to join the 2024 Voluntary Scheme as separate Scheme Members are within the same Group as your parent undertaking or within the same Group as a subsidiary undertaking of your company.

(a) Name.....

[name of company, partnership etc.]

(b) Name.....

[name of company, partnership etc.]

(c) Name.....

[name of company, partnership etc.]

4. I am duly authorised to sign this certificate.

Signed .....

Date .....

[7] Add or delete as appropriate.
[8] 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 and capacity in which signing (e.g. director/partner/other)] certify that the above name company/partnership/person[9] hereby withdrawals its/his consent to the Voluntary Scheme made between the Secretary of State and the Association of the British Pharmaceutical Industry in December 2023 (known as the 2024 Voluntary Scheme) being treated as applying to it/him.
2. I am duly authorised to sign this certificate.

Signed .....

Date .....

[9] 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 provide for "any amount payable in accordance with a voluntary scheme" be paid 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 NHS Act 2006 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. Section 263(5A) provides 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 the Secretary of State's approval and to require a sum representing the amount of any excess to be paid to the Secretary of State. 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 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 regulations may confer a right of appeal. The decisions are those made by the Secretary of State to (a) require a specific manufacturer or supplier to provide information, (b) limit, in respect of any specific manufacturer or supplier, any price or profit, (c) refuse to give 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).

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 the powers in sections 262(1)(a) and 263(1)(a) and

(b) and (6)(a) 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 2024 Voluntary Scheme, the initial values for the 2024 Voluntary Scheme.

2. The 2024 Headline Payment Percentage, Basic Payment Percentage, Top-Up Payment Percentage range, the Fixed Forecast Growth Rate for Measured Sales Of Older Medicines, Baseline Adjustments, and Allowed Growth Rate, are fixed and will not change.

3. Other parameters in Table 1 are subject to change as outlined in Annexes 4 and 5, which set out the methodology in more detail and the calculation formulae which will be used.

4. For the purposes of the key parameter calculations, it is assumed that all companies choose to join the 2024 Voluntary Scheme.

Table 1: key parameters

Parameter	2023	2024	2025	2026	2027	2028
Initial forecast growth rate of Measured Sales Of Newer Medicines		4.1%	5.0%	6.8%	6.2%	6.7%
Fixed Forecast Growth Rate for Measured Sales Of Older Medicines		4.6%	5.2%	5.5%	6.3%	2.9%
Initial forecast growth rate of Parallel Import Sales		−3.1%	−1.6%	2.1%	2.0%	0.7%
Initial forecast growth rate of Industry Measured Sales		3.9%	4.7%	6.0%	6.0%	4.8%
2023 Measured Sales Of Newer Medicines Baseline £ million	7,256					
2023 Measured Sales Of Older Medicine Baseline £ million	6,096					
Initial forecast 2024 – 2028 Measured Sales Of Newer Medicines £ million		7,556	7,935	8,477	9,002	9,605

Parameter	2023	2024	2025	2026	2027	2028
Assumed Measured Sales Of Older Medicines £ million		6,374	6,703	7,073	7,522	7,741
Initial forecast 2023 baseline Parallel Import Sales £ million	838					
Initial forecast 2024 – 2028 Parallel Import Sales £ million		812	799	815	831	837
Forecast 2023 Industry Allowed Sales Baseline £ million	11,577					
Baseline adjustments to add into subsequent year allowed sales £ million		150	150	330	380	50
Allowed growth rate (AGR %)		2.0%	3.75%	3.75%	4.0%	4.0%
Profile of Allowed Sales £ million		11,962	12,566	13,379	14,310	14,934
Initial forecast Measured Sales Of Newer Medicines and Assumed Measured Sales of Older Medicines as a % of Industry Measured Sales		94.5%	94.8%	95.0%	95.2%	95.4%
Initial forecast Calculated Total Payment		2,627	2,723	2,837	2,900	3,099
Adjusted Assumed Payment From Older Medicines		1,576	1,611	1,655	1,717	1,727
Newer Medicines Adjustment Factor		8.4%	8.7%	8.7%	8.6%	8.5%
2024 Headline Payment Percentage (applies to Q2-Q4)		15.1%				
Estimated 2025 Headline Payment Percentage			15.3%			
Basic Payment Percentage		10%	10%	10%	10%	10%

Parameter	2023	2024	2025	2026	2027	2028
Top-up Payment Percentage range		0% to 25%	0% to 25%	0% to 25%	0% to 25%	0% to 25%

Annex 4: calculation of Payment Percentages and adjustment to profile of payments

Establishing the 2023 Industry Measured Sales Baseline

1. The 2023 Industry Measured Sales Baseline will be set in relation to measured sales as defined in the 2019 Voluntary Scheme, using 2023 data returns as required by 2019 Voluntary Scheme and the Statutory Scheme as well as 2023 data on Parallel Import Sales as set out in 2019 Voluntary Scheme. The 2023 measured sales as defined in 2019 Voluntary Scheme is then adjusted for changes to the Small Company Sales exemption between the 2019 Voluntary Scheme and the 2024 Voluntary Scheme to establish the 2023 Industry Measured Sales Baseline. The 2023 Industry Measured Sales Baseline will be revised following receipt of audited and revised data in line with the rules of the 2019 Voluntary Scheme and the Statutory Scheme.

2. The adjustment for the change to the Small Company Sales exemption is calculated by reducing the 2023 measured sales by the estimated proportion of 2023 measured sales as set out in 2019 Voluntary Scheme attributable to scheme members of the 2019 Voluntary Scheme with total sales between £5 million and £6 million. The 2023 Industry Measured Sales Baseline is 99.65% of 2023 measured sales as set out in 2019 Voluntary Scheme. This relative adjustment will be revised following receipt of full year, audited and revised 2023 data only.

Establishing the 2023 Industry Allowed Sales Baseline

3. The 2023 Industry Allowed Sales Baseline is the 2023 allowed sales as calculated in the 2019 Voluntary Scheme, adjusted for the change to the Small Company Sales exemption between the 2019 Voluntary Scheme and the 2024 Voluntary Scheme. The forecast 2023 Industry Allowed Sales Baseline is set out in Annex 3.

4. The adjustment for the change to the Small Company Sales exemption is applied to the 2023 Industry Allowed Sales Baseline such that the 2023 Industry Allowed Sales Baseline is 99.65% of 2023 allowed sales as set out in 2019 Voluntary Scheme and this relative adjustment will be revised in line with 2023 data only.

Establishing Industry Allowed Sales

5. Industry Allowed Sales will be set in relation to 2023 Industry Allowed Sales Baseline. Industry Allowed Sales will be adjusted at the start of each year by

the Baseline Adjustment and subsequently grown by an Allowed Growth Rate percentage for that year.

6. Baseline Adjustments for each year of the Voluntary Scheme are:

Year	2024	2025	2026	2027	2028
Baseline Adjustments	£150 million	£150 million	£330 million	£380 million	£50 million

7. The Allowed Growth Rate for each year of the Voluntary Scheme is:

Year	2024	2025	2026	2027	2028
Allowed Growth Rate	2%	3.75%	3.75%	4%	4%

Top-Up Payment Percentage for Older Medicines

8. For Older Medicines, Payment Percentages will be determined for each Branded Presentation. All Eligible Sales of Older Medicines will be subject to the Basic Payment Percentage which is 10%.

9. In addition to the Basic Payment Percentage, a Top-up Payment Percentage may also apply. The Top-up Payment Percentage is determined for each Branded Presentation of an Older Medicine and is based on the difference between the Reference Price and the Observed Average Selling Price for that Branded Presentation.

10. Plasma Derived Medicinal Products (PDMPs), where they are considered Older Medicines, will be exempt from the Top-Up Payment Percentage applying to Older Medicines. They will be subject to the Basic Payment Percentage and VPAG Investment Programme payments only, regardless of the Observed Price Decline. For the avoidance of doubt this does not include recombinant products. Any Branded Presentation that meets this definition will be identified by the Department and identified as such within the NHS BSA portal.

11. Older Medicines with Measured Sales of less than £1.5 million across one VTM for a Scheme Member will be exempt from the Top-Up Payment Percentage. The Eligible Sales of Older Medicines through all Branded Presentations in that VTM by that Scheme Member will be subject to the Basic Payment Percentage and VPAG Investment Programme payments only, regardless of the Observed Price Decline. Any Branded Presentation that meets this definition will be identified automatically within the NHS BSA portal by linking individual Branded Presentations to the VTM as listed under in the dm+d and considering the sales at VTM and company level. For avoidance of doubt, this will not affect whether a Top-up Payment

Percentage applies to Older Medicines of other Scheme Members. The Department reserves the right to not to apply this exemption where, in the reasonable opinion of the Department, the Scheme Member has artificially reduced their annual revenues across a VTM through Commercial Relationships with other Scheme Members or companies subject to the Statutory Scheme, including but not limited to licensing arrangements

12. The process for consideration of an adjusted Top-up Payment Percentage for a Branded Presentation is set out in under Exceptional Circumstances in Chapter 6.

Determining Reference Prices for Older Medicines

13. In addition to the Basic Payment Percentage, a Top-up Payment Percentage may apply to a Scheme Member's Eligible Sales of Older Medicines.

14. The Top-up Payment Percentage is applied to the Eligible Sales of each Branded Presentation and is based on the difference between a Reference Price and an Observed Average Selling Price for a Branded Presentation across the relevant year of the 2024 Voluntary Scheme, or the relevant part year. In 2024, the Observed Average Selling Price will be the average selling price for the relevant Branded Presentation across the last three quarters of 2024 (or across the relevant part of this period).

15. The Reference Prices for Older Medicines are determined in accordance with three main categories:

    - Branded Presentations which are Originator Products and would have met the definition of an Older Medicine on 1 January 2015 or later (Older Originator Products At Or After 2015);
    - Branded Presentations which are Originator Products and would have met the definition of an Older Medicine before 1 January 2015 (Pre-2015 Older Originator Products);
    - Branded Presentations which are not Originator Products (New Entrant Products).

16. For each category, Reference Prices are established with consideration given to whether the Branded Presentation itself was launched before, on or after 1 January the calendar year prior to the Originator Product meeting the definition of an Older Medicine (Reference Anchor Date). The process for establishing the reference price is set out in the table below.

Branded presentation launch date	Process for establishing the reference price
For Branded Presentations which are Older Originator Products At Or After 2015	
1. Where the Branded Presentation was launched before or on the Reference Anchor Date.	The Reference Price will be the Observed Average Selling Price of the Branded Presentation in the full calendar year ahead of becoming an Older Medicine.
2. Where the Branded Presentation was launched after the Reference Anchor Date	The Reference Price will be set by the Department on the basis of consideration of comparators of the same VTM by the same Scheme Member launched before the Reference Anchor Date. The Reference Price will be informed by the Observed Average Selling Price of the most relevant comparator(s) in the full calendar year ahead of the Branded Presentation becoming an Older Medicine, adjusted where appropriate to consider factors including but not limited to differences in pack size and strength. Where a Reference Price cannot be established based on comparators from the same Scheme Member, the Reference Price will instead be informed by the List Prices on the Reference Anchor Date of comparators with the same VTM among Originator Products, with a 12.5% downward adjustment, further adjusted where appropriate to consider factors including but not limited to differences in pack size and strength.
For Branded Presentations which are Pre-2015 Older Originator Products	
3. Where the Branded Presentation was launched before or on the Reference Anchor Date.	The Reference Price will be the List Price of the Branded Presentation as of the Reference Anchor Date with a 12.5% downward adjustment.
4. Where the Branded Presentation was launched after the Reference Anchor Date.	The Reference Price will be set by the Department on the basis of consideration of comparators of the same VTM by the same Scheme Member launched before the Reference Anchor Date. The Reference Price will be informed by the List Prices of the most relevant comparators as of the Reference Anchor Date with a 12.5% downward adjustment, further adjusted where appropriate to

Branded presentation launch date	Process for establishing the reference price
	consider factors including but not limited to differences in pack size and strength. Where a Reference Price cannot be established based on comparators from the same Scheme Member, the Reference Price will instead be informed by the List Prices as of the Reference Anchor Date of the most relevant comparators of the same VTM among other Originator Products, and subject to the same adjustments.
For Branded Presentation which are New Entrant Products	
5. Where the Branded Presentation is launched on or after the Reference Anchor Date, and at or before the Reference Anchor Date there is one or more Originator Product with the same Virtual Medicinal Product Pack (VMPP).	The Reference Price will be based on the List Price(s) of the Originator Product(s) of the same VMPP on the Reference Anchor Date, with a 12.5% downward adjustment.
6. Where the Branded Presentation is launched before the Reference Anchor Date, and at or before the time of launch there is one or more Originator Product with the same Virtual Medicinal Product Pack (VMPP).	The Reference Price will be based on the List Price(s) of the Originator Product(s) of the same VMPP on the date of launch, with a 12.5% downward adjustment. This will be updated to the equivalent data as of the Reference Anchor Date when available, subject to the same adjustments, and will be in effect for the first full scheme year following the Reference Anchor Date.
7. Where the Branded Presentation is launched on or after the Reference Anchor Date, and as of Reference Anchor Date there is no Originator Product with the same VMPP.	The Reference Price will be set by the Department on the basis of consideration of comparators of the same VTM among Originator Products. The Reference Price will be informed by the List Prices of the most relevant comparators as of the Reference Anchor Date with a 12.5% downward adjustment, further adjusted where appropriate to consider factors including but not limited to differences in pack size and strength.
8. Where the Branded Presentation is launched	The Reference Price will be set by the Department on the basis of consideration of comparators of the

Branded presentation launch date	Process for establishing the reference price
before the Reference Anchor Date, and at the time of launch there is no Originator Product with the same VMPP.	same VTM among Originator Products. The Reference Price will be informed by the List Prices of the most relevant comparators as of the launch date of the Branded Presentation with a 12.5% downward adjustment, further adjusted where appropriate to consider factors including but not limited to differences in pack size and strength. This will be updated to the equivalent data as of the Reference Anchor Date when available, subject to the same adjustments, and will be in effect for the first full scheme year following the Reference Anchor Date.

17. Notwithstanding paragraphs 15-16, where a company is not an Originator or Originator Licensee, but is in the same Group as an Originator or Originator Licensee for a given VTM, it will normally be treated with respect to categories 1 or 2 in the table at paragraph 16, unless the company provides reasonable evidence to the Department as to why they would be prevented from doing this. Their Reference Price will be calculated with respect to the Observed Average Selling Price of the relevant Branded Presentation for the Originator or Originator Licensee within their Group in the full calendar year ahead of the Originator or Originator Licensee's Branded Presentation becoming an Older Medicine.

18. Where the Department is setting Reference Prices or identifying comparators, it will do so in a fair and consistent way. Comparators will be identified with the aim of establishing and setting Reference Prices based on the closest match or matches to the relevant Branded Presentation, having consideration to factors including but not limited to pack size, strength, and mode of application. Scheme Members will be able to query Department decisions and to provide additional supporting information.

19. Where data is not available for the relevant date for a given List Price, the Closest In Date List Price will be used instead with the same adjustments.

20. The Department and Scheme Members will operate in good faith. The Department reserves the right to seek further information from Scheme Members where the Observed Average Selling Price, when informing the Reference Price, in the reasonable opinion of the Department, appears to have been increased solely for the purpose of affecting the Reference Price, and similarly, where the List Price appears to have been lowered solely for

the purposes of affecting the Reference Price for other Branded Health Service Medicines.

21. On the request of a Scheme Member, the Department will consider where adjustments to the Reference Price may be justified based on significant price reduction (in the reasonable opinion of Department) ahead of becoming an Older Medicine. The circumstances considered will be limited to Scheme Products participating in a national level NHS England strategic category medicines competitive tendering process (or a successor process that is jointly agreed by ABPI, NHS England and the Department to be equivalent) ahead of becoming an Older Medicine.

22. Where the Reference Price cannot be identified or does not exist due to data availability, the Department reserves the right to request that Scheme Members provide information that enables the Department to establish the Reference Price. The information requested can include (but is not limited to) the SPC or Marketing Authorisation expiry date, the Observed Average Selling Price of a Branded Presentation for a given period, the List Price of the Branded Presentation on a given date, or the Originator Product for a Branded Presentation. The Department reserves the right to test any Observed Average Selling Price and List Price data against available data sources including but not limited to Pharmex, RX-Info: Define and NHS England commercial agreements and frameworks.

23. Where the requested information is not provided by the Scheme Member within 60 calendar days, or in the reasonable opinion of the Department is not reliable with respect to other available data sources, the Department reserves the right to set the Reference Price or to determine the applicable Top-Up Payment Percentage for a given Branded Presentation, and it will do so in a fair and consistent way.

Process for sharing of Reference Prices

24. The Department is responsible for establishing whether a Branded Presentation is a Newer Medicine or an Older Medicine and for Older Medicines, the appropriate Reference Price for each Branded Presentation, notwithstanding its right to request additional supporting information from Scheme Members. Scheme Members will have an opportunity to query the Reference Price and provide additional supporting information, but the final Reference Price setting will be at the discretion of the Department.

25. The Department will notify Scheme Members of the status of each Branded Presentation and, where applicable, the Reference Price, no later than 31 March 2024 based on available information. While the Department will make reasonable efforts to determine whether a Branded Presentation is a Newer

Medicine or an Older Medicine and determine any Reference Price, there will be instances where it cannot be determined based on available data. Where this occurs, the Department reserves the right to request that Scheme Members provide the supporting information on a ‘best effort’ basis as outlined above. Any initial requests for supporting information will also take place no later than 31 March 2024.

26. There are no obligations on Scheme Members to confirm receipt of data. No response within 45 calendar days will be acknowledged as confirmation. However, where a Scheme Member has reason to believe that the received information is incorrect and may lead to a non-negligible impact for them, the Scheme Member can query the information provided. Scheme Members should query the data within 45 calendar days of receipt, outlining the relevant Branded Presentations and concerns. Scheme Members can request a further extension of up to 15 calendar days by writing to the Department and providing a reason for requiring that extension. The granting of this extension is at the discretion of the Department. Where the Department has requested additional information, this must be provided by Scheme Members on a ‘best efforts’ basis within 60 calendar days of the request.

27. Reference Prices will be available on the NHS BSA portal and will be pre-populated in the Annual Presentation Level Sales Reports. However, the NHS BSA portal will not have this functionality by 31 March 2024 and as such, the Department will share initial information, based on the list of 2023 Branded Presentations as generated by NHS BSA, by email with appropriate information security measures taken. For Newer Medicines, the date from which a Branded Presentation is expected to become an Older Medicine, will be contained in the information shared and available through the NHS BSA portal in due time such that Scheme Members will have access to this data for any Branded Presentation with 2023 Sales. On an ongoing basis, this will be updated for any new Branded Presentation as identified through Annual Presentation Level Sales Reports from 2024 onwards.

Branded Presentations without a defined VTM

28. There are a limited number of Branded Presentations which do not have a VTM in the dm+d due to specific characteristics. The Department will review this on a case-by-case basis and determine whether each Branded Presentation is a Newer Medicine or Older Medicine and where relevant, determine the Reference Price. Where the Department is establishing a Reference Price informed by comparators, it will do so in a fair and consistent way.

Derivation of the Headline Payment Percentage

29. The Headline Payment Percentage will apply to Eligible Sales Of Newer Medicines to calculate payments owed by Scheme Members in respect of Newer Medicines.

30. The Headline Payment Percentage is set dynamically with respect to Industry Allowed Sales – similar to the current scheme – with certain elements in respect of Older Medicines being pre-determined, reflecting the approach to risk sharing agreed. For any year 2026 to 2028 it will not exceed the Ceiling.

31. Industry Measured Sales is the sum of:

    - Measured Sales Of Newer Medicines, consisting of Voluntary Scheme Measured Sales Of Newer Medicines and Statutory Scheme Measured Sales Of Newer Medicines.
    - Assumed Measured Sales Of Older Medicines; and
    - Parallel Import Sales.

32. Calculated Total Payment for a given year is the difference between Industry Measured Sales and Industry Allowed Sales (Allowed Sales Gap), multiplied by: the sum Measured Sales Of Newer Medicines, and Assumed Measured Sales Of Older Medicines, as a share of Industry Measured Sales.

33. Calculated Payment From Newer Medicines is the Calculated Total Payment minus the Adjusted Assumed Payment From Older Medicines.

34. The Unadjusted Headline Payment Percentage is the Calculated Payment From Newer Medicines divided by the Adjusted Sales Of Newer Medicines.

35. The Adjusted Sales Of Newer Medicines is calculated by multiplying the Measured Sales Of Newer Medicines and the Newer Medicines Adjustment Factor. The Newer Medicines Adjustment Factor is the Eligible Sales Of Newer Medicines divided by Voluntary Scheme Measured Sales Of Newer Medicines.

36. Any Under Payments or Over Payments in respect of Newer Medicines are divided by the Eligible Sales Of Newer Medicines to give the Under Payments or Over Payments Adjustment.

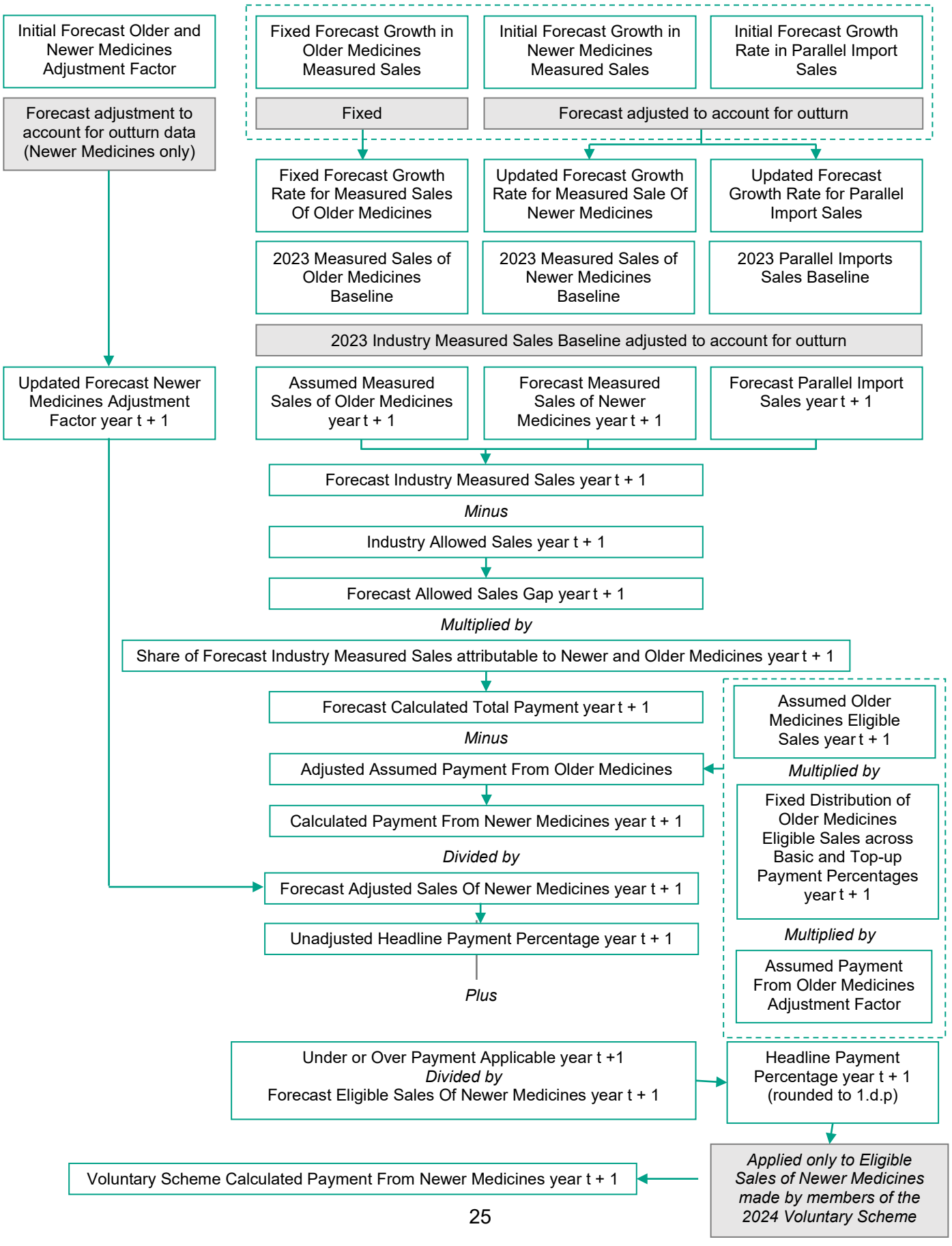
37. The Headline Payment Percentage is the sum of the Unadjusted Headline Payment Percentage and the Under Payments or Over Payments Adjustment, rounded to one decimal place. For any year 2026 to 2028 where the Headline Payment Percentage is greater than the Ceiling, it will be set at the Ceiling.

38. The Headline Payment Percentage is multiplied by the Eligible Sales of Newer Medicines to calculate the Voluntary Scheme Calculated Payment through Newer Medicines. This is the Scheme Payment due to Newer Medicines.

39. The Headline Payment Percentage for 2024 was set ahead of commencement of the 2024 Voluntary Scheme using the best available data. With the exception of the Older Medicines inputs that are fixed, as set out in sections below, the Headline Payment Percentage for 2024, and future years, will be updated as fuller, and in some cases, audited data becomes available.

40. Any discrepancy between the forecast Headline Payment Percentage and updates following receipt of data returns will be dealt with via the under-over payment process. If the under-over payment process results in a Headline Payment Percentage above the Ceiling, it will be set at the Ceiling. If the Ceiling is reached, no new Under Payments will be calculated for that year but Over Payments will continue to be calculated as they normally are. When updated sales data is available and Headline Payment Percentages for previous years are recalculated, the Ceiling will also apply to those recalculated Headline Payment Percentages.

Figure 1: Calculation of the Newer Medicines Payment Percentage in year t_{+1} (without application of the Ceiling)



41. The calculation of the Headline Payment Percentage for years 2 to 5 of the Voluntary Scheme incorporates a number of adjustments:

- Adjustment of 2023 Industry Measured Sales and 2023 Allowed Sales Baseline: The initial forecast 2023 Industry Measured Sales Baseline will be updated with outturn data, as will the 2023 Industry Allowed Sales Baseline.

- Adjustment of forecast growth rates: The initial forecast growth rate of Measured Sales Of Newer Medicines and Parallel Import Sales will be adjusted to take into account outturn Measured Sales Of Newer Medicines and Parallel Import Sales in previous years of the Voluntary Scheme. The forecast growth rate of Assumed Measured Sales Of Older Medicines will remain fixed.

- Adjustment of Headline Payment Percentage to account for prior year Under Payments or Over Payments: The Headline Payment Percentage is adjusted for any Under Payments or Over Payments relating to Newer Medicines in previous years of the Voluntary Scheme due to differences in forecast and outturn Measured Sales Of Newer Medicines and Eligible Sales Of Newer Medicines. Set out in paragraphs 56 through 59.

- Adjustment of forecast Share of Voluntary Scheme Measured Sales Of Newer Medicines exempt from Eligible Sales: The initial forecast Share of Voluntary Scheme Measured Sales Of Newer Medicines exempt from Eligible Sales is adjusted to take into account outturn data from previous years of the Voluntary Scheme.

42. In addition to the setting of each subsequent year's Headline Payment Percentage in 2024-2027, there will be an end-scheme reconciliation in relation to Newer Medicines only to account for the fact that all final Audited Sales returns will not be received until 2030 and to account for any residual rounding impact. This process will recalculate the year 5 Headline Payment Percentage on the basis of updated data and will take place in 2029 and 2030. Any Under Payments or Over Payments resulting from the revised Headline Payment Percentage will be settled between the Department and Scheme Members in 2030.

43. 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 42.

Derivation of Assumed Measured Sales Of Older Medicines

44. The derivation of the Headline Payment Percentage includes fixed elements with respect to Older Medicines to reflect the approach agreed to risk sharing in the 2024 Voluntary Scheme. The first of these fixed elements is the Assumed Measured Sales Of Older Medicines.

45. The 2023 Measured Sales Of Older Medicines Baseline means the sum of 2023 measured sales by scheme members of the 2019 Voluntary Scheme and 2023 Statutory Scheme Sales, for those medicines that would be considered an Older Medicine in 2023 if the definition of an Older Medicine set out in the 2024 Voluntary Scheme was applied. For any Branded Presentation that became an Older Medicine during 2023, the categorisation as an Older Medicine applies to the Sales of that Branded Presentation from the following quarter. Since there is no quarterly breakdown of 2023 presentation level data, the proportion of 2023 sales considered to be sales of Newer Medicines and Older Medicines, will be pro-rata based on the number of quarters the Branded Presentation was as a Newer Medicine and an Older Medicine during 2023.

46. The Assumed Measured Sales Of Older Medicines is the 2023 Measured Sales Of Older Medicines Baseline grown by the Fixed Forecast Growth Rate for Measured Sales Of Older Medicines, the Department's forecast growth rate for Older Medicines in each year of the 2024 Voluntary Scheme.

Measure	**2024**	**2025**	**2026**	**2027**	**2028**
Fixed Forecast Growth Rate for Measured Sales Of Older Medicines	4.6%	5.2%	5.5%	6.3%	2.9%

47. The initial Assumed Measured Sales Of Older Medicines is based on a forecast of the 2023 Measured Sales Of Older Medicines Baseline and the Fixed Forecast Growth Rate for Measured Sales Of Older Medicines.

48. The 2023 Measured Sales Of Older Medicines Baseline will be updated upon receipt of 2023 Annual Sales Reports and/or 2023 Audited Annual Sales Reports and Annual Presentation Level Sales Reports. The Fixed Forecast Growth Rate for Measured Sales Of Older Medicines will be applied to the updated 2023 Measured Sales Of Older Medicines Baseline to update the Assumed Measured Sales Of Older Medicines. This process will be repeated each time there is an update to the 2023 Annual Sales Reports, 2023 Audited Annual Sales Reports and 2023 Annual Presentation Level Sales Reports.

49. The Assumed Measured Sales Of Older Medicines, used to calculate the

Headline Payment Percentage, will therefore only change from the initial forecast, due to changes in the 2023 Measured Sales Of Older Medicines Baseline.

Derivation of Adjusted Assumed Payment From Older Medicines

50. Another fixed element in the calculation of the Headline Payment Percentage is the Adjusted Assumed Payment From Older Medicines.

51. The Assumed Payment From Older Medicines is calculated by applying the Basic Payment Percentage and the Top-Up Payment Percentage to the Assumed Eligible Sales Of Older Medicines according to the Fixed Distribution of Older Medicines Eligible Sales Across Basic and Top-Up Payment Percentages. This is then adjusted in line with the Assumed Payment from Older Medicines Adjustment Factor to give the Adjusted Assumed Payment From Older Medicines.

52. The Assumed Eligible Sales Of Older Medicines is calculated by adjusting the Assumed Measured Sales Of Older Medicines down in line with the Fixed Older Medicines Adjustment Factor. The Fixed Older Medicines Adjustment Factor is an estimate of the proportion of Assumed Measured Sales Of Older Medicines that are exempt from Eligible Sales. This will be set up front and not adjusted subsequently as shown below.

Measure	**2024**	**2025**	**2026**	**2027**	**2028**
Fixed Older Medicines Adjustment Factor	2.4%	2.4%	2.4%	2.4%	2.4%

53. The Fixed Distribution of Older Medicines Eligible Sales Across Basic and Top-Up Payment Percentages will be fixed throughout the 2024 Voluntary Scheme and will not change. This distribution is applied to the Assumed Eligible Sales Of Older Medicines to estimate the Assumed Payment From Older Medicines.

Fixed Distribution of Older Medicines Eligible Sales Across Basic and Top-up Payment Percentages	**Percentage**
Basic Payment Percentage only	30.4%
Basic Payment Percentage plus 1% Top-up Payment Percentage	0.2%
Basic Payment Percentage plus 2% Top-up Payment Percentage	0.2%
Basic Payment Percentage plus 3% Top-up Payment Percentage	0.3%
Basic Payment Percentage plus 4% Top-up Payment	0.1%

Percentage	
Basic Payment Percentage plus 5% Top-up Payment Percentage	0.1%
Basic Payment Percentage plus 6% Top-up Payment Percentage	0.0%
Basic Payment Percentage plus 7% Top-up Payment Percentage	0.1%
Basic Payment Percentage plus 8% Top-up Payment Percentage	0.9%
Basic Payment Percentage plus 9% Top-up Payment Percentage	0.4%
Basic Payment Percentage plus 10% Top-up Payment Percentage	0.9%
Basic Payment Percentage plus 11% Top-up Payment Percentage	0.1%
Basic Payment Percentage plus 12% Top-up Payment Percentage	0.1%
Basic Payment Percentage plus 13% Top-up Payment Percentage	0.1%
Basic Payment Percentage plus 14% Top-up Payment Percentage	1.7%
Basic Payment Percentage plus 15% Top-up Payment Percentage	0.5%
Basic Payment Percentage plus 16% Top-up Payment Percentage	2.2%
Basic Payment Percentage plus 17% Top-up Payment Percentage	0.4%
Basic Payment Percentage plus 18% Top-up Payment Percentage	1.4%
Basic Payment Percentage plus 19% Top-up Payment Percentage	0.3%
Basic Payment Percentage plus 20% Top-up Payment Percentage	1.0%
Basic Payment Percentage plus 21% Top-up Payment Percentage	1.0%
Basic Payment Percentage plus 22% Top-up Payment Percentage	0.6%
Basic Payment Percentage plus 23% Top-up Payment Percentage	0.2%
Basic Payment Percentage plus 24% Top-up Payment Percentage	0.6%
Basic Payment Percentage plus 25% Top-up Payment Percentage	56.5%

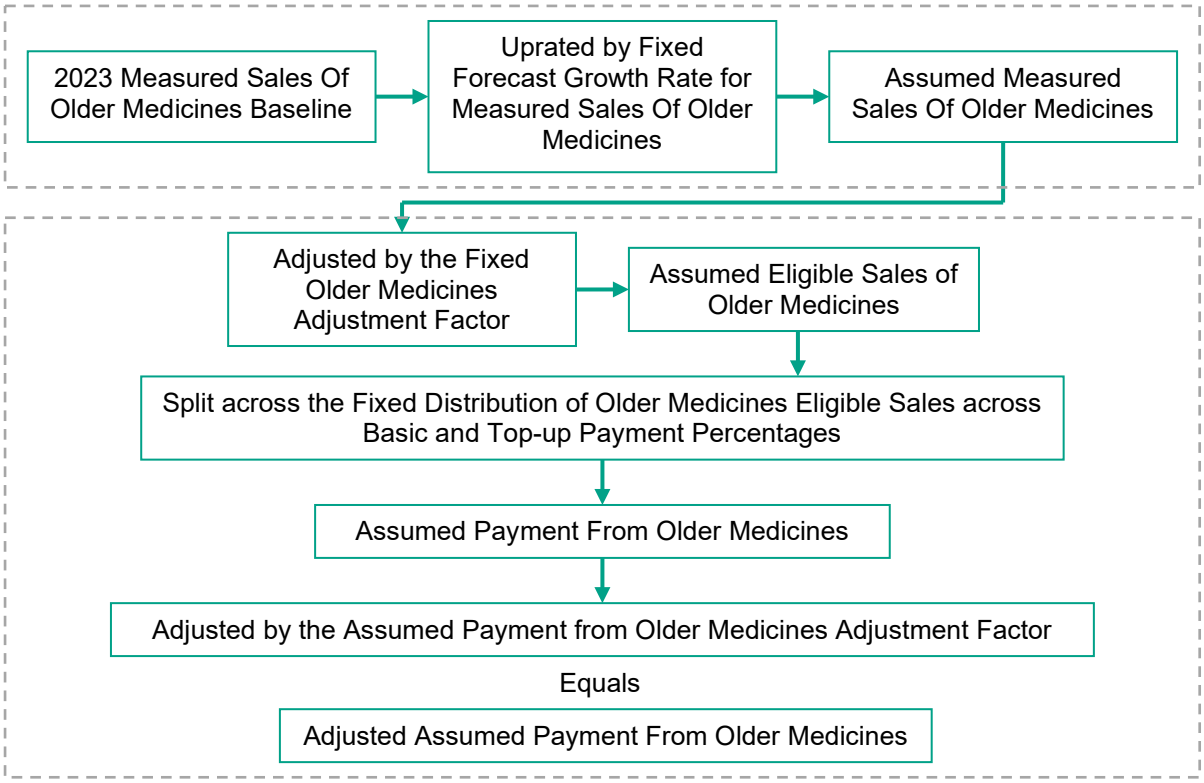
54. The Assumed Payment from Older Medicines Adjustment Factor is a proportional reduction per annum in the Assumed Payment from Older Medicines to reflect potential behavioural responses to this novel affordability mechanism for Older Medicines. As such it increases over time and is pre-

determined at the rates shown below.

Measure	2024	2025	2026	2027	2028
Assumed Payment from Older Medicines Adjustment Factor	−3.1%	−5.8%	−8.3%	−10.6%	−12.6%

55. The calculation of the Adjusted Assumed Payment From Older Medicines is illustrated below at figure 2.

Figure 2: calculation of the Adjusted Assumed Payment From Older Medicines



Adjustment of forecast growth rates

56. In each year of the 2024 Voluntary Scheme, the forecast growth rates of Measured Sales Of Newer Medicines and Parallel Import Sales (and hence the overall forecast Industry Measured Sales growth rate) will be adjusted to account for the difference between forecast and outturn Measured Sales Of Newer Medicines and Parallel Import Sales in prior years of the 2024 Voluntary Scheme. This will impact the difference between forecast Industry Measured Sales and Industry Allowed Sales for each subsequent year and will therefore affect the Headline Payment Percentage. The forecast growth rate for Measured Sales Of Older Medicines will remain fixed.

57. For each year two and following, the forecast correction is the difference between the outturn cumulative growth rates of Measured Sales Of Newer Medicines and Parallel Import Sales and forecast cumulative growth rates of Measured Sales Of Newer Medicines and Parallel Import Sales from the start of the 2024 Voluntary Scheme to the prior year of the 2024 Voluntary Scheme. At the time of adjustment the existing forecasts will be multiplicatively adjusted. This will be on the basis of the average difference between the existing forecasts and outturn for all prior years (including the current year).

58. The timing of these adjustments is 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 2024 Voluntary Scheme.

59. 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. The process for dealing with differing end year statutory accounts is covered in paragraph 76 of this Annex.

60. In the event that both parties agree on new forecasts during the lifetime of the 2024 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 2024 Voluntary Scheme.

Adjustment of Headline Payment Percentage to account for prior year payments

61. The Under Payments or Over Payments relating to Newer Medicines in a given year is the difference between the payments made and the payments subsequently recalculated (see paragraphs 57-58) for Scheme Members in relation to Newer Medicines.

62. Payments owed by Scheme Members in relation to Newer Medicines will be calculated by multiplying the updated Headline Payment Percentage (based on outturn data where relevant) and the Eligible Sales Of Newer Medicines.

63. 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. Where Scheme Members are delayed in providing updated outturn data, or additional information comes to light which requires adjustments to be made, this will be used to calculate an updated Under Payments or Over Payments figure.

64. The Under Payments or Over Payments for a given year is spread equally over the remaining Voluntary Scheme years and, along with updating elements of the forecast growth rates of Measured Sales Of Newer Medicines and Parallel Import Sales, is taken into account when calculating future year Headline Payment Percentages. In years where the Ceiling is reached, no new Under Payments will be calculated for that year but Over Payments will continue to be calculated as they normally are.

Adjustment of forecast Share of Voluntary Scheme Measured Sales Of Newer Medicines exempt from Eligible Sales

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

66. The first adjustment to the Share of Voluntary Scheme Measured Sales Of Newer Medicines exempt from Eligible Sales will be in Year 1 (2024) and will affect the forecast Share of Measured Sales Of Newer Medicines exempt from Eligible Sales (and subsequently Eligible Sales Of Newer Medicines) for Year 2 (2025). The initial forecast Share of Measured Sales Of Newer Medicines 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 2024. The outturn share will be based on company reported sales for exempt sales for the 6 months ending 30 September 2024 multiplied by two, which is used as a first estimate for the exempt sales for 2024.

67. In year 2 (November 2025), the forecast Share of Measured Sales Of Newer Medicines exempt from Eligible Sales for 2026 will be adjusted in the same

way based on the average difference between forecast and outturn in 2024 (based on best available data for 12 months ending 31 December 2024), and 2025 (based on 6 months ending 30 September 2025 multiplied by two).

68. For subsequent years of the 2024 Voluntary Scheme, the forecast Share of Measured Sales Of Newer Medicines 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

69. To reflect all final Audited and de-facto Audited Annual Sales Reports will not be received until 2029 at the earliest, and to account for any remaining rounding impact, there will be a two-phase scheme-end reconciliation in 2029 and 2030. This will account for any remaining Under Payments or Over Payments arising from the receipt of Audited and de-facto Audited reports after 2027.

70. Following the close of the third quarter of 2029, the Department should have received Audited or de-facto audited returns for Measured Sales Of Newer Medicines made in 2027, and updated data for Measured Sales Of Newer Medicines made in 2028 (this may be a mix of Audited returns for Scheme Members with a calendar Financial 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 an updated Headline Payment Percentage and corresponding payment for 2028. The revised Headline Payment Percentage will be subject to the Ceiling and be calculated to two decimal places. Any change arising in the payment due from Scheme Members following the revision of the 2028 Headline Payment Percentage will be payable (or refundable) in the first quarter of 2030.

71. Similarly, following the close of the third quarter of 2030, the Department should have received Audited and de-facto audited returns for Measured Sales Of Newer Medicines made in 2028. This will be used to calculate a re-revised Headline Payment Percentage and corresponding payment for 2028, which will be subject to the Ceiling and calculated to two decimal places. Any change arising in the payment due from Scheme Members in 2028, taking into account the scheme-end reconciliation in 2029, will be payable (or refundable) in the first quarter of 2031.

Timing of the adjustments

72. In each year of the 2024 Voluntary Scheme, initial outturn of Measured Sales

Of Newer Medicines is calculated following the close of the third quarter of that calendar year. The initial outturn consists of actual Measured Sales Of Newer Medicines for the nine months ending in September versus the same period the previous year. This is so that the adjustments can be calculated and set in advance of the following calendar year. For all years, once the Audited and de-facto Audited Annual Sales Reports have been received, the outturn growth rate of Measured Sales Of Newer Medicines will be calculated by comparing the twelve months 1 January to 31 December with the twelve months in the previous year.

73. 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 Headline Payment Percentage for the year after.

74. So for year one (2024) any corrections to the outturn following the Audited accounts received by September 2025 in year two will be fed into the adjustment calculations for the Headline Payment Percentage for year three and following years (2026, 2027 and 2028). Any scheme wide over or under payments for 2024 reflect Q2-Q4 only. Where additional updates to 2024 outturns are received in 2025 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 Headline Payment Percentages in subsequent years, and where applicable, the end scheme reconciliation exercise.

75. Each time a Scheme Member or member of the Statutory Scheme's sales exceed the sales threshold as set out in the Small Company definition of the 2024 Voluntary Scheme and the Statutory Scheme respectively, the outturn figures used to calculate the growth rate in that year will be adjusted to include outturn sales for all members of the 2024 Voluntary Scheme and the Statutory Scheme counted as part of Measured Sales Of Newer Medicines in both the current and the prior year, and only those members. For example, should a Scheme Member's sales grow to exceed £6 million in 2025 and remain above 2025 for the remainder of the Scheme, these sales will not be included in the growth rate calculation for 2025. They will however be included in the growth rate calculation for 2026.

76. 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’.

77. This also covers data relating to the baseline period (2023). It is also possible that information may come to light that means that additional adjustments are required to the Measured Sales Of Newer Medicines and therefore the component forecasts and Headline Payment Percentages. This will be agreed with the Auditors on the basis of how to best represent Measured Sales Of Newer Medicines historically and for future adjustments.

78. 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.

Table 2: timing of adjustments

Outturn year	Components		Calculated when	Headline Payment percentage profile adjusted for Years
	Measured Sales Of Newer Medicines	Parallel Import Sales		
Year 0 i.e. Baseline (2023)	Best available[10] 12 months ending 31 December 2023	Outturn PI sales for 12 months ending 31 December 2023 from IQVIA, adjusted to net prices	November 2024	Year 2-5
Year 0 i.e. Baseline (2023)	Audited/de-facto audited sales 12 months ending 31 December 2023	Revised Outturn PI sales for 12 months ending 31 December 2023 from IQVIA, adjusted to net prices	November 2025	Year 3-5
Year 1 (2024)	Unaudited 9 months ending 30 September 2024	Outturn PI sales for 12 months ending 30 September 2024 from IQVIA, adjusted to net prices	November 2024	Year 2-5
Year 1 (2024)	Best available[1] 12 months ending 31 December 2024	Revised Outturn PI sales for 12 months ending 31 December 2024 from IQVIA, adjusted to net prices	November 2025	Year 3-5

[10] 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).

Outturn year	Components		Calculated when	Headline Payment percentage profile adjusted for Years
	Measured Sales Of Newer Medicines	**Parallel Import Sales**		
Year 1 (2024)	Audited/de-facto audited sales 12 months ending 31 December 2024	Revised Outturn PI sales for 12 months ending 31 December 2024 from IQVIA, adjusted to net prices	November 2026	Year 4-5
Year 2 (2025)	Unaudited 9 months ending 30 September 2025	Outturn PI sales for 12 months ending 30 September 2025 from IQVIA, adjusted to net prices	November 2025	Year 3-5
Year 2 (2025)	Best available[1] 12 months ending 31 December 2025	Revised Outturn PI sales for 12 months ending 31 December 2025 from IQVIA, adjusted to net prices	November 2026	Year 4-5
Year 2 (2025)	Audited/de-facto audited sales 12 months ending 31 December 2025	Revised Outturn PI sales for 12 months ending 31 December 2025 from IQVIA, adjusted to net prices	November 2027	Year 5
Year 3 (2026)	Unaudited 9 months ending 30 September 2026	Outturn PI sales for 12 months ending 30 September 2026 from IQVIA, adjusted to net prices	November 2026	Year 4-5

Outturn year	Components		Calculated when	Headline Payment percentage profile adjusted for Years
	Measured Sales Of Newer Medicines	**Parallel Import Sales**		
Year 3 (2026)	Best available[1] 12 months ending 31 December 2026	Revised Outturn PI sales for 12 months ending 31 December 2026 from IQVIA, adjusted to net prices	November 2027	Year 5
Year 3 (2026)	Audited/de-facto audited sales 12 months ending 31 December 2026	Revised Outturn PI sales for 12 months ending 31 December 2026 from IQVIA, adjusted to net prices	November 2028	End scheme reconciliation
Year 4 (2027)	Unaudited 9 months ending 30 September 2027	Outturn PI sales for 12 months ending 30 September 2027 from IQVIA, adjusted to net prices	November 2027	Year 5
Year 4 (2027)	Best available[1] 12 months ending 31 December 2027	Revised Outturn PI sales for 12 months ending 31 December 2027 from IQVIA, adjusted to net prices	November 2028	End scheme reconciliation
Year 4 (2027)	Audited/de-facto audited sales 12 months ending 31 December 2027	Revised Outturn PI sales for 12 months ending 31 December 2027 from IQVIA, adjusted to net prices	November 2029	End scheme reconciliation

Outturn year	Components		Calculated when	Headline Payment percentage profile adjusted for Years
	Measured Sales Of Newer Medicines	**Parallel Import Sales**		
Year 5 (2028)	Unaudited 9 months ending 30 September 2028	Outturn PI sales for 12 months ending 30 September 2028 from IQVIA, adjusted to net prices	November 2028	End scheme reconciliation
Year 5 (2028)	Best available[1] 12 months ending 31 December 2028	Revised Outturn PI sales for 12 months ending 31 December 2028 from IQVIA, adjusted to net prices	November 2029	End scheme reconciliation
Year 5 (2028)	Audited/de-facto audited sales 12 months ending 31 December 2028	Revised Outturn PI sales for 12 months ending 31 December 2018 from IQVIA, adjusted to net prices	November 2030	End scheme reconciliation

Data Sources

79. The following key parameters for the 2024 Voluntary Scheme are based on the initial forecast. The exact figures can be found in Annex 3:

- Initial forecast growth rate of Measured Sales Of Newer Medicines;
- Fixed Forecast Growth Rate for Measured Sales Of Older Medicines;
- Initial forecast growth rate of Parallel Import Sales;
- Initial forecast growth rate of Industry Measured Sales;
- Initial forecast Measured Sales Of Newer Medicines and Assumed Measured Sales of Older Medicines as a % of Industry Measured Sales;
- Initial forecast share of Voluntary Scheme Newer Medicines Measured Sales exempt from Eligible Sales.

80. 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.

81. 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 Measured Sales Of Newer Medicines (including exempt sales) in the base year (2023) and in each subsequent year of the 2024 Voluntary Scheme;
- Outturn Measured Sales of Older Medicines (including exempt sales) in the base year (2023) only;
- Outturn Exemptions from Eligible Sales of Newer Medicines in the base year (2023) and in each subsequent year of the 2024 Voluntary Scheme;

82. 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 pharmaceutical price regulation scheme which Scheme Members are still paying).

83. 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 2019 Voluntary Scheme company returns, in respect of the year 2020 aggregated at the brand level. If newer discount data of sufficient quality becomes available during the 2024 Voluntary Scheme, this could be used in place of the 2020 discounts by mutual agreement.

Annex 5: scheme calculations

See ‘Annex 5: scheme calculations’, which has been published separately.

Annex 6: guidance notes on completion of quarterly sales reports, annual sales reports, annual presentation level (PLR) sales reports and auditing requirements

General

1. This Annex 6 sets out guidance on the completion of unaudited Quarterly Sales Reports, unaudited Annual Presentation Levels Sales Reports (PLRs), 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 online through the Branded Medicines Portal (BMP or the Portal) and separate guidance will be issued for use of this online system as well as elsewhere in this Annex 6.

5. There are two versions of the Quarterly Sales Report:

    (i) For quarter 1, 2024 (Jan 2024 to March 2024). The structure of this report can be found at Appendix 1A.

    (ii) For all remaining quarters of the 2024 Voluntary Scheme. The structure of this report can be found at Appendix 1B.

6. The layout of the online reports may appear different to the Appendixes 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.

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

8. Scheme Members with Sales of Scheme Products below £6 million 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

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

10. All Scheme Members with Sales of Scheme Products of £1 million or greater and less than £6 million will be required to submit an unaudited Annual Sales Report (see paragraphs 26 to 28 of this Annex 6).

11. All Scheme Members with Sales of Scheme Products of £6 million 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).

12. 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.

Annual Presentation Level Sales Reports

13. Scheme Members are required to submit Annual Presentation Level Sales Reports on a calendar year basis by no later than the end of March the following year for the period covered by the Annual Presentation Level Sales Report.

14. The detailed sales information contained within a completed Annual Presentation Level Sales Report will be used to establish the sales of Newer Medicines and Older Medicines and, therefore, the levels of Measured Sales, Eligible Sales and payments due on these categories of medicine. Payments already made to the Department following the end of each Quarter will be trued-up following the receipt of the Annual Presentation Level Sales Report.

15. The Annual Presentation Level Sales Report should reconcile with the audited Annual Sales Report and, given the timing difference in providing a Annual Presentation Level Sales Report and the audited Annual Sales Report, it may be necessary to resubmit the Annual Presentation Level Sales Report to update it following the audit.

16. The Annual Presentation Level Sales Report will be available through the online Portal. The structure of the Annual Presentation Level Sales Report

can be found at Annex 7. The layout of the online reports may appear slightly different from this annex but the content (and what should be provided) is substantively the same.

Defining Sales of Scheme Products & Exclusions

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

18. The Quarterly Sales Report and Annual Sales Report start with the Scheme Member's total 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[11]:
        - Customer Exclusions;
        - Product Exclusions;
        - Non-UK sales of branded Prescription Only Medicines (POMs);
        - 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

19. 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.

20. The Sales Report (line 1) must reconcile to the turnover in the Scheme Member's accounts.

[11] Customer Exclusions and Product Exclusions are defined later in Annex 6.

21. 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 added at line 2 of the Sales Report.

22. 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)

23. 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.

24. 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).

25. Where a Branded P&GSL Medicine is provided on an NHS prescription, the Department may exercise its discretion to exclude sales of such medicines from the 2024 Voluntary Scheme where total NHS prescription sales of a Branded Presentation in any calendar year within the duration of the 2024 Voluntary Scheme amount to less than £50,000.

Product Exclusions

26. 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).

27. The relevant licensing authority's marketing authorisation/summary of product characteristics states the product category. Other sources of information to determine product categories include the British National formulary (BNF), Prescription Cost Analysis (PCA) data, and the prescription drugs database, IQVIA.

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

28. 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)

29. 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).

30. Scheme Members are responsible for reporting Measured Sales split by Newer Medicines (line 19) and Older Medicines (line 20).

Exemptions from Eligible Sales

31. The following are exempt from Eligible Sales and 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

32. 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.

33. Scheme Members with a Financial Year that does not end on the last calendar day of a Calendar Year will be required to provide two Audited Sales Reports covering the Calendar Year. This will enable the Department to reconcile a Scheme Member's turnover from its statutory accounts to the two Audited Sales Reports provided. Such Sales Reports will be known as Split 1 and Split 2. A Split 1 Sales Report will cover the first period in a Calendar Year, with the Split 2 Sales Report covering the second period. For example, where a company has a Financial Year ending 30 November, it will be required to complete a Split 1 Audited Annual Audited Sales Report or the period 1 January to 30 November and a Split 2 Annual Audited Sales Report for the period 1 December to 31 December.

Reporting by Small Companies

34. Scheme Members with Sales of Scheme Products of £1 million or greater and less than £6 million 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.

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

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

Reporting by Medium Sized Companies

37. Scheme Members with Sales of Scheme Products of £6 million or over but under £30 million will have their first £6 million 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.

38. Medium Sized Companies will have the first £6 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.

39. The Quarterly Sales Report will calculate the value of the Medium Sized Company exemption automatically and adjust the level of Eligible Sales against the various Payment Percentages that are applicable for each category of Eligible Sales before the payment is calculated. The value of the Medium Sized Company exemption will be apportioned proportionately across the differential levels of Eligible Sales in each Payment Percentage category. Any remaining exemption that has not been used in a Quarter will be carried forward for use in the following Quarter.

40. Once available, the Annual Presentation Levels Sales Report and Audited Annual Sales Report will replace the Quarterly Sales Reports. The Medium Sized Company exemption will then be recalculated, on the same basis as it was during the Quarters, but using the annual information provided.

Methodology for Calculations

41. 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.

42. 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.

43. 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 in the Audited Annual Sales Report which has a nine (9) months' deadline following the Scheme Member's Financial Year end date. Scheme Members should ignore parallel export adjustments if they cannot provide a clear audit trail using company records and IQVIA or PCA data.

44. 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.

45. 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.

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

Procedures for Payment

47. 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 calendar Quarter.

48. The Total Scheme Payment will be a calculation that includes various payment elements. These include:

- a payment on Eligible Sales for Newer Medicines;
- varying levels of payment on Older Medicines for Quarterly Sales Reports this will be pre-set at 10% but updated for Audited Annual Sales Reports to reflect the correct Payment Percentage categories;
- VPAG Investment Programme payment;

49. 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 restricted to, the invoice number, description and the payment reference found on the Sales Report.

50. 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 Annual Presentation Levels Sales Report or 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

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

52. 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

53. 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. For companies with a Financial Year end of 31 December the deadline is therefore 30 September in the following year.

54. 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.

55. 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.

56. 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).

57. 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.

58. 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.

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

60. 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.

61. Where the Audited Annual Sales Report does not reconcile with an Annual Presentation Levels Sales Report covering the same Calendar Year that was submitted to the Department before the Audited Annual Sales Report, the Annual Presentation Levels Sales Report will need to be corrected and resubmitted.

62. 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.

63. 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

64. 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 Sales Report – downloadable from the portal;
- Scheme Member's Audited statutory accounts for the period, which also form the basis of the return.

The Portal allows the uploading of documents, such as the above, and this method should be used to provide this documentation.

Independent Third Party

65. All Quarterly Sales Reports and Annual Audited Sales Reports should also be submitted by Scheme Members to the independent third party appointed by the ABPI.

Annex 6, appendix 1A: unaudited quarterly sales report

2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth

Sales Report — Unaudited Quarter 1 2024

Report Completion Date

Accounting Period
01/01/2024
31/03/2024

Company:		
Company Reference:		
Medium Sized Company:	Yes/No	
Medium Sized Exemption:	£6,000,000	
Medium Sized Company Exemption Used:	£0	
Medium Sized Exemption Carried-Forward:	£6,000,000	
Payment Required [3]:	19.50%	£0

Payment Reference

	Line No.	£'000
TURNOVER PER MANAGEMENT ACCOUNTS (Unaudited Return)		
(net of any Scheme Payments and Historical 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**
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 2024 Voluntary Scheme Glossary.

Annex 6, appendix 1B: unaudited quarterly sales report

2024 Voluntary Scheme for Branded Medicines Pricing Access and Growth

Sales Report — Unaudited Quarterly (Part 1)

Company:			
Company Reference:			
Medium Sized Company:	Yes/No	**Headline Payment Percentage:**	0.00%
Medium Sized Company Exemption	£6,000,000	**VPAG Investment Programme Percentage:**	0.00%
Total Payment Required [3]:	£0		

Report Completion Date

Accounting Period

Payment Reference

	Line No.	£'000
TURNOVER PER MANAGEMENT ACCOUNTS (Unaudited Return)		
(net of any Scheme Payments and Historical 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**
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 (other than biologicals)	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 — NEWER MEDICINES	19	0
VOLUNTARY SCHEME MEASURED SALES — OLDER MEDICINES	20	0
TOTAL 2024 VOLUNTARY SCHEME MEASURED SALES (line 14 - line 18) or (line 20 + line 21)	**21**	**0**
Exemptions from Eligible Sales		
New Active Substance Sales [5]	22	0
Exemptions From Eligible Sales (line 22)	**23**	**0**
ELIGIBLE SALES (line 21 - line 23)	**24**	**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 2024 Voluntary Scheme Glossary.

2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth

Sales Report — Unaudited Quarterly (Part 2)

Report Completion Date

Accounting Period

Company:	
Company Reference:	
Medium Sized Company:	Yes/No
Medium Sized Exemption Brought-Forward:	£6,000,000
Medium Sized Company Exemption Used:	£0
Medium Sized Exemption Carried-Forward:	£6,000,000

Payment Reference

				Line No.	£'000
ELIGIBLE SALES (line 21 - line 23)				24	0
ELIGIBLE SALES: NEWER MEDICINES (line 19 - line 22)				25	0
	Payment Percentage	**Medium-Sized Eligible Sales Reduction**		26	0
Scheme Payment Required on Newer Medicines Eligible Sales at:	19.5%			27	0

BREAKDOWN OF ELIGIBLE SALES: OLDER MEDICINES	**Payment Percentage**	**Eligible Sales £'000**	**Medium-Sized Eligible Sales Reduction £'000**		**Payment Required £'000**
Scheme Payment Required on Older Medicines Eligible Sales at:	10%	0	0	28	0
TOTAL ELIGIBLE SALES: OLDER MEDICINES		0	0	29	0

Indicative Expected Total Payment from the Top-Up Payment Percentage with Regards to this Quarter's Eligible Sales of Older Medicines	0		30	N/A

TOTAL ELIGIBLE SALES (after Medium Sized Company Exemption) (line 24 - line 26 - line 29)		31	0
TOTAL PAYMENT REQUIRED ON ELIGIBLE SALES AT LINE 31 (line 27 + line 29)		32	0
VPAG INVESTMENT PROGRAMME PAYMENT		33	0
Department of Health and Social Care Adjustment		34	0
TOTAL SCHEME PAYMENT (line 32 + line 33 + line 34)		35	0

Comments:

Annex 6, appendix 2: scheme member declaration - sales report

Statement of directors' responsibilities

The directors are responsible for complying with the 2024 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] [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 2024 Voluntary Scheme. The directors must not approve the [Quarterly Sales Report] OR [unaudited Annual Sales Report] OR [Audited Annual Sales Report] [delete as applicable] 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.

In preparing the [Quarterly Sales Report] OR [unaudited Annual Sales Report] OR [Audited Annual Sales Report] [delete as applicable], 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] [delete as applicable] 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.

Unaudited Quarterly Sales Report sign-off

The unaudited Quarterly Sales Report for the quarter ended [insert quarter-end date] 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 Sales Report] sign-off

The [unaudited Annual Sales Report] OR [Audited Annual Sales Report] for the year ended [insert year-end date] 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] [delete as applicable]

[insert details of the basis of preparation (e.g. the schedule has been prepared in accordance with the 2024 Voluntary Scheme and the Guidance Notes in Annex 6 to the 2024 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]

Annex 6, appendix 3: annual sales report

2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth

Sales Report — Annual (Part 1)

Report Completion Date

Accounting Period

Company:			
Company Reference:			
Medium Sized Company:	Yes/NO	**Headline Payment**	0.00%
Medium Sized Company Exemption Carried-Forward:	£6,000,000	**VPAG Investment Programme Percentage:**	0.00%

Payment Reference

Total Payment Required [3]:	£0

	Line No.	£'000
TURNOVER PER MANAGEMENT ACCOUNTS (Unaudited Return)		
(net of any Scheme Payments and Historical 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**
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 (other than biologicals)	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 2024 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 2024 Voluntary Scheme Measured Sales (and Eligible Sales) (line 15 + line 16 + line 17)	**18**	**0**
VOLUNTARY SCHEME MEASURED SALES — NEWER MEDICINES	19	0
VOLUNTARY SCHEME MEASURED SALES — OLDER MEDICINES	20	0
TOTAL 2024 VOLUNTARY SCHEME MEASURED SALES (line 14 - line 18) or (line 20 + line 21)	**21**	**0**
Exemptions from Eligible Sales		
New Active Substance Sales [5]	22	0
Exemptions From Eligible Sales (line 22)	**23**	**0**
ELIGIBLE SALES (line 21 - line 23)	**24**	**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 2024 Voluntary Scheme Glossary.

2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth

Sales Report — Annual (Part 2)

Report Completion Date

Accounting Period

Company:	
Company Reference:	
Medium Sized Company:	Yes
Medium Sized Exemption Brought-Forward:	£6,000,000
Medium Sized Company Exemption Used:	£0
Medium Sized Company Exemption Carried-Forward:	£6,000,000

Payment Reference

		Line No.	£'000
ELIGIBLE SALES (line 19 - line 22)		24	0
ELIGIBLE SALES: NEWER MEDICINES (line 19 - line 22)		25	0
	Payment Percentage	**edium Sized Company Eligible Sales Reduction**	26	0
Scheme Payment Required on Newer Medicines Eligible Sales at	0.0%		27	0

BREAKDOWN OF ELIGIBLE SALES: OLDER MEDICINES	**Payment Percentage**	**Eligible Sales £'000**	**Medium-Sized Eligible Sales Reduction £'000**		**Payment Required £'000**
Scheme Payment Required on Older Medicines Eligible Sales at	10%	0	0	28	0
Scheme Payment Required on Older Medicines Eligible Sales at	11%	0	0	29	0
Scheme Payment Required on Older Medicines Eligible Sales at	12%	0	0	30	0
Scheme Payment Required on Older Medicines Eligible Sales at	13%	0	0	31	0
Scheme Payment Required on Older Medicines Eligible Sales at	14%	0	0	32	0
Scheme Payment Required on Older Medicines Eligible Sales at	15%	0	0	33	0
Scheme Payment Required on Older Medicines Eligible Sales at	16%	0	0	34	0
Scheme Payment Required on Older Medicines Eligible Sales at	17%	0	0	35	0
Scheme Payment Required on Older Medicines Eligible Sales at	18%	0	0	36	0
Scheme Payment Required on Older Medicines Eligible Sales at	19%	0	0	37	0
Scheme Payment Required on Older Medicines Eligible Sales at	20%	0	0	38	0
Scheme Payment Required on Older Medicines Eligible Sales at	21%	0	0	39	0
Scheme Payment Required on Older Medicines Eligible Sales at	22%	0	0	40	0
Scheme Payment Required on Older Medicines Eligible Sales at	23%	0	0	41	0
Scheme Payment Required on Older Medicines Eligible Sales at	24%	0	0	42	0
Scheme Payment Required on Older Medicines Eligible Sales at	25%	0	0	43	0
Scheme Payment Required on Older Medicines Eligible Sales at	26%	0	0	44	0
Scheme Payment Required on Older Medicines Eligible Sales at	27%	0	0	45	0
Scheme Payment Required on Older Medicines Eligible Sales at	28%	0	0	46	0
Scheme Payment Required on Older Medicines Eligible Sales at	29%	0	0	47	0
Scheme Payment Required on Older Medicines Eligible Sales at	30%	0	0	48	0
Scheme Payment Required on Older Medicines Eligible Sales at	31%	0	0	49	0
Scheme Payment Required on Older Medicines Eligible Sales at	32%	0	0	50	0
Scheme Payment Required on Older Medicines Eligible Sales at	33%	0	0	51	0
Scheme Payment Required on Older Medicines Eligible Sales at	34%	0	0	52	0
Scheme Payment Required on Older Medicines Eligible Sales at	35%	0	0	53	0
TOTAL ELIGIBLE SALES: OLDER MEDICINES		0	0	54	0

TOTAL ELIGIBLE SALES (after Medium Sized Company Exemption) (line 24 - line 26 - line 54)		55	0
TOTAL PAYMENT REQUIRED ON ELIGIBLE SALES AT LINE 55 (line 27 + lines 24 to 53)		56	0
VPAG INVESTMENT PROGRAMME PAYMENT		57	0
Department of Health and Social Care Adjustment		58	0
TOTAL SCHEME PAYMENT (line 56 + line 57 + line 58)		59	0

Comments:

Annex 7: unaudited annual presentation level sales report

2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth — Unaudited Annual Presentation Level Sales Report

Scheme Member	
Year:	
Organisation Code:	

							PRIMARY CARE SALES			HOMECARE SALES			ALL OTHER CUSTOMERS		
SNOMED Code	Product Description	Strength	Pack Size	Category	Date From	Date To	Quantity	Net Sales (£)	Gross Sales (£)	Quantity	Net Sales (£)	Gross Sales (£)	Quantity	Net Sales (£)	Gross Sales (£)
				Scheme Product											
				Valid Exemption											

Notes:

1. Where a Scheme Product becomes an Older Medicine during the relevant period, the Presentation Level Report (PLR) template will be populated with two entries for that Scheme Product. One PLR covering the period the Scheme Product was deemed a Newer Medicine and one from the date of the first calendar quarter that the Scheme Product became an Older Medicine.

2. Once the PLR information is provided, reports will be made available to show the split between Newer Medicines and Older Medicines and the relevant Top-Up Payment Percentages that will apply to the Older Medicines.

3. The PLR will be used to populate the majority of Part 2 of the Annual Sales Report, which will require auditing.

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 of the Unaudited Annual Presentation Level Sales Report have been accurately extracted from the records of:

   a. the Scheme Member; or

   b. where the Scheme Member has elected to join the 2024 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 2024 Voluntary Scheme; or

   b. where the Scheme Member has elected to join the 2024 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 2024 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 £1 million

Scheme Member or Lead Company (as applicable):

...……..

Calendar Year ended: ……

We confirm that our Sales of Scheme Products or (where the Scheme Member has elected to join the 2024 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 £1 million or more and less than £6 million

Scheme Member or Lead Company (as applicable):

.....

Calendar Year ended: ……

We confirm that:

i. the figures set out in the schedules of Annual Sales Report for Sales of Scheme Products of £1m or more and less than £6m have been accurately extracted from the records of:

   a. the Scheme Member; or

   b. where the Scheme Member has elected to join the 2024 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 2024 Voluntary Scheme; or

   b. where the Scheme Member has elected to join the 2024 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 2024 Voluntary Scheme.

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

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

Signature..... Date…….

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

Annex 11: historical cash payments (HCPs) form

2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth — Annex 11: Historical Cash Payments (HCPs) Form

Box 1

Scheme Member or Lead Company (as applicable):	
Calendar Year:	
Organisaton Code:	
HCP Percentage:	

HCP Box

Total Annual Historical Cash Payment Sales	
Annual Historical Cash Payment	

SNOMED Number	Product Description	Strength	Pack Size	NHS List Price (£)	Date From	Date To	SECONDARY CARE (Including Homecare) Quantity	PRIMARY CARE Quantity

Annex 12: independent audit report covering historical cash payments

[headed paper]

The Directors
[Company Address]

Scheme Member or Lead Company (as applicable):

.....

Year ended:
.....

We have examined the attached schedules (which we have initialed for the purposes of identification) that set out the information relating to Historical Cash Payments (HCPs) for the period …… as required under the 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth.

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's and Other Companies', underlying accounting records;

ii. agreed the extraction of the HCP price figures to the Scheme Member or, as applicable, the Lead Company's and Other Companies', published price list and to the underlying record 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 outlined in Sections 495 to 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. [12] [Delete as appropriate]

[12] This paragraph should be included only where the same audit firm provides both statutory audit and 2024 Voluntary Scheme services.

Signature.....

Date .....

Name.....

Address.....

Professional qualification.....

Annex 13: company declaration covering historical cash payments

Scheme Member or Lead Company (as applicable):

.....

Calendar Year ended: ……

We can confirm that:

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

   a. the Scheme Member; or

   b. where the Scheme Member has elected to join the 2024 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 2024 Voluntary Scheme; or

   b. where the Scheme Member has elected to join the 2024 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 2024 Voluntary Scheme.

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

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

Signature..... Date…….

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

Annex 14: guidance on the completion of price increase financial returns (PIFRs)

Introduction

1. This Annex 14 contains further detail relating to the completion of PIFRs and the calculation of ROS 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. The Department will continue to discuss with Scheme Members bilaterally and may limit costs to a level that is reasonable in its analysis of the Scheme Member's figures as provided below.

3. The PIFR should relate to business organisations that manufacture and supply Branded Health Service Medicines that ultimately are charged to the NHS. The PIFR should cover, on a consolidated basis, the company and its subsidiaries, and should include business done through branches or divisions set out for the purposes of the 2024 Voluntary Scheme within their membership or Group membership. If a Scheme Member has joined as part of a wider Group, the PIFR for the whole of the Group covered by the 2024 Voluntary Scheme should be included.

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 PIFR. It is not intended that Scheme Members should produce additional audited accounts especially for the purpose of the PIFR and where the accounting arrangements of the group are such that some other basis for the completion of the PIFR is more appropriate, such other basis may be adopted by agreement between the Scheme Member and the Department.

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. 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:

   - 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.

The PIFR Appendix to be completed as necessary.

Small Companies

7. In assessing the PIFR or other financial information provided by a Scheme Member whose total Sales of Scheme Products are less than £6m in the relevant calendar year, the Department may exercise a degree of discretion in relation to such matters as the levels of costs 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

8. The Department recognises that Scheme Members cannot always allocate costs directly to its NHS Home, NHS Exports and Other Products businesses and that various apportionment techniques have to be used to attribute shared costs to the three businesses.

9. The Scheme Member will include with the PIFR, notes identifying, with amounts, those items that have been specifically allocated against each cost 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 headings (NHS Home, NHS Export and Other Products), all relevant costs are considered and apportioned in an appropriate, reasonable and consistent manner. The Department may ask for additional information on the method of apportionment/allocation if this is unclear.

Allocation of Costs

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

11. 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.

12. Any Scheme Member must be able to demonstrate that costs included in its PIFR 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 either directly allocated or apportioned to Branded Health Service Medicines, together with explanations supporting any apportionment. Amortisation of costs should be over a reasonable period and as a minimum 5 years unless agreed otherwise with the Department.

13. Scheme Members accept that the 2024 Voluntary Scheme is not a cost plus scheme and that the Department is entitled to satisfy itself that costs claimed for medicines supplied to the NHS are properly incurred in accordance with the 2024 Voluntary Scheme and they are reasonable in the light of accepted commercial practice. Excess costs will be disallowed from the assessment.

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

    - the trends in the data reported by the Scheme Member;
    - any special features of the Scheme Member's operation;
    - ratios inferred from the PIFR for the Scheme Member's business outside the 2024 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.

15. Where the Department does not receive an adequate explanation of costs claimed in a Scheme Member's PIFR, it may limit the costs 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.

Completion of Appendix 1 - Sales, Costs and Profit

Sales

16. 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 2024 Voluntary Scheme as set out in Chapter 2.

17. 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).

18. 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

19. 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 or other expenses that would be better included elsewhere in Appendix 1.

20. 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, together with a brief description of the arrangement and of how expenditure and income has been treated in the PIFR. Where a company manufactures a product for marketing by another, the relevant costs should be shown under 'Other Products' in the PIFR of the producing company and the purchase price recorded under 'NHS Medicines' in the PIFR of the marketing company.

Transfer Pricing

21. 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).

22. 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. The Department will assume that transfer prices comprise 59% manufacturing, 21% R&D and 20% profit, subject to paragraphs 21 to 24 of this Annex 14.

23. 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. The allowed profit will be added to the Scheme Member's ROS profit target.

24. 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)

25. 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.

26. If, in the assessment of a PIFR, 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 PIFR.

27. 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

28. 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

29. 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 PIFR that the amount claimed relates to expenditure actually incurred and provide relevant supporting documentation.

Marketing Allowance

30. 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.

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

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

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

General & Administrative (G&A) costs

33. 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 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)

34. 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.

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

One-off costs

36. One-off costs 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.

Annex 14, appendix 1: sales, costs and profit

COMPANY:					
PIFR FOR YEAR ENDED:					
	Line number	NHS Medicines Home	NHS Medicines Exports	Other Products	Total
		£000	£000	£000	£000
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				

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

   VPAGdisputeresolutionpanel@dhsc.gov.uk

   and to:

   legal@abpi.org.uk

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 8.8 the Parties hereby agree that:

   - the panel shall comprise:

     - a chair appointed by the Department subject to the agreement of the ABPI (the Chair). 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 8.14) 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 8.14) 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 8.14) 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 ensure that the DRP complies with the procedures and time limits specified in Chapter 8 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 8 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, 2009, 2014 Pharmaceutical Price Regulation Schemes and the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)

25. Any dispute between the Department and the Scheme Member arising out of or in connection with the 2005, 2008, 2009, 2014 pharmaceutical price regulation schemes and the 2019 VPAS 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 2024 Voluntary Scheme.