



Department
of Health &
Social Care



2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth

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1. Purpose and Objectives

Summary

- 1.1. The Department of Health and Social Care (the Department) (representing the UK government, the governments of Scotland and Wales, and the Northern Ireland Executive, or their interests in the absence of an Executive), NHS England (or any successor body) and the Association of the British Pharmaceutical Industry (ABPI) recognise the importance of collaboration between the public and private sectors in delivering improved health gains from medicines in the National Health Service (NHS) across the United Kingdom (UK) and in supporting the pharmaceutical industry in the UK so that it can continue to innovate now and in the future.

Introduction

- 1.2. The 2024 Voluntary scheme for branded medicines pricing, access and growth (2024 Voluntary Scheme) will come into force on 1 January 2024, following expiry of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (2019 Voluntary Scheme) and shall remain in force for a period of five years. The parties to the 2024 Voluntary Scheme are:
 - the Department, acting on behalf of the UK government, the governments of Scotland and Wales and the Northern Ireland Executive, or, in the absence of an Executive in Northern Ireland, the Northern Ireland Department of Health;
 - NHS England;
 - the Association of the British Pharmaceutical Industry (ABPI); and
 - manufacturers or suppliers of Branded Health Service Medicines that have joined the 2024 Voluntary Scheme (Scheme Members).
- 1.3. The pricing of medicines in Scotland and Wales is a matter reserved to the UK government and transferred to Northern Ireland. The governments of Scotland and Wales support the 2024 Voluntary Scheme. The former Northern Ireland Executive was supportive of the 2019 Voluntary Scheme and it is considered by the Northern Ireland Department of Health in the absence of a functioning Executive that there is a public interest in support for a voluntary scheme being continued, in line with the provisions of the Northern Ireland (Executive Formation etc) Act 2022.

- 1.4. The National Institute for Health and Care Excellence (NICE) also supports the 2024 Voluntary Scheme and will have a central role in its operation.
- 1.5. Manufacturers or suppliers of Branded Health Service Medicines who choose not to join the 2024 Voluntary Scheme are subject to the statutory scheme established under the Branded Health Service Medicines (Costs) Regulations 2018 as amended from time to time (Statutory Scheme).

Purpose and Objectives of the 2024 Voluntary Scheme

- 1.6. The purpose of the 2024 Voluntary Scheme is to support excellent healthcare and a thriving economy across the UK through a sustainable approach to medicines provision.
- 1.7. The 2024 Voluntary Scheme is intended to promote innovation and access to cost-effective medicines, commensurate to their value to patients and the NHS, while also supporting the sustainability of NHS finances. The 2024 Voluntary Scheme is underpinned by a commitment from all parties to engender improvements over time to health gain relative to expenditure on new medicines across the NHS.
- 1.8. Success of the 2024 Voluntary Scheme will be measured against three objectives:
 - Promote better patient outcomes and a healthier population, by:
 - Securing rapid patient access to new clinically and cost-effective medicines through efficient, responsive and joined up approval, commercial and funding arrangements, with appropriate rewards for innovation;
 - Tackling unwarranted variation in adoption of new medicines;
 - Encouraging the development of the innovative and cost-effective medicines of the future.
 - Support UK economic growth, by:
 - Supporting the potential for a strong UK life sciences industry to drive economic growth, particularly through its investment in research and development (R&D), including clinical research;

- Ensuring that the access environment for branded medicine suppliers to the NHS is consistent with wider policies to support inward investment;
 - Delivering a net benefit to the UK economy overall.
 - Contribute to a financially sustainable NHS, by:
 - Maintaining the affordability of overall UK branded health service medicines spend and supporting the NHS and industry to develop sustainable financial and investment strategies;
 - Delivering value for money for the NHS by securing resilient provision of safe and effective medicines at reasonable prices and encouraging efficient competition in medicines supply.
- 1.9. All Parties agree that the performance of the 2024 Voluntary Scheme cannot be assessed in isolation from the NHS environment with which it interacts, and the wider functions and responsibilities of public bodies and the UK government, the governments of Scotland and Wales, and the Northern Ireland Executive, or in the absence of an Executive in Northern Ireland, the Northern Ireland Department of Health.
- 1.10. All Parties will use their best endeavours to ensure that the 2024 Voluntary Scheme is fully implemented and sustained throughout the NHS during its duration. All Parties will operate the 2024 Voluntary Scheme in good faith and recognise that there should be compliance. All Parties will use their best endeavours not to manipulate or undermine the 2024 Voluntary Scheme in a way which conflicts with the purpose and objectives set out at paragraphs 1.6 and 1.8 or in a way which makes the 2024 Voluntary Scheme ineffective as set out at paragraph 2.31. The mutual intent is that no Party will seek to abuse the 2024 Voluntary Scheme.
- 1.11. The Department, NHS England and the ABPI agree to raise any issues relating to the management and operation of the 2024 Voluntary Scheme over its duration during regular review meetings which are set out in more detail at paragraph 2.7.
- 1.12. The Department will use its best endeavours to ensure the confidentiality of any commercially sensitive information submitted by Scheme Members under the 2024 Voluntary Scheme. However, such information may still be disclosed to the bodies and for the purposes prescribed under section 264B of the National Health Service Act 2006 (NHS Act).

1.13. The ABPI acknowledges that the UK government, the governments of Scotland and Wales, and the Northern Ireland Executive, or in the absence of an Executive in Northern Ireland, the Northern Ireland Department of Health and NHS England are subject to the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002, as applicable (FOIA). In the event of a request made pursuant to the FOIA the relevant public body will take reasonable steps to notify the relevant Scheme Member of the content of any FOIA request which pertains to that Scheme Member. The decision on whether any exemption available under the FOIA applies to any request for information received under the FOIA is a decision solely for the relevant public body, but reasonable efforts to ascertain and take into account the views of any affected Scheme Member will be made in advance of any disclosures wherever possible.

Use of Defined Terms

1.14. This document incorporates defined terms identified by initial capital letters unless otherwise expressed in the Glossary. Defined terms are explained in the Chapters or Annexes where they first appear and/or in the Glossary, which contains a list of defined terms used in the 2024 Voluntary Scheme.

Territorial Application

1.15. Unless specified elsewhere in the 2024 Voluntary Scheme, the 2024 Voluntary Scheme is intended to apply to all UK nations. Where a whole Chapter or paragraphs within a Chapter are to have a more limited application, this will be expressly outlined in that Chapter.

Summaries

1.16. Each Chapter of this document contains a summary of the matters covered in that Chapter. All Parties agree that the summaries are to assist the reader and do not form part of the 2024 Voluntary Scheme.

2. Status and Membership

Summary

- 2.1. Chapter 2 summarises the legal basis of the 2024 Voluntary Scheme, arrangements for its review and amendment. The arrangements for joining and leaving the 2024 Voluntary Scheme are set out, together with the circumstances under which membership may be withdrawn. The products within the scope of the 2024 Voluntary Scheme are defined, and the requirements about which entity is responsible for making payment are described. See also Annexes 1 and 2.

Introduction

- 2.2. The 2024 Voluntary Scheme is a voluntary scheme as described under section 261(1) of the NHS Act which is not binding under the law of contract.
- 2.3. A manufacturer or supplier of a Branded Health Service Medicine that elects not to join the 2024 Voluntary Scheme, or having joined the 2024 Voluntary Scheme subsequently leaves the 2024 Voluntary Scheme or is subject to a notice by the Department determining that the 2024 Voluntary Scheme does not apply to it, shall be subject to the Statutory Scheme.
- 2.4. Annex 2 summarises the provisions contained in sections 261-266 of the NHS Act.

Amendment of the 2024 Voluntary Scheme

- 2.5. Subject to Chapter 8, the provisions of the 2024 Voluntary Scheme may only be amended by the mutual written agreement of the ABPI and the Department.
- 2.6. If the ABPI and the Department agree to amend the terms of the 2024 Voluntary Scheme in accordance with paragraph 2.5, existing Scheme Members will be deemed to accept the new terms on the date those new terms become effective. A Scheme Member has a right to leave the 2024 Voluntary Scheme as set out in paragraph 2.31.

Operational Reviews

- 2.7. Every six (6) months from 1 January 2024 operational review meetings will take place to review the operation of the 2024 Voluntary Scheme. The first operational review in 2024 will agree success factors and metrics to be reported for the 2024 Voluntary Scheme which will be reviewed every six months thereafter. There is no expectation that any such operational reviews will result in amendment of the 2024 Voluntary Scheme. In order to support the operational reviews, the ABPI shall have access to aggregated data in relation to growth and payments data submitted by Scheme Members.
- 2.8. Invitations to the operational review meetings described in paragraph 2.7 shall be extended to:
- the Department;
 - NHS England;
 - the ABPI;
 - representatives of the governments of Scotland, Wales and Northern Ireland or representatives of the Northern Ireland Department of Health in the absence of an Executive in Northern Ireland;
 - NICE;
 - the Medicines and Healthcare products Regulatory Agency (MHRA); and
 - the Office for Life Sciences.

The British Generics Manufacturers Association (BGMA) shall also be invited to attend these meetings in an observational capacity and, where appropriate, other industry representatives may also be invited in the same capacity.

Scheme Reviews

- 2.9. In addition to the operational review meetings outlined in paragraph 2.7, the 2024 Voluntary Scheme terms will be reviewed by the ABPI and the Department representatives twice during the 2024 Voluntary Scheme: in Autumn 2025 and again in Spring 2027. In the course of such reviews, changes to scheme terms may be proposed by either Party. Changes may only be made with the agreement of both Parties in accordance with paragraphs 2.5 and 2.6.

Application to Manufacturers and Suppliers

- 2.10. The 2024 Voluntary Scheme is open to manufacturers and suppliers of Branded Health Service Medicines who have applied to join the 2024 Voluntary Scheme as set out from paragraph 2.15.
- 2.11. The 2024 Voluntary Scheme will apply to a Scheme Member unless the Scheme Member leaves the 2024 Voluntary Scheme or the Department has determined that the 2024 Voluntary Scheme does not apply to that Scheme Member. The actual date the 2024 Voluntary Scheme ceases to apply in these situations is as set out in paragraphs 2.31 and 2.34.
- 2.12. Where the MA Holder for the relevant Scheme Product has a place of business in the UK, the Scheme Member for the relevant Scheme Product must be either the MA Holder or a company which has a place of business in the UK and which is in the same Group as the MA Holder.
- 2.13. Where the MA Holder for the relevant Scheme Product does not have a place of business in the UK, the Scheme Member must be a company which has a place of business in the UK and which is in the same Group as the MA Holder.
- 2.14. Where the MA Holder for the relevant Scheme Product does not have a place of business in the UK and there is no company in the same Group as the MA Holder which has a place of business in the UK, the Scheme Member must be:
- the MA Holder; or
 - the company in the same Group as the MA Holder that makes the first relevant supply of the Scheme Product to the UK, being the first occasion on which the relevant item of Branded Presentation is supplied by a company in the same Group as the MA Holder to another organisation with a place of business in the UK that is not in the same Group as the MA Holder.
- 2.15. Where:
- the MA Holder for the relevant Scheme Product does not have a place of business in the UK and there is no company in the same Group as the MA Holder which has a place of business in the UK; and
 - the Scheme Product is supplied by a company (not being the MA Holder or a company in the same Group as the MA Holder) (First Supplier) from

outside of the UK to an organisation with a place of business in the UK that is not in the same Group as the First Supplier or the MA Holder (First UK Recipient),

the Scheme Member must be either the First Supplier or the First UK Recipient.

Joining the 2024 Voluntary Scheme

- 2.16. A manufacturer or supplier of a Branded Health Service Medicine wishing to join the 2024 Voluntary Scheme with effect from 1 January 2024 must complete and submit Form A (as set out at Annex 1) and where applicable Form A1 (as set out at Annex 1) to the Department such that the deemed delivery date is no later than 15 January 2024. However, where a manufacturer or supplier submits a Form A and a Form A1, the other manufacturers and/or suppliers listed in its Form A1 do not need to submit either form. Where the deemed delivery date to the Department of a completed Form A (and Form A1, as applicable) is after 31 December 2023, but no later than 15 January 2024, that manufacturer or supplier expressly agrees that its membership of the 2024 Voluntary Scheme will have retrospective effect such that the 2024 Voluntary Scheme will apply to that manufacturer or supplier from the 1 January 2024. For the avoidance of doubt, the deemed delivery date provisions in paragraph 7.3 apply.
- 2.17. A manufacturer or supplier to which the 2019 Voluntary Scheme applied will not be automatically included in the 2024 Voluntary Scheme. Provided that the deemed delivery date to the Department of a completed Form A (and Form A1, as applicable) is no later than 15 January 2024, membership will be effective from the start of the 2024 Voluntary Scheme (1 January 2024).
- 2.18. Where a manufacturer or supplier completes and submits Form A (and Form A1, as applicable), or is included in a manufacturer or supplier's Form A1 in accordance with paragraph 2.25, the manufacturer or supplier commits that they will fulfil any outstanding obligations arising during the period of their membership of the 2019 Voluntary Scheme (if applicable), or in respect of the period that they were subject to the Statutory Scheme (if applicable).
- 2.19. After 1 January 2024 a manufacturer or supplier of a Branded Health Service Medicine may join the 2024 Voluntary Scheme by completing Form A (and Form A1, as applicable) and submitting it to the Department with at least fourteen (14) calendar days' notice. Subject to paragraph 2.18, membership will be effective from the first calendar day of the next calendar year except as otherwise agreed by the Department provided that the deemed delivery date

of Form A (and Form A1, as applicable) is at least fourteen (14) calendar days prior to the first calendar day of the next calendar year. If the deemed delivery date is fewer than fourteen (14) calendar days prior to the first calendar day of the next calendar year, membership will be effective from the first calendar day of the following calendar year (or such other date as is agreed by the manufacturer or supplier and the Department).

2.20. Where a New Manufacturer or Supplier of a Branded Health Service Medicine wishes to join the 2024 Voluntary Scheme it must complete Form A (and Form A1, as applicable) and submit it to the Department with at least fourteen (14) calendar days' notice. Provided that the New Manufacturer or Supplier is not in the same Group as any other manufacturer or supplier who is already a member of the 2024 Voluntary Scheme, membership will be effective from the first calendar day of the next Quarter except as otherwise agreed provided that the deemed delivery date of Form A (and Form A1, as applicable) by the Department is at least fourteen (14) calendar days prior to the first calendar day of the next Quarter. If the deemed delivery date is fewer than fourteen (14) calendar days prior to the first calendar day of the next Quarter, membership will be effective from the first calendar day of the following Quarter (or such other date as is agreed by the manufacturer or supplier and the Department).

2.21. The Department has the right to refuse membership of the 2024 Voluntary Scheme to any manufacturer or supplier of a Branded Health Service Medicine where, as at the deemed delivery date of the completed Form A (and Form A1, as applicable) to the Department from the manufacturer or supplier:

- any amount due from the manufacturer or supplier to the Department under the Statutory Scheme remains outstanding (excluding any amount(s) that is the subject of a bona fide dispute between the Department and the manufacturer or supplier, which (as at the deemed delivery date of the completed Form A (and Form A1, as applicable) to the Department by the manufacturer or supplier) is subject to the appeals process of the Statutory Scheme);
- any amount due from the manufacturer or supplier to the Department under the 2019 Voluntary Scheme remains outstanding (excluding any amount(s) that is the subject of a bona fide dispute between the Department and the manufacturer or supplier, which (as at the deemed delivery date of the completed Form A (and Form A1, as applicable) to the Department by the manufacturer or supplier) has been referred to the dispute resolution procedure of the 2019 Voluntary Scheme for determination in accordance with the terms of the 2019 Voluntary Scheme);

- the manufacturer or supplier has failed to submit all information requirement submissions in accordance with the requirements of the Statutory Scheme;
- the manufacturer or supplier has failed to submit all information requirements submissions in accordance with the terms of the 2019 Voluntary Scheme; or
- where the manufacturer or supplier was previously a member of the 2024 Voluntary Scheme, it did not comply with all obligations during the period it was a member of the 2024 Voluntary Scheme.

2.22. Where a manufacturer or supplier of a Branded Health Service Medicine joins the 2024 Voluntary Scheme with effect from 1 January 2024, such manufacturer or supplier acknowledges that, notwithstanding that the Department has not earlier refused the manufacturer or supplier membership of the 2024 Voluntary Scheme, upon its membership becoming effective:

- the Department will not be deemed to have accepted that the manufacturer or supplier has fulfilled all of its obligations under the 2019 Voluntary Scheme in respect of its period of membership of the 2019 Voluntary Scheme (if applicable) and/or all of its obligations under the Statutory Scheme in respect of its period of membership of the Statutory Scheme (if applicable); and
- where the Department later determines (in its absolute discretion) that the Scheme Member has failed to fulfil any obligations arising under the 2019 Voluntary Scheme (if applicable) and/or any obligations arising under the Statutory Scheme (if applicable), the Department reserves all rights to determine, at any time, in accordance with paragraph 2.34, that the 2024 Voluntary Scheme does not apply to the Scheme Member.

2.23. Where a manufacturer or supplier of a Branded Health Service Medicine is refused membership of the 2024 Voluntary Scheme under paragraph 2.21 it will receive a statement of reasons. It will also, if it wishes, be entitled to discussions with the Department, though this will not represent an appeals process.

2.24. Manufacturers or suppliers refused membership of the 2024 Voluntary Scheme will be subject to the Statutory Scheme.

Group Membership of the 2024 Voluntary Scheme

2.25. A manufacturer or supplier of a Branded Health Service Medicine may join the 2024 Voluntary Scheme on behalf of itself and other manufacturers or suppliers in its Group. In doing so it may, amongst other things, elect to submit consolidated Sales Reports and make consolidated Scheme Payments on behalf of these other manufacturers or suppliers. In which case, in its application to join the 2024 Voluntary Scheme it must:

- submit a completed Form A in accordance with the requirements of paragraphs 2.16 to 2.20; and
- at the same time, submit a completed Form A1 naming the lead company (as described in paragraph 2.26) and all other relevant companies (Other Companies), in accordance with the requirements of paragraphs 2.16 to 2.20.

2.26. Thereafter, upon membership becoming effective:

- the manufacturer or supplier named as the lead company in Form A1 (Lead Company); and
- each of the Other Companies,

will each:

- be members of the 2024 Voluntary Scheme (and therefore not subject to the Statutory Scheme); and
- unless otherwise stated, be a 'Scheme Member' within the meaning of the 2024 Voluntary Scheme and, accordingly, be responsible for complying with the requirements of the 2024 Voluntary Scheme (including without limit being liable for making any payments due under the 2024 Voluntary Scheme).

2.27. Notwithstanding the above, by virtue of joining on behalf of Other Companies in accordance with paragraph 2.25, the Lead Company shall remain responsible for all acts and omissions of the Other Companies as if they were its own (including without limit being liable for Scheme Payments and being responsible for submitting Sales Reports). An obligation on each of the Other Companies (as Scheme Members) to do, or to refrain from doing, any act or

thing shall include an obligation on the Lead Company to procure that each of the Other Companies also do, or refrain from doing, such act or thing.

- 2.28. If at any time the Lead Company and Other Companies wish to change the manufacturer or supplier named as the Lead Company in the original Form A1 (but such Lead Company does not wish to leave the 2024 Voluntary Scheme) the Lead Company and Other Companies must notify the Department in writing by completing and submitting an amended Form A1 to the Department in accordance with such instructions as the Department shall notify the Lead Company and Other Companies of from time to time.
- 2.29. If at any time any of the Other Companies no longer wish the Lead Company in the original Form A1 to act on its or their behalf, (but such Other Company does not wish to leave the 2024 Voluntary Scheme):
- such Other Company must notify the Department in writing by completing and submitting a Form A to the Department in accordance with such instructions as the Department shall notify the Other Company of from time to time; and
 - the Lead Company and Other Companies must notify the Department in writing by completing and submitting an amended Form A1 to the Department in accordance with such instructions as the Department shall notify the Lead Company and Other Companies of from time to time.

Non-ABPI Members

- 2.30. Although the 2024 Voluntary Scheme is the result of negotiations between the ABPI and the Department, a manufacturer or supplier of a Branded Health Service Medicine that is not a member of the ABPI can join the 2024 Voluntary Scheme.

Leaving the 2024 Voluntary Scheme

- 2.31. A Scheme Member may, at any time, give notice of its intention to leave the 2024 Voluntary Scheme by completing and submitting to the Department Form B (as set out at Annex 1). If a Scheme Member wishes to leave the 2024 Voluntary Scheme, it may do so on the last calendar day of the calendar year provided that the deemed date of delivery of Form B is at least three (3) months prior to the last calendar day of the year. If the deemed date of delivery of Form B is less than three (3) months prior to the last calendar day of the year, the Scheme Member will continue to be a member of the 2024

Voluntary Scheme until the last calendar day of the following calendar year. Notice given by a Scheme Member under this paragraph 2.31 is irrevocable.

- 2.32. If at any time the Lead Company gives notice to leave the 2024 Voluntary Scheme in accordance with paragraph 2.31, with effect from the Lead Company leaving the 2024 Voluntary Scheme, all of the Other Companies will each be deemed to have left the 2024 Voluntary Scheme. Thereafter, if at any time any of the Other Companies wish to re-join the 2024 Voluntary Scheme, such Other Company must complete and submit Form A (and where applicable Form A1) to the Department in accordance with the requirements of paragraphs 2.16 to 2.20 (and where applicable paragraph 2.25).
- 2.33. If at any time any of the Other Companies wish to leave the 2024 Voluntary Scheme for whatever reason:
- such Other Company must submit a completed Form B in accordance with the requirements of paragraph 2.31; and
 - at the same time, the Lead Company must submit an amended Form A1 to the Department in accordance with such instructions as the Department shall notify it of from time to time.

Disapplication of the 2024 Voluntary Scheme

- 2.34. Under the NHS Act, the Department has powers to determine that the 2024 Voluntary Scheme does not apply to a Scheme Member in certain circumstances. The Department may exercise those powers by written notice either immediately or on such date specified in the notice if any acts or omissions of a Scheme Member have shown that, in the Scheme Member's case, the 2024 Voluntary Scheme is ineffective for any of the purposes mentioned in s.261(1) of the NHS Act. The Parties agree that this will be the case in the following (non-exhaustive) circumstances:
- the Scheme Member fails to pay all sums due under the 2024 Voluntary Scheme and/or the 2019 Voluntary Scheme (where applicable) within sixty (60) calendar days of a written demand (excluding, in respect of sums due under the 2024 Voluntary Scheme, any amount(s) that is the subject of a bona fide dispute which (as at the date the payment period of any written demand expires) has been referred to the dispute resolution procedure of the 2024 Voluntary Scheme);

- the Scheme Member fails to pay any sum as directed by the dispute resolution panel (DRP) under the 2024 Voluntary Scheme within sixty (60) calendar days of a written demand;
- in relation to any dispute between the Department and the Scheme Member arising out of or in connection with the 2005, 2008, 2009 or 2014 pharmaceutical price regulation schemes or the 2019 Voluntary Scheme, the Scheme Member fails to pay any sum as directed by the relevant dispute resolution panel under the relevant scheme within sixty (60) calendar days of a written demand;
- in relation to any dispute between the Department and the Scheme Member arising out of or in connection with the 2005, 2008, 2009 or 2014 pharmaceutical price regulation schemes or the 2019 Voluntary Scheme, the Scheme Member fails to comply with any decision of the relevant dispute resolution panel under the relevant scheme within sixty (60) calendar days of the decision of the relevant dispute resolution panel;
- the Scheme Member materially fails to comply with the requirements of the 2024 Voluntary Scheme and/or the 2019 Voluntary Scheme (where applicable); and/or
- the Scheme Member has entered into an arrangement, whether or not legally enforceable, whose main purpose or one of whose main purposes is to reduce or avoid a payment in respect of a sale of a Branded Presentation that either that Scheme Member or another manufacturer or supplier would otherwise be liable to make under the 2024 Voluntary Scheme or the Statutory Scheme.

2.35. If the Department determines that the 2024 Voluntary Scheme does not apply to a Scheme Member who is:

- A Lead Company. With effect from the 2024 Voluntary Scheme no longer applying to the Lead Company, the 2024 Voluntary Scheme will no longer apply to each of the Other Companies. Thereafter, if at any time any of the Other Companies wish to re-join the 2024 Voluntary Scheme, such Other Company must complete and submit Form A (and where applicable Form A1) to the Department in accordance with the requirements of paragraphs 2.16 to 2.20 (and where applicable paragraph 2.25); or
- An Other Company. The Department may amend the original Form A1 to account for the change and send to the Lead Company and the remaining Other Companies (who, upon receipt, shall be deemed to have accepted

the amended Form A1) or instruct the Lead Company to submit an amended Form A1 to the Department in accordance with such instructions as the Department shall notify it of from time to time.

Continued Obligations

2.36. Notwithstanding the Scheme Member leaving the 2024 Voluntary Scheme under paragraph 2.33, the disapplication of the 2024 Voluntary Scheme in relation to the Scheme Member under paragraph 2.32 or expiry of the 2024 Voluntary Scheme:

- The liability of the Scheme Member under the 2024 Voluntary Scheme to pay shall be a liability to pay all Scheme Payments arising under Chapter 4 and Chapter 5 in respect of Sales while a Scheme Member, including such amounts as can only be finally calculated after the end of the period of that Scheme Member's membership of the 2024 Voluntary Scheme or after expiry of the 2024 Voluntary Scheme;
- the Scheme Member shall be required to submit all information requirement submissions arising out of the terms of the 2024 Voluntary Scheme in respect of the period of that Scheme Member's membership of the 2024 Voluntary Scheme; and
- the Secretary of State may, at any time, use any of their powers (including without limit those under the NHS Act) in relation to the manufacturer or supplier.

Products Covered

2.37. The 2024 Voluntary Scheme applies to all Branded Health Service Medicines. Accordingly, the 2024 Voluntary Scheme shall apply to the following (without limit):

- branded generics;
- in vivo diagnostics;
- blood products;
- dialysis fluids;
- branded products supplied through tendering processes and on central or local contracts; and

- all Biological Medicinal Products (regardless of whether it is a branded Health Service Medicine).
- 2.38. The 2024 Voluntary Scheme shall not apply to sales of unbranded generic medicines that are not Biological Medicinal Products or medicines for supply on private prescription or other use outside the NHS.
- 2.39. Where a branded prescription only travel vaccine is used by the NHS, the Department may exercise its discretion to exclude sales of such medicine from the 2024 Voluntary Scheme where total NHS sales in any calendar year within the duration of the 2024 Voluntary Scheme amount to less than £50,000.
- 2.40. The 2024 Voluntary Scheme shall not apply to medicinal products (as defined in the Human Medicines Regulations 2012 (SI 2012/1916)) that are:
- in relation to England, listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004;
 - in relation to Scotland, specified in any directions given by the Scottish Ministers under section 17N(6) (other mandatory contract terms) of the Scotland Act 1978 as being drugs, medicines or other substances which may not be ordered by a contractor made under section 17J for patients in the provision of primary medical services under a general medical services contract made under section 17J (health boards power to enter into general medical services contracts) of the Scotland Act 1978;
 - in relation to Northern Ireland, listed in Schedule 1 to Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs etc) Regulations (Northern Ireland) 2004;
 - in relation to Wales, listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Wales) Regulations 2004;
 - dental anaesthetics and dental suspension as part of a Band 1 treatment; and
 - over the counter (OTC) sales (except that the 2024 Voluntary Scheme shall apply to NHS Sales of Branded P&GSL Medicines).
- 2.41. Where a Branded P&GSL Medicine is provided on an NHS prescription, the Department may exercise its discretion to exclude sales of such medicine from the 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.

3. Access, Adoption and Outcomes

Summary

- 3.1. This section sets out the ambitions of the 2024 Voluntary Scheme to improve patient outcomes by supporting access to, and uptake of, clinically and cost-effective medicines. All Parties are committed to working collaboratively to promote a clear and joined up market access ecosystem that benefits patients and improves the health of the population.
- 3.2. The enhanced commercial flexibility described in this section will be available to companies in either the 2024 Voluntary Scheme or the Statutory Scheme.

Territorial application

- 3.3. The provisions dealing with horizon scanning, system readiness and system architecture (paragraphs 3.10 to 3.16) apply in all of England, Scotland, Wales and Northern Ireland. The sections dealing with value assessment, commercial agreements and equitable adoption (paragraphs 3.17 to 3.47) are devolved matters and, excepting any specific UK wide provisions, shall apply to England only.
- 3.4. The devolved administrations will determine their own value assessment, access and commercial arrangements, and support for adoption of commissioned medicines. Those administrations will work with the pharmaceutical industry and with the Department where appropriate.
- 3.5. Where the term medicines is used throughout this entire Chapter it refers to both new active substances and significant licence extensions for existing medicines.

Engagement

- 3.6. All Parties recognise the benefit of open and regular dialogue with pharmaceutical industry representatives. There will be a continued focus on regular strategic and operational engagement with Scheme Members and the ABPI. Strategic engagement will continue through existing arrangements, including the Life Sciences Council and its sub-groups, such as the Patient Access to Medicines Partnership.

- 3.7. All Parties are supportive of NHS England, NICE and MHRA providing the pharmaceutical industry with the opportunity for early engagement, advice, and signposting on the development and introduction of new medicines into the NHS. This advice may include support to find the most appropriate route for regulatory, health technology evaluation and commercial discussions, to support medicines to routine commissioning and availability to NHS patients.
- 3.8. All Parties have a shared ambition to ensure good connectivity between regulatory, health technology assessment (HTA) and commercial processes, providing clear end-to-end routes to market for new medicines.
- 3.9. Where a medicine requires a more in-depth approach, for example where a significant pathway change has to be implemented to prepare for its introduction and/or where further data collection is required, the intention is for the Scheme Member to have single points of contact within NHS England and, separately, within NICE, in line with existing processes, in order to provide greater consistency and clarity of advice.

Horizon scanning, system readiness and system architecture

- 3.10. The Department, devolved administrations, NHS England, the ABPI and the pharmaceutical industry have a shared ambition for health systems involved in all elements of the provision of medicines and health services in the UK to have complete and accurate information about the products coming through the pipeline; this includes clinical, financial and service planning information. The MHRA and UK Health Technology Assessment (HTA) agencies also require horizon scanning information that is relevant to support planning and delivery of their respective decision-making processes.
- 3.11. A single, shared approach for ensuring accurate horizon scanning will continue to be progressed, with Scheme Members committing to process-related information being shared between the organisations which receive horizon scanning information through UK PharmaScan and any other horizon scanning facilities.
- 3.12. UK PharmaScan will continue to be the primary source of horizon scanning information. VPAG Investment Programme funding will be allocated to re-develop UK PharmaScan on a new technological platform to better support the MHRA, UK HTA agencies and the NHS in their horizon scanning efforts. The UK PharmaScan Oversight and Governance Committee will be responsible for

delivering a new UK PharmaScan platform within the first three years of the 2024 Voluntary Scheme.

- 3.13. Scheme Members commit to provide timely, accurate and comprehensive information in UK PharmaScan for all their medicines being developed. This information will be provided at the earliest opportunity, with the aim of a UK PharmaScan record being created at least three years prior to expected Marketing Authorisation. The information provided will include expected plans and timings for regulatory submission routes and will be kept up to date by Scheme Members if these plans change.
- 3.14. All Parties commit, for the purposes of system planning and preparedness, to using horizon scanning information in a timely manner, including NHS England undertaking and/or commissioning more primary research and therapeutic deep dives, to support the introduction of new medicines into the NHS.
- 3.15. Emerging regulatory pathways will create opportunities for companies to bring their products to the UK market more quickly. To ensure HTA and payer processes remain interconnected with these pathways, a UK-wide cross-government working group with industry trade body representation (in a non-decision making capacity) will be established to better coordinate activities across organisational boundaries within the first year of the 2024 Voluntary Scheme.
- 3.16. An end-to-end pathway guide will be published by the end of the first year of the 2024 Voluntary Scheme, outlining the routes to market, how regulatory, HTA and commercial pathways align, and what the mechanisms are for company engagement. Other relevant policy documents, for example the NHS England Commercial Framework for New Medicines, will be updated to take account of these developments.

NICE Value assessments

- 3.17. NICE will continue in its world-leading role in producing evidence-based guidance on the use of medicines. This is an important mechanism for ensuring medicines used by the NHS are cost effective.
- 3.18. NICE will continue to evaluate all new active substances and significant indications, except where there is a clear rationale not to do so. This provides an equitable, robust approach for ensuring medicines used by the NHS are value for money. NICE evaluations for all medicines are scheduled in dialogue with the company, with the aim of publishing guidance within three months of Marketing Authorisation when this is feasible.

- 3.19. The standard cost effectiveness threshold used by NICE will be retained at the current range (£20,000 - £30,000 per QALY) and will not be changed for the duration of the 2024 Voluntary Scheme.
- 3.20. Process and methods changes will be made through modular updates to the Health Technology Evaluation manual, with NICE engaging and consulting relevant stakeholders.
- 3.21. Funding will be allocated from the VPAG Investment Programme to boost investment into further developing technology assessment methods and processes used in the UK's HTA agencies. In England, NICE's HTA Innovation Lab will test innovative value assessment methodologies for application on new medicines which may require a different evaluation approach. The Scottish Medicines Consortium (SMC), the All Wales Therapeutic and Toxicology Centre (AWTTC) and the Northern Ireland Department of Health will all also initiate projects to improve their assessment processes, support speedier adoption of recommendations and to help prepare the system for the number of new medicines which they will be assessing over the course of the 2024 Voluntary Scheme.
- 3.22. The Department expects that any future changes to NICE methods and processes would respond to the new types of innovation coming to the market, be consistent with improving the health gain achieved from spending on new innovative medicines, and support faster adoption of the most clinically and cost-effective medicines. These would be subject to public consultation in the usual way.

Commercial arrangements

- 3.23. The Parties recognise the benefits that clinically and cost-effective medicines can bring to patients. The 2024 Voluntary Scheme represents an opportunity to further enhance the commercial flexibilities offered by the health service in England.
- 3.24. Where a Scheme Member is unable to set an NHS list price that would be considered cost effective, a simple confidential discount, via a Patient Access Scheme (PAS), will remain the preferred means of providing a cost-effective price to the NHS.
- 3.25. The Department, NHS England and the ABPI recognise the benefit PASs can provide, by facilitating pricing agreements that can improve cost-effectiveness and enable patients to gain access to new medicines.

3.26. There are two types of PAS:

- Simple PAS (confidential) – these are confidential and provide a fixed price or percentage discount from the list price that is applied at source. These are always the preferred option, as they require less monitoring by all Parties and minimise the administrative burden on NHS organisations.
- Complex PAS (transparent) – these are non-confidential and will involve a more complex reimbursement proposal that, in turn, will usually be more complex to administer within the NHS. The requirement for transparency is to ensure the administrative burden and cost to the service of implementing such schemes is minimised and helps ensure the value of the treatment, as determined by NICE, is achieved.

3.27. Under the 2024 Voluntary Scheme, simple and complex published PASs will continue to operate and be available for new products using existing processes and in accordance with existing criteria and terms as set out originally in the 2014 Pharmaceutical Price Regulation Scheme (PPRS), then in 2019 Voluntary Scheme for Branded Medicines Pricing and Access, and most recently the 2022 NHS England Commercial Framework for New Medicines and guidance on the NICE [website](#).

3.28. NHS England will continue to have responsibility for agreeing PASs, with input from the Patient Access Schemes Liaison Unit (PASLU) within the Centre for Health Technology Evaluation at NICE. PASs extant as at 31 December 2023, ahead of the commencement of the 2024 Voluntary Scheme, will be maintained in accordance with their terms.

3.29. The NHS England Commercial Framework for New Medicines sets out the purpose and principles on which NHS commercial medicines activities are based. This includes clarification of commercial flexibilities that may be available to companies where deemed appropriate by NHS England, reserved for companies aspiring to deliver greater health gain relative to cost.

3.30. The arrangements detailed in paragraph 3.29 would normally correspond to medicines that would be expected to have value propositions at or below the lower end of the standard NICE cost effectiveness threshold range, with greater flexibilities made available for value propositions at even greater levels of cost effectiveness, plus any applicable QALY weighting.

3.31. NHS England will launch a consultation on an update to the NHS England Commercial Framework for New Medicines within the first six months of the 2024 Voluntary Scheme to be more explicit about enhanced commercial

flexibilities and when they can be offered, including the approach taken for assessing the eligibility for medicines treating multiple indications to qualify for indication specific pricing mechanisms.

3.32. NHS England will consider indication specific pricing mechanisms when:

- the indication meets an unmet clinical need;
- the company can demonstrate that uniform pricing would reduce the total revenue for a medicine from introducing additional indications;
- sufficient data is available within existing NHS systems to make such arrangements operationally feasible;
- the cost-effective price is highly differentiated for all indications under consideration;
- the value proposition for the indication aligns to the expectations set out in paragraph 3.30.

3.33. NHS England is supportive of transacting a solution for combination therapies under specific circumstances. The consultation will reflect on the Competition and Markets Authority Prioritisation statement on combination therapies dated 17 November 2023, and consider options for transacting a solution for some combination therapies.

3.34. NHS England will launch a further consultation on a further update to the NHS England Commercial Framework for New Medicines within the first 18 months of the 2024 Voluntary Scheme, to align with updated regulatory and access pathways, ensuring good connectivity with value assessment and commercial processes.

3.35. NHS England recognises there will be some cases where additional support is needed for introducing Advanced Therapy Medicinal Products (ATMPs) into the NHS, including innovative payment models. NHS England commits to delivering two innovative payment model pilots, to explore the practicalities of outcomes-based agreements for ATMPs.

3.36. NHS England and NICE commit to reviewing the Budget Impact Test (BIT) threshold, and to launching a consultation on increasing the threshold to £40 million, within the first six months of the 2024 Voluntary Scheme coming into effect. Following the consultation, any subsequent change to the threshold would take effect after the consultation and remain in effect until the expiry of the 2024 Voluntary Scheme.

- 3.37. Simple confidential discounts and complex published commercial arrangements will continue to be an option for companies at value propositions within the standard NICE cost effectiveness ranges. Additional support will be provided by NHS England and NICE to shape any such proposals.
- 3.38. The details of national commercial arrangements agreed with the purchasing authority in one UK country will be made available on a confidential basis to purchasing authorities in any other part of the UK. Scheme Members will work with purchasing authorities to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK.
- 3.39. NHS England will use its reasonable endeavours to ensure that the use of secondary care medicines purchased by organisations under NHS England frameworks is appropriately restricted for the treatment of NHS patients, and that prices remain confidential.

Equitable adoption of clinically and cost-effective medicines

- 3.40. The Parties have a shared ambition to ensure rapid and equitable adoption of NICE approved, clinically and cost-effective medicines throughout the NHS. The NHS works on the principle of prescribing being a clinically led decision between a healthcare professional and their patient.
- 3.41. Regional and local decisions about NICE recommended medicines must comply with the NHS Constitution and the relevant Regulations, ensuring new medicines are available to eligible patients in line with the wording in the NICE guidance. There should be no further qualification or reinterpretation of NICE guidance at a regional or local level.
- 3.42. NICE commits to increasing its efforts for timely update of clinical guidelines to incorporate technology appraisal guidance recommendations within the care pathway, in line with the guidance wording. Funding will be allocated from the VPAG Investment Programme to support this and to address the backlog of recommendations awaiting incorporation.
- 3.43. UK-wide VPAG Investment Programme funding will also be allocated to enhance NHS England and NICE's adoption and support materials to better support planning and implementation of NICE recommendations in local NHS systems.

- 3.44. Clinical leadership is an essential part of ensuring NICE guidance and clinical guidelines are adopted throughout the NHS. To better support this, NHS England will amend the national and regional clinical leadership job descriptions to embed their role in championing and advocating the use of NICE guidance and guidelines in relevant clinical communities. Clinical communication cascade at national and regional levels will be improved and integrated into formal processes for disseminating information about new medicines to prescribing systems, to support rapid and equitable adoption of NICE guidance, guidelines, and best practice care pathways.
- 3.45. The Parties agree it is important to track and assess the uptake of new medicines by licensed indication where possible. NHS England commits to the continued development of uptake measurement tools, including the Innovation Scorecard and Estimates Reports, to track variation in uptake of NICE recommended medicines between Integrated Care Boards. The Innovation Scorecard and Estimates Report will be updated and published bi-annually. The terms of reference for the Strategic Metrics Group, which has responsibility for the Innovation Scorecard and Estimates Report, will be reviewed as early as possible in 2024 to ensure it can provide adequate ownership and delivery for these measurement tools, and also monitor 2024 Voluntary Scheme implementation.
- 3.46. NHS England commits to the development of a local formulary national minimum dataset within the first half of the 2024 Voluntary Scheme to increase visibility of local variation in the implementation of NICE guidance, identify where variation in local formularies may be creating barriers to access and to confirm to NHS England when a NICE recommended treatment has been placed on a local formulary. The dataset will be developed through wider engagement with key stakeholders including trade associations, industry, prescribers, and commissioners; to ensure it provides the greatest value. NHS England will publish a report, no less frequently than annually, identifying unwarranted variation between national guidance and local formularies.
- 3.47. Several pharmaceutical companies have developed Patient Support Programmes (PSPs) linked to their treatments, which deliver services supplementary to those of the NHS and aimed at improving patients' ability to manage their care more effectively. These are often funded by the companies themselves at no cost to the NHS or the patient. The service is delivered by a third party, so the pharmaceutical company has no direct contact with the patient. These initiatives are not always visible to the local NHS. With the support of Scheme Members, NHS England commits to create within the first half of the 2024 Voluntary Scheme and then keep up to date a new PSP

database to increase the visibility and wider use of existing PSPs across the NHS in England with the agreement of companies.

4. Affordability of branded medicines

Summary

- 4.1. Chapter 4 summarises how the 2024 Voluntary Scheme controls growth in Sales of Branded Health Service Medicines. It introduces separate affordability mechanisms for newer and older medicines that collectively are intended to cap Branded Health Service Medicines' Sales at an agreed level of growth, whilst taking account of the agreed approach to balancing risk.
- 4.2. This Chapter 4 and the associated Annexes 3 to 5 set out the mechanisms – detailing how newer and older medicines are defined, how the relevant Payment Percentages are set, and how growth is calculated. This Chapter 4 (and Annexes 6 to 10) goes on to describe the Sales Reports that Scheme Members are required to provide, requirements for audit and the arrangements for making payments.
- 4.3. For the avoidance of doubt, payments in respect of the VPAG Investment Programme detailed in Chapter 5 are in addition to the payments outlined in this Chapter 4.

Introduction

- 4.4. The policy set out in this Chapter 4 aims to limit growth in the overall cost of Branded Health Service Medicines. This is to be achieved through setting a level of allowed sales of Branded Health Service Medicines for each year of the 2024 Voluntary Scheme with Scheme Members making payments intended to achieve this, whilst taking account of the agreed approach to balancing risk. This detail of this is set out in paragraphs 4.8 to 4.13.
- 4.5. When calculating payments owed, separate affordability mechanisms will apply to Sales of Newer Medicines and to Sales of Older Medicines, so as to balance the level of Scheme Payments associated with different stages of the lifecycle of a given medicine. Definitions of Newer Medicines and Older Medicines are set out in paragraphs 4.8 to 4.13. For the purposes of calculating the payment required from Newer Medicines, Older Medicines assumed growth and assumed payments are fixed so as to balance the level of risk held by industry and government.

- 4.6. The terms of the affordability mechanism for Newer Medicines are set out in paragraphs 4.26 to 4.40. The terms of the affordability mechanism for Older Medicines are set out in paragraph 4.41 to 4.52.
- 4.7. The provisions of this Chapter 4 are to be read as a whole, together with the greater detail on the working of the affordability mechanisms contained in Annexes 3 to 5 (the Technical Annexes) and the defined terms used in Chapter 4 and the Technical Annexes which are set out in the Glossary (the Affordability Mechanisms Definitions). In relation to the interpretation of any provision of the affordability mechanisms, the greater detail contained in the Technical Annexes will take priority over any less detailed text contained in Chapter 4 and the Affordability Mechanisms Definitions. This will apply unless there is a clear conflict or inconsistency between a specific statement in Chapter 4 or the Affordability Mechanisms Definitions and any of the detail contained in the Technical Annexes. In the case of a clear conflict or inconsistency, the text of Chapter 4 or the Affordability Mechanisms Definitions will prevail and the Department and the ABPI will negotiate appropriate amendments to the Technical Annexes to remove the conflict or inconsistency.

Defining Newer and Older Medicines

- 4.8. A Scheme Product by an Originator or Originator Licensee will be a Newer Medicine:
- whilst there is a Supplementary Protection Certificate (SPC) that remains in force for the active ingredient of any Branded Health Service Medicine of the same VTM as the Scheme Product; or
 - where it is a Non-SPC Scheme Product, for a period of 12 years from the date of Marketing Authorisation for the first licensed Branded Presentation of that active ingredient in any Branded Health Service Medicine of the same VTM as the Scheme Product.
- 4.9. Where the Scheme Product described in paragraph 4.8 is a Combination Product, it will be a Newer Medicine:
- where it is a SPC Combination Product and whilst at least one SPC remains in force for the combination of active ingredients for any Branded Health Service Medicine of the same VTM as the Scheme Product; or
 - where it is not a SPC Combination Product and:

- whilst there is a SPC in force for any active ingredient (or combination of active ingredients) within the Combination Product for any Branded Health Service Medicine of the Relevant VTM; or
- for a period of 12 years from the MA Date of the Latest Non-SPC Active Ingredient within the Scheme Product for any Branded Health Service Medicine of the Relevant VTM.

4.10. Where the basis for a Scheme Product being a Newer Medicine is due to the existence of a SPC in force, and that SPC:

- is invalidated for any reason, including but not limited to, the lapse of the basic patent upon which the SPC is reliant, then the effective date of the Scheme Product becoming an Older Medicine shall be the date the Scheme Product would, without a SPC, have otherwise become an Older Medicine;
- lapses as the Marketing Authorisation for that Newer Medicine is withdrawn, then, the effective date of the Scheme Product becoming an Older Medicine shall be the date of lapse of the Marketing Authorisation. Should the Marketing Authorisation be reinstated such that the SPC again takes force, then the Scheme Product shall become a Newer Medicine from the date of reinstatement for as long as the SPC remains in force; or
- is surrendered, then the effective date of the Scheme Product becoming an Older Medicine shall be the date of surrender of the SPC.

4.11. If this were to change previous years' categorisation of Scheme Products, historic payments owed with regards to that Scheme Product would be revised. For the avoidance of doubt, if two or more SPCs are in force for a Scheme Product or a SPC Combination Product, and one or more of those is invalidated, lapses, or is surrendered, the Scheme Product or SPC Combination Product will remain a Newer Medicine for as long as the remaining SPC or SPCs are in force.

4.12. In the event of contradictory or disputed data, the ultimate data sources for SPC and Marketing Authorisation data will be the Intellectual Property Office and the appropriate licensing authority respectively.

4.13. For the 2024 Voluntary Scheme, Older Medicines are Scheme Products which do not meet the definition of Newer Medicines.

4.14. Where a Scheme Product moves from being a Newer Medicine to being an Older Medicine, this takes effect from the day that it ceases to meet the Newer

Medicines definition. However, for the purpose of Scheme Payments and any underlying calculations, the change will be considered to take effect from the start of the Quarter immediately following the date it ceases to meet the Newer Medicines definition. For the avoidance of doubt, a Scheme Product can move between Newer Medicine and Older Medicine status during a calendar year and be subject to a different payment percentage in different Quarters.

- 4.15. The status of Newer Medicines and Older Medicines in the 2024 Voluntary Scheme is without prejudice to the validity or enforcement of any intellectual property protection.

Scheme payments, Industry Measured Sales, and Industry Allowed Sales

- 4.16. Scheme Members will make payments to the Department under the two affordability mechanisms. This amount of payment will be determined by the relevant Payment Percentages that apply which itself is set out in the sections below concerning the affordability mechanisms for Newer Medicines and Older Medicines.
- 4.17. In respect of Newer Medicines, Scheme Members will make payments to the Department based on the application of a percentage to their Eligible Sales of Newer Medicines. That percentage (Headline Payment Percentage) is derived from the difference between Industry Measured Sales (as described in paragraph 4.19) and Industry Allowed Sales as well as agreed assumptions (set out in this Chapter 4).
- 4.18. In respect of Older Medicines, Scheme Members will make payments to the Department based on the application of the Basic Payment Percentage plus a Branded Presentation specific payment percentage (the Top-Up Payment Percentage) to their Eligible Sales of Older Medicines.
- 4.19. Industry Measured Sales is the sum of:
- Measured Sales Of Newer Medicines, consisting of 2024 Voluntary Scheme Measured Sales Of Newer Medicines and Statutory Scheme Measured Sales Of Newer Medicines;
 - Assumed Measured Sales Of Older Medicines (as set out in Annex 3 and 4); and
 - Parallel Import Sales.

- 4.20. Industry Allowed Sales is set in relation to the 2023 Industry Allowed Sales Baseline as calculated in the 2019 Voluntary Scheme, adjusted for changes to the Small Company Sales exemption introduced for the 2024 Voluntary Scheme. The Industry Allowed Sales will be adjusted at the start of each year by a Baseline Adjustment and subsequently be grown by an Allowed Growth Rate percentage (as set out in Annex 4). Sales of Branded Health Service Medicines above this level will be paid back to the Department by Scheme Members in proportion to the 2024 Voluntary Scheme's share of Industry Measured Sales and in accordance with the agreed affordability mechanisms.
- 4.21. The Department does not expect to receive a payment on Parallel Import Sales through the 2024 Voluntary Scheme.

Exemptions from Measured Sales and Eligible Sales

4.22. Some Sales are exempt from Measured Sales. These are:

- Sales of Scheme Products by a Scheme Member relating to Exceptional Central Procurements;
- Sales of Scheme Products by a Scheme Member relating to Centrally Procured Vaccines;
- Small Company Sales (as defined in the Glossary); and
- Low Value Sales (as defined in the Glossary).

4.23. Some Sales are exempt from Eligible Sales. These are:

- Sales of Scheme Products by a Scheme Member relating to Exceptional Central Procurements;
- Sales of Scheme Products by a Scheme Member relating to Centrally Procured Vaccines;
- NAS Sales;
- Small Company Sales;
- Medium Sized Company Sales (up to the £6 million threshold as described in paragraph 4.81); and
- Low Value Sales.

4.24. Definitions of these terms are set out in the Glossary.

Transition

4.25. The first quarter of the 2024 Voluntary Scheme, the period from 1 January 2024 to 31 March 2024, will be a transitional period and, during this period, a fixed payment rate of 19.5% will apply to all Eligible Sales. From 1 April 2024, the affordability mechanisms for Newer Medicines and for Older Medicines will operate as set out below.

Affordability mechanism for Newer Medicines

4.26. Scheme Members will make payments to the Department based on the application of the Headline Payment Percentage to their Eligible Sales of Newer Medicines.

4.27. The Calculated Payment From Newer Medicines is derived from the Calculated Total Payment. The Calculated Total Payment is the difference between Industry Measured Sales and Industry Allowed Sales for a given year, multiplied by the sum of Measure Sales Of Newer Medicines and Assumed Sales Of Older Medicines, as a share of Industry Measured Sales.

4.28. Calculated Payment From Newer Medicines is the Calculated Total Payment minus the Adjusted Assumed Payment From Older Medicines (set out in Annex 3 at the commencement of the 2024 Voluntary Scheme and only subject to revisions as set out below and in Annex 4).

4.29. The Headline Payment Percentage will be calculated as the Calculated Payment From Newer Medicines divided by the Adjusted Sales Of Newer Medicines and adding the Under Payments or Over Payments Adjustment as set out in Annex 4.

4.30. Adjusted Sales Of Newer Medicines is calculated by multiplying Measured Sales Of Newer Medicines and the Newer Medicines Adjustment Factor to account for NAS Sales and Medium Sized Company Sales exemptions.

4.31. The Newer Medicines Adjustment Factor is calculated by dividing the Eligible Sales Of Newer Medicines by the 2024 Voluntary Scheme Measured Sales Of Newer Medicines.

- 4.32. Assumed Measured Sales Of Older Medicines and Adjusted Assumed Payment From Older Medicines inform Industry Measured Sales, Calculated Payment From Newer Medicines, and the Headline Payment Percentage. They are derived from 2023 Measured Sales Of Older Medicines Baseline, grown by the Fixed Forecast Growth Rate for Measured Sales Of Older Medicines. Assumed Measured Sales Of Older Medicines and Adjusted Assumed Payment From Older Medicines will be updated through the 2024 Voluntary Scheme in line with revisions made to 2023 Measured Sales Of Older Medicines Baseline but will not, and are not intended to, reflect actual sales of Older Medicines during the 2024 Voluntary Scheme. Further detail is set out in Annex 4.
- 4.33. The Headline Payment Percentage for the first calendar year is 15.1% and this will not change. For the avoidance of doubt, this will apply from the second quarter of 2024 onwards. The Industry Measured Sales, Industry Allowed Sales, Calculated Payment From Newer Medicines and Headline Payment Percentage will be calculated on a full-year basis throughout the duration of the 2024 Voluntary Scheme.
- 4.34. In the final Quarter of the first calendar year, the forecast of Industry Measured Sales, the forecast of Calculated Payment From Newer Medicines and the forecast of Adjusted Sales Of Newer Medicines for the second and each subsequent calendar year will be reviewed against the initial forecasts upon which the Headline Payment Percentage for the first calendar year was based. These will be adjusted through a process to reconcile the difference between forecast and actual data. In summary, this will follow a pre-agreed process in accordance with Annexes 3 to 5, incorporating the following adjustments:
- recalculation of the Industry Allowed Sales profile based on actuals for the baseline calendar year 2023;
 - adjustment of the forecast growth rate of Industry Measured Sales going forward attributable to Newer Medicines and Parallel Import Medicine based on the cumulative deviation of outturn from initial forecast to date (including the corrections for audited sales);
 - the calculation of any cumulative under or over payments in respect of preceding calendar years in the 2024 Voluntary Scheme resulting from the difference in the Headline Payment Percentage when calculated on the basis of outturn, rather than forecast, Measured Sales of Newer Medicines (Under Payments or Over Payments);

- a smoothed uplift or reduction (depending on the direction of the change) to future Headline Payment Percentages to spread the impact of the resulting Under Payments or Over Payments for preceding calendar years split equally over the remaining duration of the 2024 Voluntary Scheme, further detail of this can be found in Annexes 4 and 5.

4.35. The revised Industry Allowed Sales will then be compared to the adjusted forecasts of Industry Measured Sales to estimate the updated Calculated Total Payment, as described in paragraph 4.26.

4.36. The Calculated Payment From Newer Medicines, as described in paragraph 4.26, will then be divided by the updated forecast Adjusted Sales Through Newer Medicines and adjusted to reflect any Under Payments or Over Payments to calculate the Headline Payment Percentage for the second calendar year. An equivalent process will be undertaken during the fourth quarter of the second, third and fourth calendar years. The detailed process for reviewing and adjusting the Payment Percentage is set out at Annexes 3 to 5.

4.37. The initial forecast growth rate of Industry Measured Sales is the Department forecast and is set out below, rounded to 1 decimal place. This does not constitute the ABPI forecast.

2024	2025	2026	2027	2028
3.9%	4.7%	6.0%	6.0%	4.8%

4.38. An adjusted forecast will be calculated under the process outlined in paragraph 4.34 during the period of the 2024 Voluntary Scheme which reflects actual growth in Industry Measured Sales. This is the forecast growth rate for gross Industry Measured Sales i.e. excluding any payments under either a 2024 Voluntary Scheme or the Statutory Scheme.

4.39. Industry Allowed Sales in each calendar year of the 2024 Voluntary Scheme will be calculated from a baseline position of 2023 Industry Allowed Sales Baseline. Individual component forecasts can be found in Annex 3.

4.40. Following the end of the first calendar year of the 2024 Voluntary Scheme, and then on an annual basis, the automatic adjustment under the process outlined in paragraph 4.34 will be reviewed. Following this review, amendments to the forecast growth rate of Industry Measured Sales can be made by agreement between the Department and the ABPI.

- 4.41. To reflect the fact that final Audited Annual Sales Reports for all Scheme Members will not be received until 2030, there will be a two phase 2024 Voluntary Scheme-end reconciliation in 2029 and 2030 following a pre-agreed process in accordance with Annex 3 to account for any remaining Under Payments or Over Payments arising from these final Audited Annual Sales Reports. In the final Quarter of each of 2029 and 2030, the Headline Payment Percentage for the fifth calendar year will be recalculated, based on Audited Annual Sales Reports where available and otherwise on unaudited Sales Reports. Adjustments of Scheme Payments will be payable (or refundable) in the first Quarter of 2030 and 2031 following the immediately preceding recalculation of the Headline Payment Percentage for the fifth calendar year. Following the recalculation of the Headline Payment Percentage in the final Quarter of 2030, the Headline Payment Percentage for the fifth calendar year will be final and will not change.
- 4.42. For 2024, the Headline Payment Percentage only applies from 1 April – 31 December 2024. Scheme Members will make payments to the Department based on applying the Headline Payment Percentage to their Eligible Sales of Newer Medicines for 1 April – 31 December 2024 only. As part of the process to reconcile the difference between payments made and payments owed by Scheme Members in relation to Newer Medicines, the calculation of Under and Over Payments will only account for the proportion of Eligible Sales Of Newer Medicines for 1 April – 31 December 2024. Further detail is set out in Annex 4.

Affordability mechanism for Older Medicines

- 4.43. In respect of Older Medicines, Scheme Members will make payments to the Department based on the application of payment percentages to their Eligible Sales of Older Medicines. All Eligible Sales of Older Medicines will be subject to the Basic Payment Percentage which is 10%.
- 4.44. In addition to the Basic Payment Percentage, a Top-Up Payment Percentage may also apply. The Top-Up Payment Percentage is applied to individual Branded Presentations of Older Medicines and is based on the difference between the Observed Average Selling Price for the Branded Presentation for the relevant year of the 2024 Voluntary Scheme and the Reference Price. The Reference Price is determined at a Branded Presentation level on either an Observed Average Selling Price or List Price in accordance with Annex 4.
- 4.45. For 2024, the Observed Average Selling Price will be calculated across the last three quarters of 2024 only, following the transitional period in the first quarter of 2024.

- 4.46. Where the Branded Presentation changes status between being a Newer Medicine and being an Older Medicine part way through a year, the Observed Average Selling Price for the year will be calculated across the remaining quarters following the Branded Presentation becoming an Older Medicine (in accordance with paragraph 4.14).
- 4.47. Where the Observed Average Selling Price is less than the Reference Price, this is considered to be an Observed Price Decline. The Observed Price Decline for each Branded Presentation is expressed as a percentage and is calculated as one minus the Observed Average Selling Price divided by the Reference Price, rounded to the nearest whole percentage point..
- 4.48. The Top-Up Payment Percentage is set out in the table below and depends on the percentage of Observed Price Decline.

Observed price decline	2024	2025	2026	2027	2028
10% or less	25%	25%	25%	25%	25%
11%	24%	24%	24%	24%	24%
12%	23%	23%	23%	23%	23%
13%	22%	22%	22%	22%	22%
14%	21%	21%	21%	21%	21%
Each percentage point drop in observed price decline equates to a 1% point reduction in the Top-Up Payment Percentage until the percentage of observed price decline reaches 35%					
35% or more	0%	0%	0%	0%	0%

- 4.49. A Scheme Member introducing a new Scheme Product, where not the Originator Product, will be required to declare whether there is any Commercial Relationship between that new product and the Originator Medicine.
- 4.50. Where a Commercial Relationship exists, and the new Scheme Product is launching as an Older Medicine, the Top-Up Payment Percentage applied shall be no lower than that of the Originator Product.
- 4.51. Where a Scheme Member fails to submit the Annual Presentation Level Sales Report within required timelines without reasonable cause, the Department

reserves the right to apply the highest Top-Up Payment Percentage to that Scheme Member's Eligible Sales of Older Medicines.

- 4.52. 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.
- 4.53. Older Medicines with annual 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 will be subject to the Basic Payment Percentage and VPAG Investment Programme payments only for that Scheme Member, regardless of the Observed Price Decline. For avoidance of doubt, this will not affect whether a Top-Up Payment Percentage applies to Older Medicines of other Scheme Members.
- 4.54. The process for consideration of an adjusted Top-Up Payment Percentage for a Branded Presentation is set out in paragraph 7.8.

Arrangements for Making Scheme Payments

- 4.55. Scheme Payments in relation to Newer Medicines and as a result of the Basic Payment Percentage in relation to Older Medicines must be paid in Quarterly instalments by individual Scheme Members at the same time as Quarterly Sales Reports are submitted.
- 4.56. Scheme payments in relation to the Top-Up Payment Percentage for Older Medicines must be paid annually by individual Scheme Members at the same time as unaudited Annual Presentation Level Sales Reports are submitted.

Sales Reports

- 4.57. Quarterly Sales Reports must be submitted by the Scheme Member via the relevant portal designated by the Department (and notified by the Department to Scheme Members from time to time) within one (1) month after the end of each Quarter of the calendar year. The Quarterly Sales Report must be completed in accordance with the guidance at Annex 6 and using the Sales Report pro-forma at Annex 6, Appendix 1).

- 4.58. For all Scheme Members, following the statutory audit of the Scheme Member's statutory accounts, an Audited Annual Sales Report must be submitted by the Scheme Member via the relevant portal in accordance with the requirements for audit of the Scheme Payments set out at paragraphs 4.59 to 4.60. The Audited Annual Sales Report must be submitted within nine (9) months of the end of the Scheme Member's Financial Year end. For companies with a Financial Year end of 31 December the deadline is therefore 30 September in the following calendar year. Scheme Members are required to submit an Audited Annual Sales Report relating to each calendar year in which they were a member of the Scheme.
- 4.59. 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, known as a Split 1 and Split 2 Sales Reports. Further details about these can be found at Annex 6, which provides guidance notes on completion of Sales Reports together with the following appendices:
- a pro-forma for the Quarterly Sales Reports and Annual Sales Report (Appendixes 1 and 3 respectively);
 - a Scheme Member Declaration for the Sales Reports (Appendix 2); and
 - the Audit Report on the Audited Annual Sales Reports (Appendix 4).
- 4.60. In addition to the Audited Annual Sales Report an Annual Presentation Level Sales Report must be submitted by the Scheme Member not later than three (3) months following the calendar year end via the relevant portal using the pro-forma at Annex 7 and the Scheme Member Declaration at Annex 8. The Annual Presentation Level Sales Report will be available through the online portal.
- 4.61. The detailed sales information contained within an Annual Presentation Level Sales Report will be used to establish the sales of Newer and Older Medicines at Branded Presentation level and, therefore, the levels of Industry 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 corrected, including the level of payments that apply to the Top-Up Payment Percentage, following the receipt of the Annual Presentation Level Sales Report. As part of routine assurance of company returns, the Department will compare administrative data on spend on Branded Health Service Medicines with Scheme Member data from Annual Presentation Level Sales Reports.

- 4.62. There is no requirement for the Annual Presentation Level Sales Report to be Audited but the data should reconcile with the relevant Quarterly Sales Reports, and it will be necessary for the Annual Audited Sales Report to reflect the data included within the Annual Presentation Level Sales Report. Given the timing difference in providing an 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.
- 4.63. For the purpose of completing Annex 7 the following data should be included:
- Under Primary Care Sales: those Branded Presentations which are dispensed by community pharmacists or dispensing doctors;
 - Under Homecare Sales: those Branded Presentation that are sold direct to homecare providers; and
 - Under All Other Customers: all other Branded Presentation (including wholesaler sales to homecare providers).
- 4.64. The Company Declaration must declare that the sales information provided has been accurately extracted from the Scheme Member records and complies with the requirements of the 2024 Voluntary Scheme.
- 4.65. All Quarterly and Annual Sales Reports for the Scheme Payments (as described in Annex 6) must also be submitted to the independent third party, as soon as they have been appointed by the ABPI (such appointment subject to the Department's reasonable right of veto) and details of whom have been confirmed to Scheme Members.
- 4.66. Where a sale of an item of Branded Presentation is made by both the Scheme Member and by a company (or companies) in the same Group as the Scheme Member, the Scheme Member must:
- itself submit Sales Reports in accordance with the requirements of this Chapter 4 and Annex 6; and
 - submit Sales Reports for each company (or companies) in the same Group as the Scheme Member that has (or have) made sales of that item of Branded Presentation.
- 4.67. If there are reasonable and objective grounds for the Department to believe that the exclusion of sales of items of Branded Presentation by a company (or companies) in the same Group as the Scheme Member from the calculation of Scheme Payments by the Scheme Member have had a material adverse net

impact on the Scheme Payments made by the Scheme Member under the 2024 Voluntary Scheme then the Department and the Scheme Member will discuss and agree any reasonable adjustments to the basis of calculation of Sales by the Scheme Member and companies within its Group on which the Payment Percentage should be applied. This may include, without limit, a change in the Group company being named as Scheme Member with respect to that item of Branded Presentation and/or the Scheme Member separately paying a sum of money to the Department equal to the payment that would have been made by the Scheme Member had the Payment Percentage been applied to the total Sales for that item of Branded Presentation made by the Scheme Member and the company (or companies) in the same Group as the Scheme Member.

Audit Arrangements

- 4.68. The following arrangements for Auditing Scheme Members' Audited Annual Sales Reports for the Scheme Payments will apply.
- 4.69. Following the end of the Financial Year there will be an independent Audit of each Scheme Member's Audited Annual Sales Report for that Financial Year.
- 4.70. The Audited Annual Sales Report must be Audited by an Auditor. Any resulting cost will be met by the Scheme Member.
- 4.71. The Audited Annual Sales Report must show how the reported Sales, and the reported Sales of Scheme Products relate to the sales figures set out in the Scheme Member's statutory accounts submitted under the Companies Act 2006. The Audited Annual Sales Report must be accompanied by an Audit Report as set out in Annex 6, Appendix 4. This Audit Report must provide a Reasonable Assurance opinion in an agreed form, performed by the Auditor in accordance with ISA (UK) 800 and ISA (UK) 805 and reported for each calendar year of sales applicable to the 2024 Voluntary Scheme including the baseline calendar year sales (2023) against which the 2024 Voluntary Scheme Measured Sales have been measured. Annex 6 sets out further guidance required for Auditors to undertake the engagement only to the extent that this does not override applicable accounting or auditing standards.
- 4.72. Any differences between the Scheme Payment by an individual Scheme Member derived from the Quarterly Sales Report and Audited Annual Sales Report must be corrected following the Audit. Any amounts owed by either party 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.

- 4.73. 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.
- 4.74. While the Annual Presentation Level Sales Report does not require to be audited annually, the Department reserves the right to request an audit for any Annual Presentation Level Sales Report. Scheme Members shall be responsible for their own audit costs.

Smaller Companies

- 4.75. Scheme Members with Sales of Scheme Products of less than £6 million in the previous calendar year will not be required to make Scheme Payments to the Department. In the case of Scheme Members with Sales of Scheme Products of less than £1 million in the calendar year 2023, eligibility for the exemption will be established at the start of the 2024 Voluntary Scheme and will continue throughout the period of the 2024 Voluntary Scheme provided that annual Sales of Scheme Products do not grow to £1 million or greater.
- 4.76. For Scheme Members with Sales of Scheme Products of £1 million or greater but under £6 million, eligibility for the exemption will be established on or around 31 March for that calendar year on the basis of the Scheme Member's sales data for the previous calendar year and will apply for the whole of the calendar year concerned whether or not the Sales during that calendar year are above or below the threshold. This eligibility will be reassessed at the same time of the following calendar year in the same way.
- 4.77. Scheme Members with Sales of Scheme Products of less than £1 million must submit a Company Declaration on the value of their Sales in the calendar year 2023 by 31 March 2024 using the Company Declaration at Annex 9. These Scheme Members will continue to be exempt for the period of the 2024 Voluntary Scheme subject to submitting annual Company Declarations on the value of their Sales of Scheme Products for the previous calendar year by 31 March in each subsequent calendar year of the 2024 Voluntary Scheme and the value of those Sales as stated in the relevant Company Declaration remaining below £1 million. If the value of those sales as stated in the relevant Company Declaration reaches or exceeds £6 million, the exemption will cease to apply for the whole of the following calendar year.
- 4.78. Scheme Members with Sales of Scheme Products of £1 million or greater and less than £6 million in the calendar year 2023 must submit an unaudited Annual Sales Report of Sales of Scheme Products for the calendar year 2023 by 31 March 2024 using the Sales Report at Annex 6 and the Company

Declaration at Annex 10. The Department will establish whether or not the Scheme Member falls within the criteria for the exemption based on this data. If their total Sales of Scheme Products for the calendar year 2023 are less than £6 million then they will not be required to make Scheme Payments or to submit Quarterly Sales Reports or Audited Annual Sales Reports for the calendar year 2024. Thereafter, Scheme Members with Sales of Scheme Products of £1 million or greater and less than £6 million in any calendar year must submit an unaudited Annual Sales Report for that calendar year by 31 March of the following calendar year and, if the Scheme Member remains eligible for the exemption, for each subsequent calendar year of the 2024 Voluntary Scheme by 31 March of the following calendar year.

- 4.79. If a Scheme Member which is eligible for the exemption in a calendar year reports total Sales of Scheme Products in the unaudited Annual Sales Report for that calendar year of £6 million or greater, then the exemption will cease to apply for the whole of the following calendar year. So, for example, if the sales total for the calendar year 2024 submitted by 31 March 2025 shows that the Scheme Member's Sales of Scheme Products in the calendar year 2024 were £6 million or greater, then the Department will require the Scheme Member to make Scheme Payments for the whole of the calendar year 2025, submitting the Quarterly Sales Reports and Scheme Payments and an Audited Annual Sales Report and Annual Presentation Level Sales Report for 2025 according to the same procedure as other Scheme Members.
- 4.80. If a Scheme Member has been making Scheme Payments because its Sales of Scheme Products were £6 million or greater in the previous calendar year, but during the calendar year its Sales of Scheme Products (gross of the Scheme Payment) fall below the £6 million threshold, then it will become eligible for the exemption in the following calendar year. For example if a Scheme Member was at or above the £6 million threshold according to its Sales of Scheme Products for the calendar year 2024 and made Scheme Payments for 2025, but the Scheme Member's Sales of Scheme Products gross of the Scheme Payment in the calendar year 2025 fell below the £6 million threshold, then it could apply for the exemption for 2026 based on an Sales Report for 2025 submitted by 31 March 2026.

Medium Sized Companies

- 4.81. Scheme Members with Sales of Scheme Products of £6 million or over but under £30 million in the preceding calendar year will be exempt from the assessment of Eligible Sales up to a threshold of £6 million on Sales of Scheme Products (excluding NAS Sales). Within a Group, only one entity can

qualify for this exemption annually, regardless of whether entities have become Scheme Members in an individual company capacity or as part of a Group. The Department will monitor this through Form A. A company should advise the Department of any change to the Group structure within 28 calendar days of this coming into effect.

- 4.82. The exemption will be applied on the basis of the proportion of Eligible Sales within each quarter that are subject to the Headline Payment Percentage and to the Basic Payment Percentage up until the £6 million threshold is reached.
- 4.83. The exemption will subsequently be recalculated with the submission of the PLR. This adjustment will apply the exemption to up to £6 million of sales on the basis of the proportion of Eligible Sales within that full year that are subject to the Headline Payment Percentage, the Basic Payment Percentage and each Top-Up Payment Percentage. If this results in an increase to the total payment exempt, this will be settled by an equivalent reduction in the amount owed for the Top-Up Payment Percentage, or by a payment by the Department to the Scheme Member. If this results in a decrease to the total payment exempt, this will be settled by an equivalent increase in the amount owed for the Top-Up Payment Percentage, or by a payment to the Department by the Scheme Member.
- 4.84. Eligibility for this exemption will be established at the start of each calendar year on the basis of the Scheme Member's Sales Reports for the previous calendar year and will apply for the whole of the calendar year concerned whether or not the Sales of Scheme Products during that calendar year are above or below the threshold. This eligibility will be reassessed at the start of the following calendar year in the same way. Scheme Members with Sales of Scheme Products of £6 million or greater and less than £30 million in 2023 must submit an unaudited Annual Sales Report of Sales of Scheme Products for each calendar year by 31 March in the following calendar year using the Sales Report at Annex 6 Appendix 3 and the Company Declaration at Annex 6 (Appendix 2).
- 4.85. Scheme Members' eligibility for the exemption in respect of each calendar year will be reconfirmed upon receipt of their Audited/de-facto Audited Sales Report for the previous calendar year which will be submitted in accordance with paragraph 4.57 and Annex 6. Where this exercise results in a change in eligibility status for a given calendar year from that originally set based on the Scheme Member's unaudited Sales Reports for the previous calendar year, the Department will require the Scheme Member to make an additional payment equal to the Payment Percentages in the calendar year for which the exemption was given, with that exemption removed. So, for example, if the

unaudited sales total for 2023 submitted by 31 March 2024 shows that the Scheme Member's Sales of Scheme Products in 2023 were less than £30 million, that company would make Scheme Payments in 2024 exempting £6 million of non-NAS sales from the assessment of Eligible Sales. Then, if their Audited/de-facto Audited Sales Report submitted at a later date showed that the Scheme Member's Sales of Scheme Products in 2023 were actually £30 million or greater, that Scheme Member would be required to pay the Department the additional payment on the £6 million of Sales of Scheme Products that was originally exempt from the assessment of their Eligible Sales in 2024. Similarly, if a Scheme Member's Audited/de-facto Audited Sales Report for a given calendar year showed that they should have qualified for the exemption in the subsequent calendar year where their unaudited Sales Report did not, the Department would repay that Scheme Member the Scheme Payments made on £6 million of their Sales of Scheme Products in that subsequent calendar year.

- 4.86. If a Scheme Member who is eligible for the exemption in a calendar year reports total Sales of Scheme Products in the unaudited Annual Sales Report for that calendar year of £30 million or greater, then the exemption will cease to apply for the whole of the following calendar year. So, for example, if the total Sales of Scheme Products for 2024 submitted by 31 March 2025 shows that the Scheme Member's Sales of Scheme Products in 2024 were £30 million or greater, then the Department will require the Scheme Member to make Scheme Payments for the whole of 2025 without exempting £6 million of sales from the assessment of Eligible Sales and submitting the Quarterly Sales Reports and Scheme Payments and an Audited Annual Sales Report and Annual Presentation Level Sales Report for 2025 according to the same procedure as other Scheme Members not eligible for the exemption.
- 4.87. If a Scheme Member has been making Scheme Payments without exempting £6 million of sales from the assessment of Eligible Sales because its Sales of Scheme Products were £30 million or greater in the previous calendar year, but during the calendar year its Sales of Scheme Products (gross of the Scheme Payment) fall below the £30 million threshold, then it will become eligible for the exemption in the following calendar year. For example if a Scheme Member was at or above the £30 million threshold according to its Sales of Scheme Products for 2023 and made Scheme Payments for 2024 without exempting £6 million of sales from the assessment of Eligible Sales, but the Scheme Member's Sales of Scheme Products gross of the Scheme Payment in 2024 fell below the £30 million threshold, then it could apply for the exemption for 2025 based on a Sales Report for 2024 submitted by 31 March 2025. The Scheme Member will be subject to the same reporting requirements set out in paragraphs 4.81 and 4.82.

Historical cash payments

- 4.88. Members of the 2009 Pharmaceutical Price Regulation Scheme that elected to deliver up to two per cent (2%) of the price cuts in that voluntary scheme (HCP Scheme Members) by making payments to the Department will have the option to either continue to deliver that value through Historical Cash Payments (HCPs) or by making a one-off payment in settlement, calculated by multiplying the Audited HCP value for the relevant Scheme Member in 2022 by a factor of three (3).
- 4.89. Scheme Members opting to make a one-off payment, must give notice to the Department by 31 March 2024 and pay the amount of the one-off payment calculated by the Department within sixty (60) calendar days of being notified of that amount by the Department.
- 4.90. Scheme Members opting to continue with HCPs should continue to make the relevant payments for the relevant products and net them off against their sales figures prior to the calculation of the Scheme Payment. The process for calculating HCPs is set out at paragraphs 4.91 to 4.92.
- 4.91. The historical cash payment percentage set for HCP Scheme Members under the 2014 PPRS (Historical Cash Payment Percentage) and the 2019 Voluntary Scheme will continue at the same level under the 2024 Voluntary Scheme.
- 4.92. For 1 January to 31 December for each calendar year of the 2024 Voluntary Scheme, HCP Scheme Members must complete an Historical Cash Payment Form (Annex 11), annotating it appropriately so that sales against which the Historical Cash Payment Percentage will be applied can be identified. The completed Annex 11 must be submitted to the Department along with a completed Independent Audit Report (Annex 12) and a completed Company Declaration (Annex 13) by 31 March of the following calendar year. The Branded Presentations annotated must be those that were on the market on 31 December 2008 (and any subsequent Line Extensions of those Branded Presentations) and that continue to be sold by the HCP Scheme Member. The total Sales at NHS list prices of these Branded Presentations will be known as annual Historical Cash Payment sales (Annual Historical Cash Payment Sales).
- 4.93. For convenience, a pre-populated HCP report, which can be used for independent auditing purposes, will be available from the online portal if a company has submitted an Annual Presentation Level Sales Report.

- 4.94. The HCP for each calendar year of the 2024 Voluntary Scheme will be calculated by applying the Historical Cash Payment Percentage against the respective calendar year's Annual Historical Cash Payment Sales.
- 4.95. HCP Scheme Members must estimate the HCP in advance of each calendar year of the 2024 Voluntary Scheme. Twenty five per cent (25%) of the annual estimate of the HCP must be paid each Quarter at the same time that the Scheme Payment is made. Any balancing amount following the Department's assessment of each HCP Scheme Member's Annual Historical Cash Payment Sales must be made in the Quarter following the issue of the Department's assessment.

5. Supporting the growth of the UK life sciences industry

Summary

5.1. This section sets out the ambitions of the 2024 Voluntary Scheme to drive investment-led economic growth, improving the UK’s health and life sciences ecosystem and harnessing the strength, innovation and support for access to and uptake of clinically and cost-effective medicines for the benefit of patients.

VPAG Investment Programme

5.2. The VPAG Investment Programme (the Programme) is a new joint government-industry programme to strengthen the UK’s global competitiveness in health and life sciences and drive innovation-led growth. Enabled by circa £400 million of funding from scheme members, the programme will target investment across the four nations, with initiatives in three focus areas - clinical trials, health technology assessment and manufacturing.

5.3. Scheme Members will provide additional funding on top of the 2024 Voluntary Scheme payments made under Chapter 4 to support implementation of the Programme. The estimated £400 million payment will be split across the five years of the 2024 Voluntary Scheme, as set out below, based on a premium on Eligible Sales (i.e. non-exempt sales of both Newer Medicines and Older Medicines).

Year	2024	2025	2026	2027	2028
Premium payment rate	0.03%	0.6%	1.0%	0.9%	0.3%

5.4. The three UK-wide initiatives, and indicative funding allocations (as stated in the summary of each initiative below as a percentage of the available Programme funding) that will make up the Programme are as follows:

- Clinical Trials (~75%) – boost workforce capacity, resources and infrastructure to expedite delivery of commercial trials in the UK. This initiative will:

- Expand on and enhance existing dedicated commercial clinical research infrastructure across the UK; and
- Deliver flexible funding to pump prime clinical trial resources, by increasing workforce capacity and infrastructure relevant to the delivery of commercial clinical research.
- Innovative Health Technology Assessment approaches (~5%) - to support NICE, the SMC the AWTTC and the Northern Ireland Department of Health to improve pre and post assessment methods and processes related to the access and adoption of clinically and cost-effective medicines. This collection of projects will include support for the development of innovative approaches to HTA assessment, such as the NICE HTA Innovation Laboratory; accelerated incorporation of Technology Appraisal recommendations in NICE and / or Scottish Intercollegiate Guidelines Network (SIGN) Guidelines; the development of comprehensive implementation support (uptake) toolkits; and the rebuild of UK PharmaScan.
- Manufacturing (~20%)- To further improve the manufacturing innovation ecosystem in the UK and the UK's overall global competitiveness, the Programme will invest in capabilities associated with delivering sustainable pharmaceutical manufacturing in line with global commitments to deliver net zero. This will primarily focus on co-developed challenge funding and collaborative R&D programmes administered through Innovate UK.

Governance

- 5.5. The Department will administer the Programme using existing processes for accountability and governance and ensure that funding is allocated in line with an agreed per annum funding model to ensure successful delivery.
- 5.6. Each devolved administration will use their own delivery mechanisms and governance structures for the elements of the Programme delivered within their nations, feeding into an overarching UK-wide governance structure. Each individual initiative's UK governing body will report into the VPAG Operational Review Group via a new working level Programme subgroup, which will provide UK-wide governance of the Programme as a whole. The Programme subgroup will comprise government, the ABPI, devolved administration representatives and key system delivery partners. The Programme subgroup will report annually on implementation progress and escalate any concerns, as required and as identified by the ABPI and/or government, to the VPAG Operational Review Group. Figure 1, below, outlines the structure.

- 5.7. The ABPI will liaise with Scheme Members to identify any disputes or delivery concerns relating to the operation of the Programme and report any such matters to the VPAG Operational Review Group on a periodical basis.

Administration

- 5.8. The Parties will, by the end of April 2024, develop a work programme for each initiative included in the Programme, in advance of delivery. Work programmes will be agreed by the VPAG Investment Programme Board prior to commencing. Where relevant, UK-wide coordination groups will be established to ensure a four nations approach. These groups will be non-decision making in nature, acting as a forum for coordination and discussion between government officials in the devolved administrations. Each initiative will report to into the VPAG Investment Programme Board against these work programmes in line with agreed governance arrangements.
- 5.9. Once the additional payments made by Scheme Members for the Programme have been received by the Department, this will constitute public funding and, as a result, the Department will have responsibility for the fair and legal use of those funds, and for accounting for use. Further, the Department shall have responsibility for all decision making relating to the allocation of these public funds, in line with agreed work programmes as set out in paragraph 5.11.
- 5.10. Neither the ABPI nor its membership shall have any role in decision making for funding allocation.
- 5.11. Full work programmes, including metrics for successful delivery will be developed by the Parties, at both the Programme and initiative level. These indicators will be reported into the VPAG Operational Review Group. Investments made by the Programme will align to and supplement ongoing government activities and funding streams, and therefore the government will not account specifically for spending against the allocations funded by the Programme.
- 5.12. At the midpoint of the 2024 Voluntary Scheme (June 2026), all Scheme Members, via the ABPI, will have the option to review delivery across the Programme. Within two (2) weeks of this review, if the review demonstrates clear evidence of non-delivery, i.e. objective evidence of repeated or material failure, without reasonable justification, to comply with the work programmes set in accordance with paragraph 5.11, the ABPI may issue a twelve-month

notice for the Programme to cease, beyond which the Programme payments as detailed in paragraph 5.3 may cease.

- 5.13. There is no expectation that Programme funded initiatives will continue beyond 2028 and, as such, all initiatives should plan for activities ending with the closure of the Programme at the end of the 2024 Voluntary Scheme. The delivery team responsible for each initiative will be required to develop and agree exit plans at least twelve (12) months prior to the end of the 2024 Voluntary Scheme for each initiative.

Funding flows

- 5.14. The Programme will where relevant be supplementing and scaling up existing funding streams across policy areas. Funding from the Programme will be accounted for as public funding and incorporated into core funding for the government and the devolved administrations, with reporting in line with standard government processes.
- 5.15. The Programme is solely funded by financial contributions by Scheme Members and there is no expectation of matched or supporting funding by the government to the Programme. If the Programme does not reach its aggregate target of £400 million over five years, there is no obligation on the government to raise the difference.
- 5.16. Funding is provided to the Department as programme funding for agreed activities. No return on / return of capital is expected for this investment.
- 5.17. Funding will be made available quarter by quarter in arrears, in line with standard payment processes.
- 5.18. There is no expectation that VPAG Investment Programme funded initiatives will continue beyond 2028, as set out in paragraph 5.13. Therefore, VPAG Investment Programme payments will not be adjusted after 2028 and will not be included or adjusted as part of the 2024 Voluntary Scheme-end reconciliation set out in paragraph 4.40.

6. Pricing and Exceptional Treatment of Older Medicines

Summary

- 6.1. Chapter 6 and Annex 14 set out the arrangements for agreeing prices of medicines, whether new or existing, and in specific instances exemptions to Top-Up payments. Under the terms of the 2024 Voluntary Scheme medicines that are classified as New Active Substances (and their subsequent Line Extensions) launched within thirty-six (36) months of licensing of the first indication in the UK will benefit from freedom of list pricing at Launch. This Chapter 6 describes the arrangements for this, and the profit control arrangements that come into effect should the expected profits exceed the stated limits. The procedures for determining the price of other products and their Line Extensions are also set out, together with arrangements for applying for NHS list price increases and decreases.

Pricing of New Medicines

Medicine Launches

- 6.2. A Scheme Member wishing to place for sale on the UK market (Launch) a Branded Health Service Medicine is required to give the Department a minimum of twenty eight (28) calendar days' written notice before the date of Launch. A Scheme Member must not Launch a medicine until it has received confirmation from the Department either that it has freedom of pricing as a New Active Substance or that the proposed price is acceptable.
- 6.3. As part of its notice the Scheme Member must supply the Department with details of the medicine including the proposed NHS list price and the Summary of Product Characteristics (or draft thereof). The Scheme Member may give such notice prior to receipt of the Marketing Authorisation in order to avoid patient access delays. The Department may provisionally respond to a Scheme Member's notice of a medicine which is awaiting the grant of a Marketing Authorisation. Final consideration and confirmation will follow receipt by the Department of the Marketing Authorisation.
- 6.4. The Department will acknowledge the submission and seek confirmation of the Marketing Authorisation status from the appropriate Licensing Authority.

- 6.5. Where a Scheme Member Launches a medicine that does not have an NHS list price the Department may by notice communicate to the Scheme Member the NHS list price which may be charged for that medicine by taking into account the factors listed at paragraph 6.13. Where that NHS list price is lower than the price the Scheme Member previously charged for that Branded Presentation, the Scheme Member shall be required to pay to the Department a sum equal to the additional costs incurred by the NHS as a result of the Scheme Member's actions (including without limit the difference between the gross sales income that the Scheme Member received for the supply of the Scheme Product prior to the determination of the NHS list price and the gross sales income that would have been accrued at the NHS list price determined by the Department).

New Active Substances

- 6.6. New Active Substances and subsequent Line Extensions Launched within thirty six (36) months of licensing of the first indication in the UK will benefit from freedom of list pricing at Launch. Having received confirmation from the Department that the Scheme Product is a New Active Substance or subsequent Line Extension and therefore has freedom of pricing, when an NHS list price is agreed for a New Active Substance with freedom of pricing, the Scheme Member will confirm its intention to price the product for sale to the NHS at a level consistent with securing a positive NICE appraisal . Pricing the product at a level consistent with securing a positive NICE appraisal may be achieved through the NHS list price proposed, or through a confidential discount or other commercial arrangement agreed with NHS England or other relevant NHS body. For the avoidance of doubt, maximum list price controls will apply to products that do not benefit from freedom of list pricing.
- 6.7. Line Extensions relating to a New Active Substance, may be priced at the discretion of the Scheme Member, as set out in paragraph 6.6 provided that the Launch of the Line Extension in the UK occurs within thirty six (36) months of the date of the Marketing Authorisation of the relevant New Active Substance.
- 6.8. Increased strengths of existing formulations may not be priced at a level greater than pro-rata to existing formulations. The freedom of pricing of reduced strengths should not be coupled with product deletions so as to achieve hidden price increases.
- 6.9. Once the Department has established that a medicine is a New Active Substance it will write promptly, and in any event within five (5) working days, to the Scheme Member confirming that the product has freedom of pricing.

6.10. If forecast NAS Sales of any new Branded Health Service Medicine in any one calendar year of the first five calendar years following Launch are expected to exceed the Budget Impact Test threshold currently in place, a Scheme Member must inform the Department of both the NHS list price and the anticipated level of Sales in each of the first five calendar years.

All Other Products and Their Line Extensions

6.11. Where a new Branded Presentation does not have freedom of pricing the following applies.

6.12. Increased strengths of existing formulations may not be priced at a level greater than pro-rata to existing formulations. Introducing reduced product strengths should not be coupled with product deletions so as to achieve hidden price increases.

6.13. In reaching a decision on the acceptability of a proposed NHS list price, the Department may take into account factors such as the following:

- Clinical need (UK and global);
- Price of therapeutically equivalent or comparable products;
- Price and operational costs of the new product in the EEA and other markets;
- Date that patent protection expires;
- Estimated total quantity of the product to be supplied and estimated sales income over the first three (3) Financial Years with the option to ask for (5) Financial Years if required;
- Reasonableness of the estimated costs, including: manufacturing and supply costs, R&D costs; and operational costs;
- Price at which the reasonable costs would be met and a reasonable profit earned (and the Department will consider a reasonable profit to be broadly the same level of profits required for an NHS list price increase to be approved as set out in paragraph 6.21); and
- The Scheme Member's profit over the first three (3) Financial Years with the option to ask for (5) Financial Years if required

- 6.14. As part of its assessment, the Department may request additional information from the Scheme Member.
- 6.15. The Department will consider the acceptability of the price and provide the Scheme Member with its decision within twenty eight (28) calendar days of receipt of the original notification or from the receipt of any additional information it has requested from the Scheme Member. The decision shall contain a statement of reasons based on relevant criteria such as those set out at paragraph 6.12.
- 6.16. If, following discussions, agreement cannot be reached on the NHS list price of the Branded Presentation, a Scheme Member may request that the matter is referred to the Department's decision committee within fourteen (14) calendar days of the final decision of the Department's pricing committee on what represents a suitable price and if that does not result in agreement, the Scheme Member may refer the issue to the DRP within fourteen (14) calendar days of the decision committee's final decision.

Requirement to set a list price

- 6.17. The parties reiterate their commitment to supporting innovation, by continuing to support new medicines which are classified as being a new active substance, in the spirit of previous voluntary schemes. The parties reiterate their commitment to supporting patient access and affordability for the NHS, through responsible pricing of Branded Health Service Medicines.

NHS List Price Increases

- 6.18. No Scheme Member may increase the NHS list price of any Scheme Product without the Department's prior approval. An NHS list price increase will not be granted unless a Scheme Member has complied fully with its obligations under Chapter 4 and has no outstanding Scheme Payments due (except for any Scheme Payments which are the subject of a bona fide dispute which (as at the date of the original notification) has been referred to the DRP).
- 6.19. Where a Scheme Member wishes to increase the NHS list price of any Scheme Product, it must give the Department not less than eight (8) weeks' notice of this request. This notice must state the amount of the proposed increase and the reason in sufficient detail to satisfy the Department that the increase is justified and include a Price Increase Financial Return (PIFR) containing the information listed at Annex 14. The Department will consider the acceptability of the proposed new price. If the information supporting the

notice is inadequate, the Department shall request the additional information from the Scheme Member required in order to take its final decision. If the Department decides not to permit the proposed increase of the Scheme Product concerned, the decision shall contain a comprehensive statement of reasons. The Department may by notice communicate to the Scheme Member the NHS list price which may be charged for that medicine by taking into account the relevant factors.

- 6.20. Where a Scheme Member increases the NHS list price of any Scheme Product without the Department’s prior approval, whether pursuant to a request for an increase or otherwise, the Scheme Member shall be required to pay to the Department a sum equal to the additional costs incurred by the NHS as a result of the Scheme Member’s actions (including without limit the difference between the gross sales income that the Scheme Member received for the supply of the Scheme Product subsequent to the unapproved price increase and the gross sales income that would have been accrued at the NHS list price approved or determined by the Department).
- 6.21. The Department will not approve an NHS list price increase unless the Scheme Member’s estimated and forecast profits (inclusive of transfer price profit and the allowances referred to in paragraph 6.22) on its portfolio of all Scheme Products sales to the NHS for the current and the following Financial Year respectively (excluding the effect of the proposed NHS list price increase), as assessed by the Department having regard to the PIFR, are below 50% of the Return on Sales (ROS) target referred to in paragraph 6.22. Where the Scheme Member’s estimated and forecast profits as assessed by the Department are below 50% of the ROS target, the maximum NHS list price increase that the Department will approve is the level of increase required for the Scheme Member’s estimated and forecast profits for the current and following Financial Year (inclusive of the effect of the proposed NHS list price increase) to achieve the relevant ROS.
- 6.22. The ROS target is 6%. The maximum allowances for the purposes of assessing ROS in relation to a proposed price increase are:

Category of Cost	Maximum Allowance of Value of Sales of Scheme Products
Research and development	Up to 22%
Marketing	Up to £900,000 per annum plus a variable rate of up to 2%
Information	Up to 2%

- 6.23. Further information on the calculation of the ROS target and these allowances and the completion of PIFRs is set out in Annex 14.
- 6.24. If a price increase is approved, the Scheme Member may be required to provide updated financial information in respect of their portfolio for the full financial year following the award of the price increase. The Department reserves the right to request that this information is independently audited by the company.
- 6.25. No Scheme Member may be awarded an NHS list price increase for a Scheme Product within a period of twelve (12) months following an approved NHS list price increase for that Scheme Product.

Exceptional circumstances

- 6.26. If a Scheme Member considers there are exceptional circumstances where:
- long-term and systemic global supply constraints mean that wider factors should be considered to support a proposed NHS list price increase or adjusted Top-Up Payment Percentage; or
 - a Scheme Product does not qualify for a price increase (including, in the exception circumstances set out in the preceding sub-paragraph, through the consideration of wider factors) but where there is clear evidence that the Scheme Product is uneconomic to supply, that there is the likelihood of a product discontinuation, withdrawal, or non-supply, and that a discontinuation, withdrawal, or non-supply would have either a subsequent negative impact on patient health, or a significant increased cost to the Department as a result of supplying alternative medicines following such discontinuation, withdrawal, or non-supply,

the Scheme Member may put a proposal to the Department for consideration on its own merit for a permanent or temporary presentation level price increase or, if that is an Older Medicine, a permanently or temporarily adjusted Top-Up Payment Percentage for the product. The duration of any change in treatment for an Older Medicine would be determined by the Department as part of the exception mechanism process. However, any decision on such a proposal will be at the Department's entire discretion and may not be referred to the Dispute Resolution Procedure. For Scheme Members with Sales of Scheme Products of under £30 million per annum the Department may agree with the Scheme Member that a Scheme Product would not qualify for a price increase

under the provisions in paragraph 6.19 to 6.25 and, in such circumstances, the Department may, at its discretion, waive the requirement to submit a product portfolio-wide PIFR.

- 6.27. If a price increase is approved under paragraph 6.26, the Scheme Member may be required to provide updated financial information in respect of the product for the full financial year following the award of the price increase. The Department reserves the right to request that this information is independently audited by the company.
- 6.28. A Scheme Member may request that the Department's decision on a price increase request (other than a request falling within paragraph 6.26) is referred to the DRP within fourteen (14) calendar days of the Department's final decision.

Permanent Reductions to NHS List Prices

- 6.29. Scheme Members may permanently reduce an NHS list price. Scheme Members must inform the Department at least twenty one (21) calendar days before the changes take effect and provide information on the existing and new prices. Following a permanent reduction to an NHS list price, the NHS list price will not be permitted to be increased other than through the price increase process set out at paragraph 6.18 to 6.28.

Temporary Changes to NHS List Prices

- 6.30. Scheme Members may make temporary reductions to an NHS list price and increase the NHS list price to a level no more than the NHS list price before the reduction without the agreement of the Department. Scheme Members must inform the Department at least twenty one (21) calendar days before the changes take effect and provide information on the existing and new prices, and the expected duration of the reduction.
- 6.31. The Department may agree a temporary price increase to the permanent NHS list price under the price increase provisions of the Scheme as an alternative to a permanent increase. This is solely at the discretion of the Department. At the end of the temporary period of the award the price will revert to the permanent NHS list price.
- 6.32. Where temporary price reductions or temporary price increases in NHS list prices have been made, Scheme Members will continue to be required to pay the Scheme Payment at the rate applying to all Scheme Members as a

percentage of their Eligible Sales and in accordance with Chapter 5 and Annexes 3 to 5.

Updating Dictionary of Medicines and Devices

6.33. A Scheme Member must update the dictionary of medicines and devices (dm+d) pricing information (via the [in-demand portal](#)) within 24 hours of a change to their NHS list price becoming effective. If a Scheme Member does not have access to the in-demand system, you must notify the NHSBSA of the product launch via the following mailbox, including the brand name, agreed NHS list price, strength, pack size/s and effective date of launch, along with a copy of the Summary of Product Characteristics: pprs@nhsbsa.nhs.uk

Scheme Products Sold On

6.34. The requirements set out in this paragraph 6.34 refer to the treatment of Scheme Products transferring between a Scheme Member and another organisation (whether or not the recipient is a Scheme Member). Accordingly, when a Scheme Product covered by the 2024 Voluntary Scheme is transferred on:

- the Scheme Member transferring the Scheme Product must notify the Department of the Scheme Product and the name of the acquiring organisation within fourteen (14) calendar days of the transfer;
- the Scheme Member acquiring the Scheme Product must notify the Department of the Scheme Product and the name of the transferring organisation within fourteen (14) calendar days of the transfer; and
- where the transferring Scheme Member continues to manufacture or supply the Scheme Product, and whether or not the acquiring organisation is a Scheme Member, the Department may require that the transferring Scheme Member provide relevant information to support the justification of any NHS list price increase application by the acquiring organisation.

NHS List Price Increases for Branded P&GSL Medicines

6.35. Where the Department has not exercised its discretion to exclude sales under paragraph 2.41 and a Scheme Member wishes to increase the NHS list price

of a Branded P&GSL Medicine, the Scheme Member may utilise the approach in paragraphs 6.38 to 6.39 in place of the approach set out in paragraphs 6.18 to 6.28. Where a Scheme Member wishes to increase the NHS list price of a Branded P&GSL Medicine under this paragraph 6.35, it must give the Department not less than twenty eight (28) calendar days' notice of this request. This notice must state the amount of the proposed increase and the reasons for the proposed increase. On receipt of notice, the Department will promptly indicate whether the increase is approved. For the avoidance of doubt, where a medicine becomes a Scheme Product as a result of a transfer, an increase in the NHS list price must still follow the process outlined in paragraphs 6.36 to 6.39.

- 6.36. Any NHS list price increase to a Branded P&GSL Medicine must not be greater than 20% above the reference price for the relevant Branded P&GSL Medicine unless agreed separately with the Department.
- 6.37. The reference price for a relevant Branded P&GSL Medicine will be the NHS list price of that Branded P&GSL Medicine as at 31 December 2023. If there is no NHS list price as at 31 December 2023, the reference price will be, for any new Branded P&GSL Medicine, the NHS list price agreed in line with paragraph 6.2 and for a Line Extension, a notional reference price (i.e. the price that would have been in place as at 31 December 2023 were the Branded P&GSL Medicine on the market at that time) determined by the Department and based on the ratio of the agreed price of the Line Extension and the price(s) of the existing formulation(s) or pack size(s).
- 6.38. Where the Department approves an increase to the NHS list price made under paragraph 6.35 of a Branded P&GSL Medicine, the Scheme Member shall be required to pay to the Department a sum equal to the additional cost incurred by the NHS as a result of the increase. The Department shall calculate the additional cost as follows:

Additional cost	=	(increased NHS list price – reference price)	X	number of times the relevant Branded P&GSL Medicine is prescribed on a FP10 or EPS prescription and reimbursed in England	X	1.25
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- 6.39. The Department shall endeavour to notify the Scheme Member by the end of July each calendar year of the additional costs incurred in the previous calendar year in which there was an increase to the NHS list price of a Branded P&GSL Medicine. The Scheme Member will pay the additional costs

to the Department within sixty (60) calendar days of being notified of the amount by the Department. This payment will be separate to the any Scheme Payment made by that Scheme Member.

Review

6.40. The pricing provisions set out in this Chapter, including but not limited to those relating to the exceptional treatment of Older Medicines in paragraph 6.26, shall be considered at the scheme reviews (as detailed in paragraph 2.9) to monitor impact during the 2024 Voluntary Scheme.

Statutory Scheme

6.41. Where a Scheme Member has joined the 2024 Voluntary Scheme, having previously been subject to the Statutory Scheme, the NHS list price of the presentation is the maximum price as was determined under regulation 8 of the Statutory Scheme during the period that the Scheme Member was subject to the Statutory Scheme.

7. Additional Duties and Requirements

Introduction

7.1. Chapter 7 contains information on a number of additional duties and requirements relating to matters relevant to the 2024 Voluntary Scheme. The formal timescales for communications are defined. It places requirements on Scheme Members to notify the Department of changes to distribution arrangements under certain circumstances. An expectation is set that Scheme Members should not take any unreasonable action to delay or discourage generic entry to the market.

Communications

7.2. A notice given to a Party under or in connection with the 2024 Voluntary Scheme shall be in writing and sent to the relevant Party at the address notified in writing to the other Party.

7.3. The following table sets out methods by which a notice may be sent and its corresponding deemed delivery date and time.

Delivery method	Deemed delivery date and time
Delivery by hand	On signature of a delivery receipt or at the time the notice is left at the address
Pre-paid first class post or other next working day delivery services providing proof of postage	9am on the second working day after posting
Email	At the time of transmission but only if, following transmission, the sender does not receive a non-delivery message

7.4. This paragraph 7.4 shall not apply to the service of any proceedings or other documents in any legal action.

Distribution Margin

- 7.5. One of the objectives of the 2024 Voluntary Scheme is to encourage the efficient and competitive supply of medicines to the NHS. Scheme Members are expected to follow good commercial practice in the distribution of their products.
- 7.6. Any Scheme Member that intends to change its overall distribution arrangements during the duration of the 2024 Voluntary Scheme will notify the Department of such changes as early as possible, and at least four (4) months in advance of any such change being made operational. Scheme Members are not required to notify the Department of routine commercial transactions that would not be expected to have a cost to the NHS.
- 7.7. The Department will collect information on sales from Scheme Members annually and monitor any changes in the supply chain. Information is required from Scheme Members with Sales of Scheme Products to the NHS of £6 million or greater a calendar year in the form of the Annual Presentation Level Sales Report. This information should be submitted via the Department's portal, as set out in Annex 7 within three (3) months of the Calendar Year end. A Company Declaration (in the form set out at Annex 8) should accompany the data submitted.
- 7.8. If there are reasonable and objective grounds to believe that changes made to a Scheme Member's distribution arrangements during the duration of the 2024 Voluntary Scheme have, or would have, an adverse net impact on NHS expenditure in relation to the purchasing from that Scheme Member then the Department and the Scheme Member will discuss and agree any adjustments to those distribution arrangements and where the Scheme Member has influence on the pharmacy discount, this may include the Scheme Member separately paying a sum of money to the Department equal to any additional costs to the NHS.
- 7.9. Paragraph 7.8 does not affect the right of Scheme Members unilaterally to offer or withdraw competitive trade discounts at any time, nor to determine individually how to distribute their own products.

Patent Expiry and Generic Market Entry

- 7.10. As products near the end of their patent lives, Scheme Members will not engage in anti-competitive practices with the objective of delaying or discouraging biosimilar or generic entry to the market.

Medicines Sustainability

- 7.11. Many countries, including the UK, have committed to reaching net zero by introducing legislation and policies to move to a more sustainable future. In October 2020, the NHS England Board approved the NHS 2045 net zero target, and subsequently the NHS became the first health system to embed net zero into legislation through the Health and Care Act 2022.
- 7.12. Medicines account for around 25% of the NHS emissions in England, with 80% of these medicines' emissions embedded in manufacturing and supply chains¹. The life sciences industry is already innovating to reduce their carbon emissions, with growing number of pharmaceutical suppliers introducing their own greenhouse gas emission reduction targets, greener chemistry processes being introduced into medicine manufacturing, and commitments to develop lower carbon alternative medicines.
- 7.13. In 2021, NHS England approved the NHS Net Zero Supplier Roadmap to provide clarity to health system suppliers on the journey to net zero within the NHS from 2022 through to 2030. The Supplier Roadmap builds on UK government procurement policy (PPN 06/20 and PPN 06/21) and requirements include the inclusion of net zero and social value in all new procurements of NHS goods and services, including medicines; suppliers publishing carbon reduction plans and reporting on these commitments; and suppliers providing carbon foot printing of individual products supplied to the NHS.
- 7.14. The commitment to decarbonise has already been made by the pharmaceutical industry on a UK and global level. The government similarly has committed to leading and supporting the development of aligned international standards and their implementation across the UK. Through the 2024 Voluntary Scheme, the UK government, the NHS, and the pharmaceutical industry agree to collaborate to work towards delivering the NHS net zero goals by increasing transparency and consistency in environmental impact assessments and reducing the environmental impact of medicines.

¹ <https://www.england.nhs.uk/greenernhs/publication/delivering-a-net-zero-national-health-service/>

8. Dispute Resolution

Summary

8.1. Chapter 8 summarises the dispute resolution procedure that applies to all parts of the 2024 Voluntary Scheme except Chapter 3 (Access, Uptake and Outcomes), Chapter 5 (Supporting the Growth of the Life Sciences Industry), and any other elements of the 2024 Voluntary Scheme that expressly state that the dispute resolution process does not apply. It is agreed by all Scheme Members, the Department and the ABPI that early discussion should be used to address any potential Disputes without recourse to the formal procedure. This Chapter 8, in conjunction with Annex 15, goes on to describe the formal Dispute Resolution Procedure. The processes for referral, the procedures that will be followed by the dispute resolution process, and the arrangements for responding to any decision, including amendment of the 2024 Voluntary Scheme, withdrawal of membership of the 2024 Voluntary Scheme and enforcement are described.

Introduction

- 8.2. The Department and each Scheme Member undertake to operate the Scheme so that issues arising between the Scheme Member and the Department shall normally be resolved by discussion between the Scheme Member and the Department. Such discussions may be escalated at the option of the Scheme Member and the Department to a more senior level within that organisation as described in this Chapter 8. Nevertheless, significant issues between the Scheme Member and the Department may arise that cannot be resolved by discussion. These issues may be referred to the DRP by the Scheme Member or the Department as described in this Chapter 8.
- 8.3. For the purposes of this Chapter 8 and Annex 15, except as otherwise provided, the Department and each Scheme Member are each a Party and together the Parties.
- 8.4. The provisions of this Chapter 8 and Annex 15 shall not apply to any dispute, difference or question of interpretation arising out of or in connection with Chapter 3, Chapter 5 (Supporting the Growth of the Life Sciences Industry), and any other elements of the 2024 Voluntary Scheme that expressly state that the Dispute Resolution Procedure does not apply.

8.5. A diagrammatical representation of the process described in this Chapter 8 is set out at paragraph 8.12.

Early Discussion

8.6. The Parties shall attempt, in good faith, using all reasonable endeavours, to resolve any Dispute promptly by early discussion.

8.7. If the Parties are unable, or fail, to resolve the Dispute through discussion (using all reasonable endeavours), either Party may then serve a Dispute Notice on the other. Upon service of a Dispute Notice the Dispute shall be referred to:

- for the Department, Department Representative; or
- for the Scheme Member, such Director (or equivalent) as the Scheme Member shall notify the Department of,

8.8. for resolution. In attempting to resolve the Dispute, if possible, the Head of Branded Medicines Pricing Operations and the Director (or equivalent) must meet on at least one occasion. If the Dispute cannot be resolved by the Head of Branded Medicines Pricing Operations and the Director (or equivalent) within fourteen (14) calendar days after the Dispute Notice, either Party may refer the Dispute to the Scheme Member Representative and the Department Representative for resolution.

Referral to the DRP

8.9. If the Scheme Member Representative and the Department Representative are unable, or fail, to resolve the Dispute within fourteen (14) calendar days following the referral of the Dispute to them then:

- an event (Event) shall be deemed to have occurred; and
- within fourteen (14) calendar days of such Event, either Party may, by written notice to the other, then refer the Dispute to the DRP for resolution.

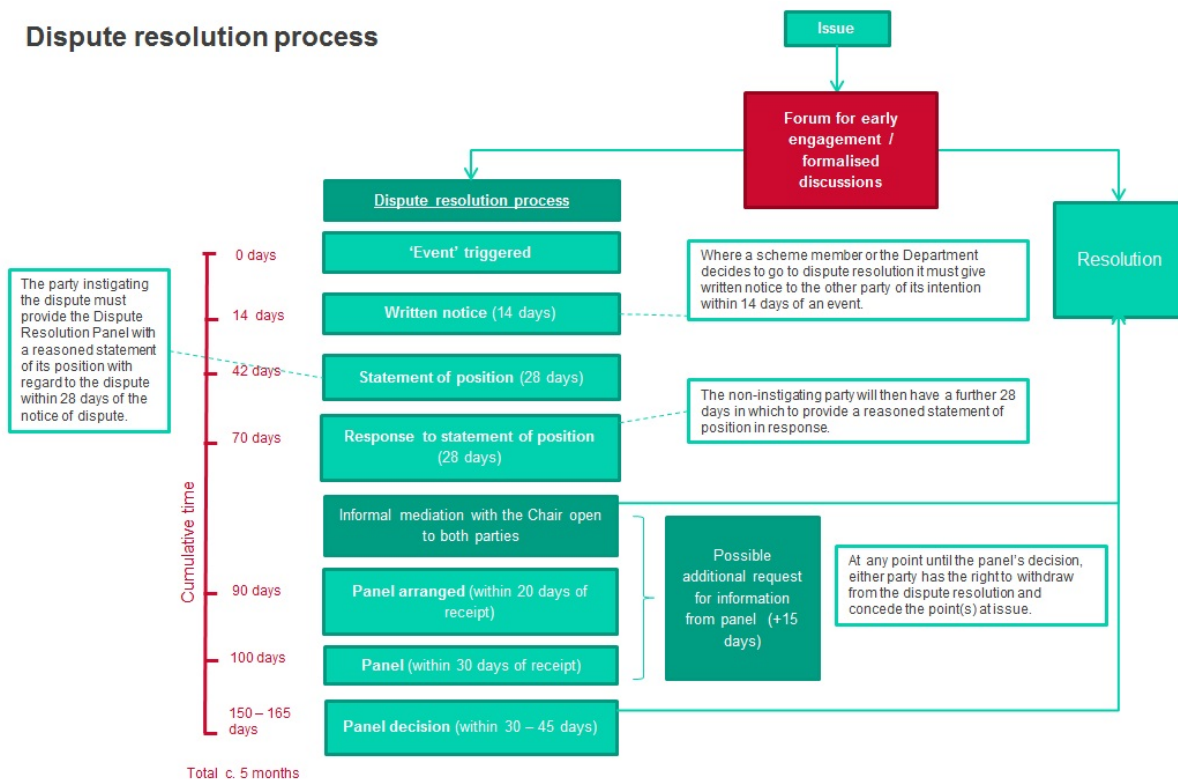
8.10. If neither Party refers the Dispute to the DRP within fourteen (14) calendar days of the Event, the Dispute Notice will automatically be deemed to have been withdrawn and neither Party may then refer the Dispute to the DRP.

8.11. Neither Party may refer the Dispute to the DRP until the procedure set out at paragraphs 8.6 and 8.9 has been followed and an Event has occurred.

Dispute Resolution Procedure

8.12. A summary of the Dispute Resolution Procedure is set out below. Annex 15 contains detailed provisions relating to the Dispute Resolution Procedure.

Dispute resolution process



ABPI Referral

8.13. Where:

- a Dispute arises which relates to a matter which, in the opinion of the ABPI, impacts on the interests of the ABPI's broader membership; or
- a dispute between the Department and the ABPI arises out of or in connection with the Scheme with the exception of Chapter 3, Chapter 5 (Supporting the Growth of the Life Sciences Industry), and any other elements of the 2024 Voluntary Scheme that expressly state that the Dispute Resolution Procedure does not apply.

8.14. (each being an ABPI Dispute) the Department and the ABPI shall attempt, in good faith, using all reasonable endeavours, to resolve the ABPI Dispute promptly by early discussion.

- 8.15. If the Department and the ABPI are unable, or fail, to resolve the ABPI Dispute within fourteen (14) calendar days either the Department or the ABPI may, by written notice to the other, then refer the ABPI Dispute to the DRP for resolution.
- 8.16. Where the ABPI Dispute is referred to the DRP for resolution in accordance with the timescales specified in paragraph 8.15:
- as modified by the sub-paragraphs below, the provisions in Annex 15 shall apply as between the ABPI and the Department;
 - a reference to the “Referring Party” shall be a reference to the “ABPI”; and
 - where a DRP Decision is made, the DRP Decision shall be final on all Scheme Members (regardless of whether the Scheme Member(s) did or did not have any part in the Dispute). There shall be no right of appeal against the DRP Decision.

Confidentiality

8.17. Except as otherwise provided:

- the Department;
- the ABPI;
- the Scheme Member; and
- the members of the DRP,

shall each treat any information provided to it (in the course of the Dispute Resolution Procedure) by another party which has clearly been designated by the party as being confidential to it, or which ought reasonably to be considered to be confidential, as confidential and not disclose such information to any other person without the owner’s prior written consent.

DRP Decision

8.18. In furtherance of the Dispute Resolution Procedure set out in Annex 15, each Party must comply with the DRP Decision (including without limit any effective dates).

- 8.19. Where, as part of the DRP Decision, the DRP has made a determination on a question of interpretation of the 2024 Voluntary Scheme, the ABPI and the Department shall amend the provisions of the 2024 Voluntary Scheme to reflect such determination and/or DRP Decision and to clarify the interpretation of the 2024 Voluntary Scheme. In which event all Scheme Members shall be deemed to have accepted the amendment and may not refer the same issue to the DRP.
- 8.20. The Secretary of State may use any of their powers (including without limit those under the NHS Act) to enforce and uphold the DRP Decision. The Parties acknowledge and agree that nothing in this Chapter 8 shall prevent the Secretary of State from using any of their powers (including without limit those under the NHS Act) in circumstances where a DRP Decision has not been made.
- 8.21. The DRP Decision shall not give rise to any action under the Arbitration Act 1996.
- 8.22. It is intended that the use of the Dispute Resolution Procedure shall not entail any forfeiture of any other judicial remedy available to either Party.

Withdrawal from the 2024 Voluntary Scheme

- 8.23. Where the Scheme Member serves notice under paragraph 2.29 to leave the 2024 Voluntary Scheme and an Event occurs before or on the date on which that Scheme Member ceases to be a member of the 2024 Voluntary Scheme the Parties agree that:
- the Dispute may be referred to the DRP for a DRP Decision in accordance with the timescales specified in paragraph 8.9; and
 - the Secretary of State may, at any time, use any of their powers (including without limit those under the NHS Act) in relation to the manufacturer or supplier.
- 8.24. Where the Scheme Member serves notice under paragraph 2.31 to leave the 2024 Voluntary Scheme and a Dispute arises after the date on which that Member ceases to be a member of the 2024 Voluntary Scheme, the Parties agree that:
- neither Party may refer the Dispute to the DRP; and

- the Secretary of State may, at any time, use any of their powers (including without limit those under the NHS Act) in relation to the manufacturer or supplier.

Enforcement

8.25. The Parties agree that the Secretary of State may exercise any of their powers under section 261(9) of the NHS Act in cases where:

- a DRP Decision has been made; or
- neither Party has referred the Dispute to the DRP for resolution in accordance with the timescales specified in paragraph 8.9 but monies remain unpaid by the manufacturer or supplier.

Continued Obligations

8.26. Notwithstanding the Scheme Member leaving the 2024 Voluntary Scheme under paragraph 2.33, the disapplication of the 2024 Voluntary Scheme in relation to the Scheme Member under paragraph 2.32 or expiry of the 2024 Voluntary Scheme, such manufacturer or supplier shall remain liable to pay any outstanding amounts that are due to the Department as a result of a DRP Decision and the Secretary of State may, at any time, use any of their powers (including without limit those under the NHS Act) in relation to such manufacturer or supplier.

Glossary

Unless otherwise expressly provided for herein, in the event of a conflict between the meanings of defined terms set out in the Chapters and/or Annexes to the 2024 Voluntary Scheme and the meanings of the defined terms set out in this Glossary, the meanings of the defined terms as set out in this Glossary shall take precedence.

2019 Voluntary Scheme	means the 2019 Voluntary Scheme for Branded Medicines Pricing and Access
2023 Industry Allowed Sales Baseline	means the 2023 allowed sales as calculated in the 2019 Voluntary Scheme, adjusted for changes to Small Company Sales introduced for the 2024 Voluntary Scheme
2023 Industry Measured Sales Baseline	means the 2023 measured sales as calculated in the 2019 Voluntary Scheme, adjusted for changes to Small Company Sales introduced for the 2024 Voluntary Scheme
2023 Measured Sales Of Older Medicines Baseline	means the 2023 measured sales by scheme members of the 2019 Voluntary Scheme and companies subject to the Statutory Scheme for those medicines that would be considered an Older Medicine in 2023 if the definition of an Older Medicine, as set out in the 2024 Voluntary Scheme, was applied to them. For any Branded Presentation that became an Older Medicine during 2023, the 2023 Measured Sales Of Older Medicines reflects the proportion of the full year measured sales of the Branded Presentation corresponding to the number of quarters where it was in effect and will not reflect quarterly sales data
2024 Voluntary Scheme	means the 2024 Voluntary scheme for branded medicines pricing, access and growth
ABPI	means the Association of the British Pharmaceutical Industry
ABPI Dispute	means either:

	<ul style="list-style-type: none"> • a Dispute which relates to a matter which, in the opinion of the ABPI, impacts on the interests of the ABPI's broader membership; or • a dispute between the Department and the ABPI out of or in connection with the 2024 Voluntary Scheme with the exception of Chapter 3 and any other elements of the 2024 Voluntary Scheme that expressly state that the DRP does not apply
Accounting Reference Period	shall have the meaning given to it under section 391 of the Companies Act 2006
Actual Medicinal Product or AMP	means a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form), attributable to an identified supplier that contains a specified amount of an ingredient substance. It describes an actual product which is known to have been available linked to the name of a particular supplier (as defined within dm+d)
Actual Medicinal Product Pack or AMPP	means the packaged product that is supplied for direct patient use or from which AMPs are supplied for direct patient use. The AMPP describes an actual product which is known to have been available linked to both the name of a particular supplier and information on the pack size of the product. It may contain multiple components each of which may or may not be an AMP in their own right.(as defined within dm+d)
Adjusted Assumed Payment From Older Medicines	means Assumed Payment From Older Medicines multiplied by the Assumed Payment From Older Medicines Adjustment Factor
Adjusted Sales Of Newer Medicines	is calculated by multiplying Measured Sales Of Newer Medicines and the Newer Medicines Adjustment Factor
Affordability Mechanisms Definitions	shall have the meaning given to it in paragraph 4.7

All Other Customers	means all Sales that are not Primary Care Sales or Homecare Sales and includes but is not limited to wholesaler sales to homecare providers
Allowed Growth Rates	shall have the meaning set out in Annex 4
Allowed Sales Gap	means, in respect of each calendar year, the difference between Industry Measured Sales and Industry Allowed Sales (where Industry Measured Sales is greater than or equal to Industry Allowed Sales). If Industry Measured Sales is less than Industry Allowed Sales, the Allowed Sales Gap will be zero.
Annual Historical Cash Payment Sales	shall have the meaning set out in paragraph 4.92
Annual Presentation Level Sales Report	means the annual presentation level sales report based on the template report set out in Annex 7 and referred to in Annex 8
Annual Sales Report	means an annual sales report based on the template report set out in Appendix 3 of Annex 6 and which may be an unaudited Annual Sales Report or an Audited Annual Sales Report as the context indicates
Assumed Eligible Sales Of Older Medicines	means the Assumed Measured Sales Of Older Medicines adjusted down by the Fixed Older Medicines Adjustment Factor as set out in Annex 4
Assumed Measured Sales Of Older Medicines	means the 2023 Measured Sales Of Older Medicines Baseline grown each year by the Fixed Forecast Growth Rate for Measured Sales Of Older Medicines
Assumed Payment From Older Medicines	means the payment implied by applying the Fixed Distribution of Older Medicines Eligible Sales Across Basic + Top-up Payment Percentages to the Assumed Eligible Sales Of Older Medicines
Assumed Payment From Older Medicines Adjustment Factor	means a fixed proportional reduction to the initially calculated Assumed Payment from Older Medicines to reflect uncertainty and optimism bias

Audited	means audited in accordance with applicable auditing standards to provide a reasonable assurance (as provided for in the applicable auditing standards) that the relevant information has not been materially misstated, and "applicable auditing standards" in this definition means any relevant International Standard on Auditing and related Statements or Standards produced by the Financial Reporting Council Limited
Audited Annual Sales Report	means the report referred to in paragraph 4.41
Auditor	means a qualified independent auditor (as defined in the Statutory Scheme) appointed by a Scheme Member
Audit Report	means the report set out in Annex 6 Appendix 4
Baseline Adjustment	means the adjustment set out in Annex 4
Basic Payment Percentage	means 10%
Biological Medicinal Products	means a product, the active substance of which is a biological substance where a biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control as is defined in Regulation 8(1) of the Human Medicines Regulations 2012
BIT or Budget Impact Test	shall have the meaning given to it in the NHS Commercial Framework for New Medicines
Branded Health Service Medicine	means a Relevant Medicine, a Branded P&GSL Medicine both covered by the 2024 Voluntary Scheme (as defined at paragraphs 2.37 to 2.41), or a Parallel Import Medicine

Branded P&GSL Medicine(s)	means all relevant medicine (as defined in the Statutory Scheme) except that the reference in the definition in the Statutory Scheme to "prescription only medicines" is replaced with "Pharmacy or General Sale List Medicines" which is defined in this Glossary
Branded Presentation	means the AMPP of a Branded Health Service Medicine which may be distinguished from other forms of the medicine by reference to its active ingredients, strength and excipients, pack size, method of administration or formulation. For the avoidance of doubt, this includes all Branded Health Services Medicines as set out in paragraph 2.37, including all Biological Medicinal Products, regardless of whether it has a brand name
Calculated Payment From Newer Medicines	means the Calculated Total Payment minus the Adjusted Assumed Payment From Older Medicines
Calculated Total Payment	means in respect of each calendar year, Allowed Sales Gap multiplied by the sum of forecast Measured Sales Of Newer Medicines and Assumed Measured Sales Of Older Medicines, as a share of Industry Measured Sales
Central Government Body	means a Government Department, Non-ministerial Department or Executive Agency (but, for the avoidance of doubt, excludes a Non-Departmental Public Body such as, without limit, NHS England) as defined in the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics
Centrally Procured Vaccines	<p>means a vaccine procured by a Central Government Body in accordance with a recommendation made or advice given by the Joint Committee on Vaccination and Immunisation</p> <ul style="list-style-type: none"> • for a national vaccination programme, or • for a branded medicine to be included in a national vaccination programme; and <p>either—</p>

	<ul style="list-style-type: none"> ○ UKHSA manages the distribution of the vaccine as part of a national vaccination programme, or ○ the Department gives notice to the manufacturer or supplier to the effect that above paragraph need not be satisfied.
Chair	shall have the meaning given to it in paragraph 7 of Annex 15
Closest In Date List Price	means the available list price as published in the dictionary of medicines and devices (dm+d) that is the closest in date to the 1 January of the relevant calendar year, as set out in Annex 4.
Combination Product	means a Scheme Product with: <ul style="list-style-type: none"> • multiple active ingredients and registered as a unique VTM, which is different from the VTM of any of the individual active ingredients, in dm+d (UVTM); or, • multiple active ingredients and isn't registered as a UVTM but would be registered as a UVTM if the dm+d allowed registration for medicines with more than four active ingredients.
Commercial Relationship	means a contractual or commercial relationship with regards to the manufacturing or distribution of Branded Health Service Medicine, including but not limited to licensing
Department	means the Secretary of State for Health and Social Care acting through the Department of Health and Social Care
Department Representative	means the Deputy Director of Medicines Pricing (or equivalent)

Dispensing Contractor	means an NHS chemist, a LPS chemist or a dispensing doctor (as defined in Regulation 2 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013)
Dispute	means any dispute between the Department and the Scheme Member directly arising out of the 2024 Voluntary Scheme but not including disputes, differences, or questions of interpretation which are expressly excluded in paragraph 8.4
Dispute Notice	means when, in the opinion of either Party, a Dispute arises, the Party in question may give written notice to the other that a Dispute has arisen
Dispute Resolution Procedure	means the dispute resolution procedure set out in paragraph 8.12 and Annex 15
dm+d	means the Dictionary of Medicines and Devices
DRP	means the dispute resolution panel which is explained in more detail in paragraph 7 of Annex 15
DRP Decision	shall have the meaning given to it in paragraph 7 of Annex 15
Effective Date	shall have the meaning given to it in paragraph 54 of Annex 14
Eligible Sales	means Sales of Scheme Products by Scheme Members but excluding Exemptions From Eligible Sales
Eligible Sales Of Newer Medicines	means Sales of Scheme Products, which meet the criteria of Newer Medicines excluding Exemptions From Eligible Sales
Event	shall have the meaning given to it in paragraph 8.9
Exceptional Central Procurements	means a procurement by a Central Government Body for the purpose of emergency preparedness or stockpiling for national security or pandemic preparedness; and

	<p>either</p> <ul style="list-style-type: none"> • UKHSA manages the stockpiling and distribution, or • the Department gives notice to the manufacturer or supplier to the effect that the paragraph above need not be satisfied.
<p>Exemptions From Eligible Sales</p>	<p>means:</p> <ul style="list-style-type: none"> • Sales of Scheme Products by a Scheme Member relating to Exceptional Central Procurements; • Sales of Scheme Products by a Scheme Member relating to Centrally Procured Vaccines; • NAS Sales; • Small Company Sales; • Medium Sized Company Sales; and • Low Value Sales
<p>Exemptions From Measured Sales</p>	<p>means:</p> <ul style="list-style-type: none"> • Sales of Scheme Products by a Scheme Member relating to Exceptional Central Procurements; • Sales of Scheme Products by a Scheme Member relating to Centrally Procured Vaccines; • Small Company Sales; and • Low Value Sales

Exemptions from Top-up Payment Percentage	<ul style="list-style-type: none"> • means: Sales of Plasma Derived Medicinal Products • Sales of Older Medicine where, for an individual Scheme Member, the total Measured Sales of Scheme Products across a VTM is less than £1.5m
Financial Year	means, in relation to a Scheme Member, the financial year of that Scheme Member as determined in accordance with section 390 of the Companies Act 2006
First Supplier	is as defined in paragraph 2.15
First UK Recipient	is as defined in paragraph 2.15
Fixed Distribution of Older Medicines Eligible Sales across Basic and Top-up Payment Percentages	means the distribution of Older Medicines Eligible Sales across the Basic Payment Percentage and the Top-up Payment Percentages used to calculate the Assumed Payment from Older Medicines as set out in Annex 4
Fixed Forecast Growth Rate for Measured Sales Of Older Medicines	means the fixed forecast rate applied to the 2023 Measured Sales of Older Medicines Baseline as set out in Annex 4 to derive Assumed Measured Sales Of Older Medicines
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 set out in Annex 4
FOIA	means the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002, as applicable
Governments	means the UK government, and the governments of Scotland, Wales and Northern Ireland
Group	has the meaning given to it under section 474(1) of the Companies Act 2006

Headline Payment Percentage	sum of the Unadjusted Headline Payment Percentage and the Under Payments or Over Payments Adjustment
health service in England	means the health service continued under section 1(1) of the NHS Act
Health Service Medicine	has the meaning given to it under section 266(6) of the NHS Act
Hearing	shall have the meaning given to it in paragraph 7 of Annex 15
Homecare Sales	means Sales of Presentations that are sold directly to homecare providers
Industry Allowed Sales	is calculated from the 2023 Allowed Sales Baseline and adjusted at the start of each year of the 2024 Voluntary Scheme by a Baseline Adjustment and subsequently be grown by an Allowed Growth Rate percentage
Industry Measured Sales	is the sum of Measured Sales Of Newer Medicines, Assumed Measured Sales Of Older Medicines and Parallel Import Sales
Launch	means to place for sale to the NHS on the UK market
Latest Active Ingredient	means the active ingredient that has the most recent MA Date
Latest Non-SPC Active Ingredient	means the active ingredient within a Scheme Product that has the most recent MA Date for which: <ul style="list-style-type: none"> • no SPC has been granted for the active ingredient; or • the only SPC or SPCs that have been granted for the active ingredient have been invalidated at any point (whether before or after coming into force)
Lead Company	shall have the meaning given to it in paragraph 2.26

Licensing Authority	means the Medicines and Healthcare products Regulatory Agency or the European Medicines Agency (or any statutory successor) as the case may be
Line Extension	means a new Presentation of a known active substance marketed under the same brand name by the same manufacturer as an existing Presentation
List Price	means the list price as published in the dictionary of medicines and devices (dm+d)
Low Value Sales	means Sales of any Scheme Products by a Scheme Member where the NHS list price of such Scheme Product is less than £2
MA Date	means the date of the Marketing Authorisation of the first licensed Branded Presentation
MA Holder	means the Marketing Authorisation holder
Marketing Allowance	shall have the meaning given to it in Annex 14
Marketing Authorisation	<p>means:</p> <ul style="list-style-type: none"> • a UK marketing authorisation (which means a marketing authorisation granted by the licensing authority under Part 5 of the Human Medicines Regulations 2012 or Chapter 4 of Title III to the DIRECTIVE 2001/83/EC (mutual recognition and decentralised procedure) and is an authorisation in force in: <ul style="list-style-type: none"> ○ the whole United Kingdom; ○ Great Britain only; ○ Northern Ireland only); • an EU marketing authorisation (which means a marketing authorisation granted or renewed by the European Commission under Regulation (EC) No 726/2004); or

	<ul style="list-style-type: none"> • a Parallel Import Licence
Measured Sales	means Sales of Scheme Products by Scheme Members, Statutory Scheme Sales and Parallel Import Sales, but excluding Exemptions from Measured Sales
Measured Sales Of Newer Medicines	means the sum of Voluntary Scheme Measured Sales Of Newer Medicines and Statutory Scheme Measured Sales Of Newer Medicines
Medium Sized Company	means a Scheme Member whose total Sales of Scheme Products (including NAS Sales) are £6m or more but less than £30m in the calendar year preceding the relevant calendar year
Medium Sized Company Sales	means the first £6m of Sales (excluding NAS Sales) of Scheme Products by a Medium Sized Company
Month (or month)	means a calendar month except where otherwise stated
NAS Sales	<p>means Sales of any New Active Substance by a Scheme Member where such Sales occur within the period of thirty six (36) months from the date of the Marketing Authorisation granted for the first indication in respect of the New Active Substance (if that Marketing Authorisation was granted on or after 1st January 2021). Sales of Line Extensions of New Active Substances will qualify as NAS Sales if they occur within a period of thirty six (36) months from the date of the Marketing Authorisation granted for the first indication in respect of the New Active Substance (if that Marketing Authorisation was granted on or after 1st January 2021). Sales of Line Extensions of New Active Substances will not qualify as NAS Sales if they occur after the period of thirty six (36) months from the date of the Marketing Authorisation granted for the first indication of the New Active Substance.</p> <p>For the purposes of the 2024 Voluntary Scheme:</p> <ul style="list-style-type: none"> • where a manufacturer or supplier Launches the same active substance but under a

	<p>different brand name (for example, a new combination product), Sales of such new medicinal product (having the meaning set out at section 266 of the NHS Act) or any of its related line extensions will not be deemed to be NAS Sales unless the new medicinal product is a New Active Substance; and</p> <ul style="list-style-type: none"> the thirty six (36) month period referred to above will be deemed to expire on the last day of the thirty sixth month immediately following the date that the Marketing Authorisation is granted for the first indication of that New Active Substance (where the Marketing Authorisation was granted on or after 1st January 2021) <p>If the relevant Marketing Authorisation granted for the first indication was granted by the European Medicines Agency with effect in Northern Ireland but not in Great Britain then – should the New Active Substance subsequently be granted a Marketing Authorisation by the MHRA the thirty six (36) month period referred to above will reset from the date of the first MHRA Marketing Authorisation.</p>
New Active Substance	<p>means any presentation which satisfies the requirements of paragraph (10) of Regulation 9 of the Statutory Scheme, namely:</p> <ul style="list-style-type: none"> the European Public Assessment Report published by the European Medicines Agency in relation to the presentation in accordance with Article 13.3 of the Regulation (EC) 726/2004 of the European Parliament and of the Council of 31st March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency confirms that the presentation contains a new active substance; or

	<ul style="list-style-type: none"> the Assessment Report published by the licensing authority in relation to the presentation in accordance with Article 21 or regulation 64(6) of the 2012 Regulations of the Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use M36 confirms that the presentation contains a new active substance
New Entrants Products	means, Branded Presentations which are not Originator Products
New Manufacturer or Supplier	means a manufacturer or supplier that is within its first Accounting Reference Period
Newer Medicines	means Scheme Products that meet the requirements of paragraphs 4.8 to 4.12 to be a Newer Medicine
Newer Medicines Adjustment Factor	is calculated as Eligible Sales Of Newer Medicines divided by Voluntary Scheme Measured Sales Of Newer Medicines
NHS	<p>means the health services:</p> <ul style="list-style-type: none"> continued under section 1(1) of the NHS Act; provided by virtue of Health and Social Care (Reform) Act (Northern Ireland) 2009; within the meaning of the National Health Service (Scotland) Act 1978; and continued under section 1(1) of the National Health Service (Wales) Act 2006
NHS Act	means the National Health Service Act 2006
NICE	means the National Institute for Health and Care Excellence or any successor body

Non Referring Party	shall have the meaning given to it in paragraph 7 of Annex 15
Non Referring Party Documents	shall have the meaning given to it in paragraph 7 of Annex 15
Non-SPC Scheme Product	means a Scheme Product to which any of the below applies: <ul style="list-style-type: none"> • no SPC has been granted for the active ingredient of the Scheme Product; or • the only SPC or SPCs to have been granted for the active ingredient of the Scheme Product have been invalidated at any point (whether before or after coming into force)
Observed Average Selling Price	means the average selling price for the relevant Branded Presentation calculated as total net sales divided by total quantities across the relevant calendar year (or relevant part year) based on 2014, 2019 or 2024 voluntary scheme presentation level sales returns or Statutory Scheme presentation level sales returns
Observed Price Decline	where the Observed Average Selling Price is less than the Reference Price
Older Medicine	means a Scheme Product that is not a Newer Medicine
Older Originator Products At Or After 2015	means Branded Presentations which are Originator Products and met or would have met the definition of an Older Medicine on 1 January 2015 or later
Originator	means a company (or their successor, where relevant, or where ownership of the relevant Branded Health Service Medicine has been transferred to another company or corporate group): and <ul style="list-style-type: none"> • which received the first Marketing Authorisation for the relevant Branded Health Service Medicine containing a specific active ingredient or, for a Combination Product, the first Marketing Authorisation for the relevant

	<p>Branded Health Service Medicine with that combination of active ingredients; or</p> <ul style="list-style-type: none"> • which holds or held a valid SPC for a Branded Health Service Medicine
Originator Licensee	<p>means a company (or their successor, where relevant, or where ownership of the Branded Presentation has been transferred to another company or corporate group) which:</p> <ul style="list-style-type: none"> • is the company responsible for marketing of a Branded Health Service Medicine licensed by an Originator to the Originator Product prior to it becoming an Older Medicine; or • is the company responsible for marketing of a Branded Health Service Medicine and is in the same Group as the Originator for that Branded Health Service Medicine prior to the Originator Product becoming an Older Medicine
Originator Products	<p>means any Branded Health Service Medicine within a VTM by the Originator or Originator Licensee for that VTM</p>
Other Company or Other Companies	<p>shall have the meaning given to it in paragraph 2.25</p>
Parallel Import Licence	<p>means a licence that is granted by the licensing authority under this Part authorising the holder to place on the market a medicinal product imported in to the United Kingdom from an EEA State where that product—</p> <ul style="list-style-type: none"> • has been granted an EU marketing authorisation or a marketing authorisation in an EEA State under the 2001 Directive; and • is essentially similar to a product that has been granted a UK marketing authorisation

Parallel Import Medicine	<p>means a Health Service Medicine which is:</p> <ul style="list-style-type: none"> • a parallel distributed presentation (as defined in the Statutory Scheme); or • a branded medicine with a Parallel Import Licence (where “branded medicine” means branded medicine as defined in the Statutory Scheme)
Parallel Import Sales	<p>means Sales of Presentations in respect of which a Parallel Import Licence has been granted and Sales of any parallel distributed presentation (as defined in the Statutory Scheme)</p>
Party or Parties	<p>means the Department, NHS England, the ABPI and Scheme Members</p>
Payment Percentages	<p>means the percentages applied in accordance with the affordability mechanisms set out in the 2024 Voluntary Scheme to determine Scheme Payments</p>
Pharmacy or General Sale List Medicine	<p>means a pharmacy medicine or a medicinal product subject to general sale, both as defined in the Human Medicines Regulations 2012</p>
Plasma Derived Medicinal Products or PDMP	<p>The following Virtual Therapeutic Moieties:</p> <ul style="list-style-type: none"> • High Purity Factor IX • Factor X • Factor XIII • Factor VIII + von Willebrand factor • von Willebrand factor • Fibrinogen • Protein C human

	<ul style="list-style-type: none"> • C1-esterase inhibitor • Normal immunoglobulin human • Anti-D immunoglobulin • Albumin human • Human alpha1-proteinase inhibitor • Human prothrombin complex concentrate
PPN	means Procurement Policy Note(s) as detailed at https://www.gov.uk/government/collections/procurement-policy-notes
Pre-2015 Older Originator Products	means, Branded Presentations which are Originator Products and met or would have met the definition of an Older Medicine before 1 January 2015
Price Increase Financial Return or PIFR	means a return that contains the information listed in Annex 14
Primary Care Sales	means Sales of Presentations which are dispensed by a Dispensing Contractor
QALY	means quality-adjusted life year
Quarter (quarter)	means each period of three calendar months ending on 31 March, 30 June, 30 September and 31 December
Quarterly Sales Report	means the report set out in Annex 6 Appendix 1
Reasonable Assurance	means an opinion that the relevant information has been Audited in accordance with the definition of that term in this 2024 Voluntary Scheme
Reference Price	means for each Branded Presentation a price in accordance with Annex 4
Reference Anchor Date	means 1 January the calendar year prior to an Originator Product meeting the definition of an Older Medicine, or

	for New Entrant Products, 1 January the calendar year prior to an Originator Product of the same VTM meeting the definition of an Older Medicine
Referring Party	shall have the meaning given to it in paragraph 7 of Annex 15
Relevant Medicine	<p>shall have the meaning in the Statutory Scheme, namely, means a health service medicine</p> <ul style="list-style-type: none"> • which is a branded medicine; • which is a medicine in respect of which a marketing authorisation has been granted; • which is a prescription only medicine; and • which is not— <ul style="list-style-type: none"> ○ in relation to England, listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, ○ in relation to Scotland, specified in any directions given by the Scottish Ministers under section 17N(6) (other mandatory contract terms) of the 1978 Act as being drugs, medicines or other substances which may not be ordered by a contractor made under section 17J for patients in the provision of primary medical services under a general medical services contract made under section 17J (health boards power to enter into general medical services contracts) of the 1978 Act in relation to Scotland, ○ in relation to Northern Ireland, listed in Schedule 1 to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc.) Regulations (Northern Ireland) 2004, or

	<ul style="list-style-type: none"> ○ in relation to Wales, listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004
Referring Party Documents	shall have the meaning given to it in paragraph 7 of Annex 15
Relevant VTM	means the same VTM associated with any active ingredient or combination of active ingredients of the Branded Presentation
Return	shall have the meaning given to it in paragraph 12 of Annex 14
Return on Sales or ROS	shall have the meaning given to it in paragraph 6.21
Sales	means income from sales of Branded Presentations made on or after 1st January 2024, excluding value added taxes, but after deduction of all trade and other discounts (howsoever named), including settlement discounts and rebates but before deduction of any payments made under the 2024 Voluntary Scheme
Sales Reports	means Quarterly Sales Reports, Annual Sales Reports and Annual Presentation Level Sales Reports as required under Chapter 4 and Annex 6
Secretary of State	means the Secretary of State for Health and Social Care
Scheme Member	means a manufacturer or supplier of Branded Health Service Medicines who has consented in the manner required by the Department to be a member of the 2024 Voluntary Scheme
Scheme Member Representative	means the Scheme Member's UK General Manager or equivalent
Scheme Payment	means a payment due from a Scheme Member and which is calculated as set out in the 2024 Voluntary Scheme

Scheme Products	means all relevant medicines (as defined in the Statutory Scheme) – whether or not sold by a Scheme Member or a manufacturer or supplier subject to the Statutory Scheme, but excluding any parallel distributed presentation as defined in the Statutory Scheme – and Branded P&GSL Medicines both covered by the 2024 Voluntary Scheme
Share of Voluntary Scheme Measured Sales Of Newer Medicines exempt from Eligible Sales	means the proportion of Voluntary Scheme Measured Sales Of Newer Medicines that are exempt from Eligible Sales
Small Company	means a Scheme Member whose total Sales of Scheme Products are less than £6m in the calendar year preceding the relevant calendar year
Small Company Sales	means Sales of Scheme Products by a Small Company
SPC or Supplementary Protection Certificate	means, in relation to a Scheme Product, a supplementary protection certificate with effect across the whole of the UK or GB for the active ingredient(s) of that Scheme Product including, where applicable, any paediatric extension to that supplementary protection certificate
SPC Combination Product	means a Scheme Product for which a SPC has been granted for that Combination Product
Statutory Scheme	means the statutory scheme for branded health service medicines established under The Branded Health Service Medicines (Costs) Regulations 2018 as amended by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2023
Statutory Scheme Measured Sales Of Newer Medicines	means measured sales in the Statutory Scheme as defined in the Statutory Scheme for sales where medicines meet the definition of Newer Medicines set out in the 2024 Voluntary Scheme if that definition was applied to them

Statutory Scheme Sales	means net sales income in respect of which payments are due (or forecast to be due) under Regulation 3 of the Statutory Scheme plus the net sales income received (or forecast to be received) by manufacturers or suppliers in respect of the total supply of presentations excluded from the calculation of net sales income, as reported to the Department in accordance with Regulation 21 of the Statutory Scheme
Summary of Product Characteristics	means the summary of product characteristics approved by the Licensing Authority for the Marketing Authorisation
Top-Up Payment Percentage	means the payment percentage set out in paragraph 4.18
Unadjusted Headline Payment Percentage	means the Calculated Payment From Newer Medicines divided by the Adjusted Sales Of Newer Medicines
Under Payments or Over Payments	means the calculation of any cumulative under or over payments in respect of preceding calendar years resulting from the difference between initial forecast and actual values for Newer Medicines as set out in Annex 4
Under Payments or Over Payments Adjustment	means any Under Payments or Over Payments divided by Eligible Sales Of Newer Medicines
UVTM	means a unique VTM, which is different from the VTM of any of the individual active ingredients, in the dm+d
Virtual Therapeutic Moiety or VTM	means the abstract representation of the substance(s), formulated as a medicinal product, intended by an authorising health care professional for use in the treatment of the patient as set out in the dm+d
Virtual Medicinal Product Pack or VMPP	means the abstract concept representing one or more quantitatively equivalent actual medicinal product packs (AMPP)

Voluntary Scheme Calculated Payment From Newer Medicines	is the Headline Payment Percentage multiplied by Eligible Sales Of Newer Medicines
Voluntary Scheme Measured Sales	means Measured Sales made by Scheme Members
Voluntary Scheme Measured Sales Of Newer Medicines	means Sales of Scheme Products by Scheme Members where those medicines meet the definition of Newer Medicines, subject to the Exemptions From Measured Sales
VPAG Investment Programme	the programme detailed in Chapter 5, also referred to as "the Programme"
VPAG Operational Review Group	means the group first referred to as such in paragraph 5.6

Except as expressly stated herein, any reference to any statute or statutory provision includes a reference to that statute or statutory provision as from time to time updated, amended, extended, supplemented, re-enacted or replaced. "Amended" includes any update, supplement, extension, re-enactment or replacement and "amendment" shall be construed accordingly.

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