



Department
of Health &
Social Care



The 2019 Voluntary Scheme for Branded Medicines Pricing and Access - Chapters and Glossary

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1. Purpose and Objectives

Summary

- 1.1 The Department of Health and Social Care (representing the UK Government, and the governments of Scotland, Wales and Northern Ireland), NHS England and the Association of the British Pharmaceutical Industry recognise the importance of collaboration between the public and private sectors in delivering improved health gains from medicines in the national health service across the United Kingdom (NHS), and in supporting the pharmaceutical industry in the United Kingdom so that it can continue to innovate now and in the future.

Introduction

- 1.2 This 2019 voluntary scheme for branded medicines pricing and access (Voluntary Scheme) will come into force on 1 January 2019, following expiry of the Pharmaceutical Price Regulation Scheme 2014 (2014 PPRS). The parties to the Voluntary Scheme are:
- the Department of Health and Social Care (Department), acting on behalf of the UK Government and the governments of Scotland, Wales and Northern Ireland;
 - NHS England, legally referred to as the National Health Service Commissioning Board (NHS England);
 - the Association of the British Pharmaceutical Industry (ABPI); and
 - manufacturers or suppliers of Branded Health Service Medicines that have joined the Voluntary Scheme (Scheme Members).
- 1.3 The pricing of medicines in Wales and Scotland is a matter reserved to the UK Government and devolved to Northern Ireland. The governments of Scotland and Wales support the Voluntary Scheme. The former Northern Ireland Executive was supportive of the 2014 PPRS and it is considered by the Northern Ireland Departments in the absence of a functioning Executive that there is a public interest in that support being continued, in line with the provisions of the Northern Ireland (Executive Formation and Exercise of Functions) Act 2018.
- 1.4 The National Institute for Health and Care Excellence (NICE) also supports the 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 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 of the Voluntary Scheme

- 1.6 The Voluntary Scheme has two parts:
- first, it sets out a range of measures for England, unless otherwise stated, to support innovation and better patient outcomes through improved access to the most transformative and cost effective medicines; and
 - second, it sets out a UK wide affordability mechanism under which Scheme Members make a financial contribution to the Department for sales of Branded Health Service Medicines above the agreed allowable growth rate.
- 1.7 These two parts taken together are intended to promote innovation and access to cost effective medicines, commensurate to their value to patients and the NHS, while also supporting sustainability of NHS finances. Patient health is at the heart of the ambitions and approach set out in the Voluntary Scheme, including the proposals for earlier commercial engagement and uptake support for high value products, faster NICE appraisals, and the commitment from all Parties (the Department, NHS England, ABPI and Scheme Members) to engender improvements over time to health gain relative to expenditure on new medicines across the NHS.

Objectives of the Voluntary Scheme

- 1.8 The overarching objectives of the Voluntary Scheme relate to patients, affordability, the economy and innovation.
- 1.9 In relation to patients, the objectives are to:
- simplify, streamline and improve access, pricing and uptake arrangements for cost effective medicines; and
 - deliver faster adoption of the most clinically and cost effective medicines with the aim of improving patient outcomes.

- 1.10 In relation to affordability, the objectives are to ensure that the Voluntary Scheme contributes to maintaining affordability of overall UK Branded Health Service Medicines' spend and to provide predictability for all Parties:
- to enable certainty of planning and to help the NHS and industry develop sustainable financial and investment strategies; and
 - to deliver value for money for the NHS by securing the provision of safe and effective medicines at reasonable prices and encourage the efficient development and competitive supply of medicines.
- 1.11 In relation to the economy and innovation, the objectives are to:
- deliver a net benefit to the UK economy overall; and
 - support the life sciences industry across the UK and future innovation.
- 1.12 All Parties agree that the performance of the 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 Governments.
- 1.13 All Parties will use their best endeavours to ensure that the Voluntary Scheme is fully implemented and sustained throughout the NHS during its duration. All Parties will operate the 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 Voluntary Scheme in a way which conflicts with the purpose and objectives set out at paragraphs 1.6 to 1.11 or in a way which makes the Voluntary Scheme ineffective as set out at paragraph 2.35. The mutual intent is that no Party will seek to abuse the Voluntary Scheme.
- 1.14 The Department, NHS England and the ABPI agree to raise any issues relating to the management and operation of the Voluntary Scheme over its duration during regular review meetings which are set out in more detail at paragraph 2.9.
- 1.15 The Department will use its best endeavours to ensure the confidentiality of any commercially sensitive information submitted by Scheme Members under the 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).
- 1.16 The ABPI acknowledges that the Governments 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 Government or NHS England 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 Government or NHS England, but reasonable efforts to ascertain the view of any affected Scheme Member will be made in advance of any disclosures wherever possible.

Use of Defined Terms

- 1.17 This document incorporates defined terms identified by initial capital letters. 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 Voluntary Scheme.

Summaries

- 1.18 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 Voluntary Scheme.

2. Status and membership

Summary

- 2.1 Chapter 2 summarises the legal basis of the Voluntary Scheme, its commencement, duration, and arrangements for review and amendment. The arrangements for joining and leaving the Voluntary Scheme are set out, together with the circumstances under which membership may be withdrawn. The products within the scope of the 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 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 Voluntary Scheme, or having joined the Voluntary Scheme subsequently leaves the Voluntary Scheme or is subject to a notice by the Department determining that the 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.

Commencement Date and Duration

- 2.5 The Voluntary Scheme will continue to operate for five years starting from 1 January 2019 and ending on 31 December 2023. Any adjustments for Under Payments or Over Payments made under the Voluntary Scheme may have to be paid up to 2025.
- 2.6 The Voluntary Scheme succeeds the 2014 PPRS. Paragraph 25 of Annex 15 applies to any unresolved disputes that arose in relation to the 2014 PPRS.

Amendment of the Voluntary Scheme

- 2.7 Subject to Chapter 7, the provisions of the Voluntary Scheme may only be amended by the mutual written agreement of the ABPI and the Department.
- 2.8 If the ABPI and the Department agree to amend the terms of the Voluntary Scheme in accordance with paragraph 2.7, 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 Voluntary Scheme as set out in paragraph 2.32.

Operational Reviews

- 2.9 Every six (6) months from 1 January 2019 operational review meetings will take place between the Department, NHS England and the ABPI to review the operation of the Voluntary Scheme. The first operational review in 2019 will agree success factors for the Voluntary Scheme which will be reviewed annually thereafter. The Department may involve the governments of Scotland, Wales and Northern Ireland in the operational review meetings (as appropriate). There is no expectation that any such operational reviews will result in amendment of the 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.
- 2.10 The discontinuation of the brand equalisation provisions in the 2014 PPRS from the Voluntary Scheme will be reviewed during the first half of the Voluntary Scheme to assess the impact on market dynamics and consider the verifiable information that would need to be available for any form of brand equalisation exemption to be introduced if the ABPI and the Department agreed to do so.

Application to Manufacturers and Suppliers

- 2.11 The Voluntary Scheme is open to manufacturers and suppliers of Branded Health Service Medicines who have applied to join the Voluntary Scheme as set out from paragraph 2.17.
- 2.12 The Voluntary Scheme will apply to a Scheme Member unless the Scheme Member leaves the Voluntary Scheme or the Department has determined that the Voluntary Scheme does not apply to that Scheme Member. The actual date the Voluntary Scheme ceases to apply in these situations is as set out in paragraphs 2.32 and 2.35.

- 2.13 Where the Marketing Authorisation holder (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.
- 2.14 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.
- 2.15 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, 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 presentation is supplied by the 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.
- 2.16 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 Voluntary Scheme

- 2.17 A manufacturer or supplier of a Branded Health Service Medicine wishing to join the Voluntary Scheme with effect from 1 January 2019 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 (refer to paragraphs 6.2 and 6.3 for detail as to deemed delivery dates) is no later than 31 December 2018. 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.

- 2.18 A manufacturer or supplier to which the 2014 PPRS applied will not be automatically included in the 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 31 December 2018, membership will be effective from the start of the Voluntary Scheme (1 January 2019).
- 2.19 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 2.26, the manufacturer or supplier commits that they will fulfil any outstanding obligations arising during the period of their membership of the 2014 PPRS (if applicable), or in respect of the period that they were subject to the Statutory Scheme (if applicable).
- 2.20 After 1 January 2019 a manufacturer or supplier of a Branded Health Service Medicine may join the 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 2.21, membership will be effective from the first calendar day of the next calendar year 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 calendar year. If the deemed delivery date is less 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).
- 2.21 Where a New Manufacturer or Supplier of a Branded Health Service Medicine wishes to join the 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 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 less 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).
- 2.22 The Department has the right to refuse membership of the 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) by 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) by the Department from 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 2014 PPRS 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) by the Department from the manufacturer or supplier) has been referred to the dispute resolution procedure of the 2014 PPRS for determination in accordance with the terms of the 2014 PPRS);
- 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 2014 PPRS; or
- where the manufacturer or supplier was previously a member of the Voluntary Scheme, it has not complied with all obligations during the period it was a member of the Voluntary Scheme.

2.23 Where a manufacturer or supplier of a Branded Health Service Medicine joins the Voluntary Scheme with effect from 1 January 2019, such manufacturer or supplier acknowledges that, notwithstanding that the Department has not earlier refused the manufacturer or supplier membership of the 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 2014 PPRS in respect of its period of membership of the 2014 PPRS (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 2014 PPRS (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 2.35 that the Voluntary Scheme does not apply to the Scheme Member.

- 2.24 Where a manufacturer or supplier of a Branded Health Service Medicine is refused membership of the Voluntary Scheme under paragraph 2.22 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.
- 2.25 Manufacturers or suppliers refused membership of the Voluntary Scheme will be subject to the Statutory Scheme.

Group Membership of the Voluntary Scheme

- 2.26 A manufacturer or supplier of a Branded Health Service Medicine may join the 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 Scheme it must:
- submit a completed Form A in accordance with the requirements of paragraphs 2.17 to 2.21 ; and
 - at the same time, submit a completed Form A1 naming the lead company and all other relevant companies (Other Companies), in accordance with the requirements of paragraphs 2.17 to 2.21.
- 2.27 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 Voluntary Scheme (and therefore not subject to the Statutory Scheme); and
 - unless otherwise stated, be a 'Scheme Member' within the meaning of the Voluntary Scheme and, accordingly, be responsible for complying with the requirements of the Voluntary Scheme (including without limit being liable for making any payments due under the Voluntary Scheme).

- 2.28 Notwithstanding the above, by virtue of joining on behalf of Other Companies in accordance with paragraph 2.26, 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.
- 2.29 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 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.
- 2.30 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 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

- 2.31 Although the 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 Voluntary Scheme.

Leaving the Voluntary Scheme

- 2.32 A Scheme Member may, at any time, give notice of its intention to leave the 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 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 Voluntary Scheme until the last calendar day of the following calendar year. Notice given by a Scheme Member under this paragraph 2.32 is irrevocable.

- 2.33 If at any time the Lead Company gives notice to leave the Voluntary Scheme in accordance with paragraph 2.32, with effect from the Lead Company leaving the Voluntary Scheme, all of the Other Companies will each be deemed to have left the Voluntary Scheme. Thereafter, if at any time any of the Other Companies wish to re-join the 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 2.17 to 2.21 (and where applicable paragraph 2.26).
- 2.34 If at any time any of the Other Companies wish to leave the Voluntary Scheme for whatever reason:
- such Other Company must submit a completed Form B in accordance with the requirements of paragraph 2.32; 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 Voluntary Scheme

- 2.35 Under the NHS Act, the Department has powers to determine that the 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 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 Voluntary Scheme and/or the 2014 PPRS (where applicable) within sixty (60) calendar days of a written demand (excluding, in respect of sums due under the 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 Voluntary Scheme);

- the Scheme Member fails to pay any sum as directed by the dispute resolution panel (DRP) under the 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 or 2009 pharmaceutical price regulation schemes or the 2014 PPRS, the Scheme Member fails to pay any sum as directed by the 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 or 2009 pharmaceutical price regulation schemes or the 2014 PPRS, the Scheme Member fails to comply with any decision of the dispute resolution panel under the relevant scheme within sixty (60) calendar days of the decision of the dispute resolution panel;
- the Scheme Member materially fails to comply with the requirements of the Voluntary Scheme and/or the 2014 PPRS (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 Presentation that either that Scheme Member or another manufacturer or supplier would otherwise be liable to make under the Voluntary Scheme or the Statutory Scheme.

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

- a Lead Company, with effect from the Voluntary Scheme no longer applying to the Lead Company, the 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 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 2.17 to 2.21 (and where applicable paragraph 2.26); 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

2.37 Notwithstanding the Scheme Member leaving the Voluntary Scheme under paragraph 2.32, the disapplication of the Voluntary Scheme in relation to the Scheme Member under paragraph 2.35 or expiry of the Voluntary Scheme:

- the liability of the Scheme Member under the 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 Voluntary Scheme or after expiry of the Voluntary Scheme;
- the Scheme Member shall be required to submit all information requirement submissions arising out of the terms of the Voluntary Scheme in respect of the period of that Scheme Member's membership of the Voluntary Scheme; and
- the Secretary of State may, at any time, use any of his/her powers (including without limit those under the NHS Act) in relation to the manufacturer or supplier.

Products Covered

2.38 The Voluntary Scheme applies to all Branded Health Service Medicines. Accordingly, the 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
- Biological Medicinal Products whether or not a branded medicine (as defined in the Statutory Scheme).

2.39 The Voluntary Scheme shall not apply to sales of medicines for supply on private prescription or other use outside the NHS.

2.40 The 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
- over the counter (OTC) sales (except that the 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 Voluntary Scheme where total NHS prescription sales of a Presentation in any calendar year within the duration of the Voluntary Scheme amounts to less than £50,000.

3. Access, Uptake and Outcomes

Summary

- 3.1 This section sets out the ambitions of the Voluntary Scheme to further improve patients' outcomes and the health gain from medicines spend by simplifying, streamlining and improving access, pricing and uptake arrangements for cost effective medicines; and delivering faster adoption of the most clinically and cost effective medicines. Patients will benefit from the ambitions in this Chapter 3 for earlier commercial engagement and uptake support for high value products, faster NICE appraisals, and the commitment from all Parties to improve health gain relative to medicines expenditure.
- 3.2 These ambitions will be achieved through:
- Enhanced horizon scanning – enhancing the NHS approach to horizon-scanning to improve planning and forecasting;
 - Improving engagement – further improving strategic engagement between the health service in England, the pharmaceutical industry, and other relevant bodies, to improve multi-agency learning; and enable earlier company engagement with the health service in England and more proactive case management;
 - NICE Value assessment – more and faster NICE appraisals for all New Active Substances (see Glossary) and significant extensions to the Marketing Authorisation by speeding up appraisals for non-cancer medicines to be in line with cancer medicine appraisal timelines, where there is sufficient evidence to enable a NICE appraisal to be conducted with the same level of rigour as expected currently;
 - Evolving commercial arrangements – increasing commercial flexibilities, preferentially applied for the best value propositions to support patient access to medicines at cost effective prices; and developing and publishing a new commercial framework for the health service in England;
 - Increasing transparency – improving visibility of upcoming tenders; and increasing transparency of national commercial arrangements to NHS purchasing authorities in each of the four UK countries; and

- Promoting uptake – investing in NHS data infrastructure in England; and taking a more proactive approach to supporting, understanding and promoting the uptake of the most clinically and cost effective products in the health service in England.

Territorial Application

3.3 The section of this Chapter 3 dealing with horizon scanning (paragraph 3.4 to 3.9) and the sub-section dealing with transparency of national commercial arrangements across the UK (paragraph 3.49) apply in England, Scotland, Wales and Northern Ireland. The sections dealing with value assessment of medicines and decisions about the prioritisation of NHS resources (paragraphs 3.10 to 3.57 except paragraph 3.49) are devolved matters and, excepting any specific UK wide provisions, shall apply to England only. It is for the governments of Scotland, Wales and Northern Ireland to determine their own value assessment, access and commercial arrangements. Those governments will work with industry on making progress in these areas, and work with the Department where appropriate.

Horizon Scanning

3.4 The Governments and the pharmaceutical industry have a shared ambition for the NHS to have complete and accurate information about the products coming through the pipeline; this includes clinical, financial and service planning information. Continuing to improve and refine the approach used for horizon scanning would enable the NHS to:

- plan more effectively for financial and service change implications;
- ensure that more timely preparation and support is in place to facilitate the introduction of new products; and
- ultimately enable more appropriate uptake of clinically and cost effective products to improve patient outcomes, with benefit for industry and patients through accelerating access and uptake to new clinically and cost effective medicines.

3.5 The 2014 PPRS set out an ambition to extend the use of UK PharmaScan to promote consistency and minimise duplication; since then it has been recognised that progress has been made, but there remain areas for improvement.

3.6 Through the Voluntary Scheme, all Parties are restating their ambition to have a single, shared approach for ensuring accurate horizon scanning. More effective horizon scanning will support better forecasting and planning for implementation in the NHS.

- 3.7 Scheme Members will therefore be required to commit to providing timely, accurate and comprehensive information on products in development. This information will be made available to relevant agencies to enable better financial, clinical and service planning for the introduction of new medicines. UK PharmaScan, or any successor, is most likely to be the primary source of information for all relevant agencies.
- 3.8 The health service in England commits to work toward aligning horizon scanning tools for health technologies, including with medical devices and diagnostic tools. This alignment is intended to streamline the data input for companies, reduce omission or duplication, and make the data more accessible for the NHS.
- 3.9 NHS England and the ABPI, along with other partners including NICE, will work together to establish an approach for regularly reviewing the approach to horizon scanning, ensuring that relevant information is provided in a timely way to identify themes and trends. Operational detail will be developed by NHS England, NICE and other sector partners, as well as with ABPI and the pharmaceutical industry.

Engagement

- 3.10 The Department and NHS England recognise the benefit of open and regular dialogue with pharmaceutical industry representatives, and intend to improve information sharing through structured, multi-agency engagement.
- 3.11 NICE and NHS England will further develop their approach to strategic engagement with Scheme Members and their representative bodies, ensuring that there are regular forums where issues can be discussed. This strategic engagement will be aligned with existing arrangements, including: the Life Sciences Council, and any sub-groups; the NICE Implementation Collaborative (NIC); and the Accelerated Access Collaborative (AAC).
- 3.12 All Parties are supportive of NHS England and NICE providing the pharmaceutical industry the opportunity for earlier engagement, advice, and signposting on the development of new products. This advice may include support to find the most appropriate route for health technology evaluation and commercial discussions, and to support products to routine commissioning where appropriate. This will enable the health service in England to more readily identify new medicines and plan for the introduction of the most clinically and cost effective products, which provide substantial health gain for patients.
- 3.13 Where products require a more proactive approach, for example where a significant pathway change has to be implemented to prepare for their introduction or where further data collection is required, the intention is for the Scheme

Member to have a single point of contact with NHS England and NICE, in order to provide greater consistency and clarity of advice.

- 3.14 NICE and NHS England will together develop and implement a joined-up approach to earlier engagement and case management, working closely with industry.
- 3.15 NHS England also commits to developing a 'relationship management' approach with a number of individual companies, including with small companies, in order to establish a closer working relationship.

NICE Value Assessment

- 3.16 NICE will continue its world-leading role in producing evidence-based guidance and advice on the use of medicines. This is an important mechanism for ensuring medicines used by the NHS offer value.
- 3.17 All New Active Substances in their first indication, and extensions to their Marketing Authorisation to add a significant new therapeutic indication, will undergo an appropriate NICE appraisal, except where there is a clear rationale not to do so. NICE expects to achieve this by April 2020.
- 3.18 NICE will adopt the principle of appraisal timelines for non-oncology treatments matching those for oncology treatments, subject to the evidence base for the product being sufficiently developed to enable a NICE appraisal with the same level of rigour and certainty as would be expected currently.
- 3.19 NICE has committed to scoping, and where appropriate initiating, a review of the methods for the Technology Appraisal Programme (TAP) in 2019/20, and encourages industry to feed in its views. Industry and other relevant stakeholders will be active participants in the review, including inputting on scope, participating in working discussions, and providing views on recommendations.
- 3.20 The standard cost effectiveness threshold used by NICE will be retained at the current range (£20,000 - £30,000 per QALY) and not changed for the duration of the Voluntary Scheme.
- 3.21 NICE has committed to reviewing the process and methods for the Highly Specialised Technology (HST) Evaluation Programme in 2019/20, and encourages industry to feed in its views. Industry and other relevant stakeholders will be active participants in the review, including inputting on scope, participating in working discussions, and providing views on recommendations.

- 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 by 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 Department, the ABPI and NHS England understand the benefits that clinically- and cost effective medicines can bring to patients and taxpayers. During previous schemes the health service in England has offered commercial flexibilities in particular cases, including both simple and complex Patient Access Schemes (PAS). Further flexibility has been offered in certain circumstances, including in the context of the Cancer Drugs Fund (CDF), for HSTs and the Budget Impact Test (BIT). The Voluntary Scheme represents an opportunity to further expand the commercial flexibility 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 will remain the preferred means of providing a cost effective price to the NHS.
- 3.25 The 2009 Pharmaceutical Price Regulation Scheme included agreement to introduce PAS, aimed at better reflecting value. PAS can facilitate patient access to a medicine where NICE's assessment of value, on the current evidence base, is unlikely to support the NHS list price. The 2014 PPRS set out a commercial approach which provided members of that scheme with the ability to offer simple confidential PAS or published complex PAS. PAS that are extant as at 31 December 2018 shall be maintained in accordance with their terms.
- 3.26 NHS England's commercial framework will set out the approach to commercial arrangements. NHS England will continue to offer an equivalent approach to simple confidential discounts and to published complex PAS, the operational detail of which will be set out in the commercial framework. These flexibilities, where appropriate, will be available to Scheme Members and non-Scheme Members.
- 3.27 In order for Scheme Members and other stakeholders to be clear about the parameters for the commercial approach in the health service in England, NHS England, with input from NICE, will develop and publish a 'commercial framework' which will set out further operational detail including on escalation. This framework will be tested with and informed through consultation with the ABPI and other stakeholders.

- 3.28 As a transitional arrangement, commercial flexibilities analogous to simple confidential and complex published PAS 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 PPRS, and guidance on NICE's website. Once NHS England establishes the approach in the commercial framework as referred to in paragraph 3.26, any new commercial flexibilities analogous to simple confidential and complex published PAS will operate in accordance with the commercial framework.
- 3.29 Since 2016 NHS England has supported NICE by undertaking confidential commercial negotiations for time-limited managed access agreements in the areas of HSTs, oncology drugs in the CDF and for products which trigger the BIT, to address uncertainty, value, affordability and risk.
- 3.30 NHS England's experience in undertaking such commercial negotiations has led to two conclusions: firstly, the increasing availability of confidential commercial flexibilities will be beneficial to patients and the pharmaceutical industry. Secondly, the recently enhanced commercial approaches have highlighted the importance of timely, high quality data and that managing and transacting these deals can be highly resource intensive for all parties.
- 3.31 It has therefore been agreed that NHS England will support the introduction of the most clinically and cost effective medicines by offering enhanced commercial arrangements where appropriate and practical.
- 3.32 The enhanced commercial arrangements may include complex confidential commercial arrangements, where deemed appropriate by NHS England and reserved for where companies aspire to deliver greater levels of health gain relative to cost. These arrangements 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 weightings.
- 3.33 Commercial flexibilities will need to be proportionate to the risk, affordability and value challenges to be managed. NHS England will lead a single integrated commercial negotiation with companies, with the aim of addressing issues of both affordability and cost effectiveness in one commercial arrangement, working with NICE and aligned with the NICE appraisal processes.
- 3.34 NHS England will consider the following goals when evaluating any flexible commercial approach:
- to substantially improve value for the NHS;

- to ensure and improve affordability for the NHS;
- to address commercial risk;
- to address value for money risk; and
- to ensure that continuity of treatment for patients can be assured upon expiry of any agreement.

- 3.35 The nature of commercial flexibility that would best apply to a product will be determined on a case by case basis, drawing on the available NHS commercial options. It will be possible for commercial arrangements to include commercial flexibility as well as commitments on uptake and adoption support. Where appropriate, commercial arrangements may include a data collection element to help manage uncertainty. NHS England will take into account the overall burden imposed on the NHS by the potential adoption of complex arrangements before agreeing to them.
- 3.36 The health service in England will continue to adopt uniform pricing by medicine. The health service in England does not operate blended pricing or pricing by indication. In cases where uniform pricing would lead to a reduction in total revenue for a medicine overall from the introduction of additional indications, other forms of commercial flexibility may be considered for medicines with a strong value proposition. In these cases, commercial flexibility would only be considered where the level of clinical effectiveness is highly differentiated, but substantial in all indications under consideration.
- 3.37 The additional commercial flexibility described above will be available to companies in either the Voluntary Scheme or the Statutory Scheme.
- 3.38 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, with additional support from NHS England and NICE to shape proposals.
- 3.39 The availability of enhanced commercial arrangements will not affect existing provisions for CDF products, HSTs, and products which trigger the BIT.

Managing Uncertainty

- 3.40 Medicines which provide more certainty of benefit are important to the NHS and to patients. Consistency of outcome is an important dimension of quality which is valued by the NHS.

- 3.41 NICE will clarify its approach to managing uncertainty in the appraisal of a new technology, brief its committees on the types of uncertainty and ensure that committee discussions focus on those areas of uncertainty that have the most significant impact on estimates of cost effectiveness.
- 3.42 In addition, NHS England will consider options for managing uncertainty through commercial arrangements, where appropriate.

Combination Branded Therapies

- 3.43 Realising the full potential health benefits from combination drug therapies can be challenging, given the need for commercial confidentiality and the need to maintain competition. The Department and NHS England will support ABPI's efforts to find solutions to enable companies to engage with one another where health-improving combination therapies face challenges coming to market.
- 3.44 The Department and NHS England will provide feedback on ABPI's proposed solutions to allow company-to-company engagement, to ensure that the combined cost of combinations can be developed for NICE appraisal, at the standard NICE threshold, in line with competition law.
- 3.45 All Parties recognise that, in the UK, the Competition and Markets Authority (CMA) represents the sole competent authority. Scheme Members will need to satisfy themselves that the commercial aspects of bringing combination therapies to the market are compliant with relevant legislation.

Transparency

Tendering

- 3.46 Public bodies including those in the NHS, and providers to the NHS, must comply with EU and UK law on procurement and competition. However, the outcome of any tender in England is not a barrier to patient access to medicines recommended in NICE appraisals or highly specialised technology evaluations.
- 3.47 NHS England will work to improve visibility of upcoming invitations to tender for pharmaceutical products, further to the statutory requirements for advertisement, by publishing details on the NHS England website.
- 3.48 Subject to compliance with applicable legislation, approaches will continue to be determined on a case by case basis.

Transparency of commercial arrangements across the UK

- 3.49 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 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.

Uptake Support

- 3.50 The Parties aspire to further improve health gain from medicines spend, and to see greater uptake of the most clinically and cost effective current and future innovative medicines which provide significant health gain. To this end the health service in England will more proactively support the implementation, planning and support for uptake of the most clinically and cost effective new medicines.
- 3.51 NHS England commits to offer tailored uptake and implementation support for products that offer exceptional value and provide significant health gain. This would apply to medicines with the strongest value propositions, and with substantial health gain for the treatment population. It will also be taken into account whether these medicines demonstrably address conditions with high unmet need for those affected, or where there is evidence that these treatments will address health inequalities in terms of healthy life expectancy.
- 3.52 For some new innovations, the NHS will need time to support pathway change, from a clinical, financial and logistical perspective. However, the requirements for individual products will vary. NHS England will offer tailored support for the most clinically and cost effective new medicines to support uptake on a case-by-case basis.
- 3.53 The support will be tailored to what is most appropriate and effective for each product and could include, for example, supporting clinicians and commissioners to change pathways and approach through NHS RightCare and Getting It Right First Time (GIRFT), using commercial flexibilities, or introducing financial or other incentives where appropriate and transactable.

Data Infrastructure

- 3.54 Building on the UK's data infrastructure will be important for the future of health delivery. The Parties are therefore committed to continuing discussions around the

development of the data infrastructure in the health service in England, such as e-prescribing, to enable improved information collection and generation of 'real world' evidence, including on an indication-specific basis where appropriate. This will likely be enhanced by longer term planning work within NHS England.

Uptake Measurement

- 3.55 The Parties agree that it is important to track and assess the uptake of new products and their impact on patient outcomes.
- 3.56 The Parties commit to work together to continue development of measurement tools, including the Innovation Scorecard, to provide a more comprehensive approach to tracking uptake and, where possible, measuring the impact on incremental health outcomes in a meaningful way relative to comparable alternatives. This will help to identify variation in prescribing and further investigation into warranted and unwarranted variation.
- 3.57 The Parties are committed to the objective of reaching the upper quartile of uptake (in relation to comparator countries) for the five highest health gain categories during the course of the first half of the Voluntary Scheme. In addition, the Department, NHS England and the ABPI will aim to better understand both national and international variation around uptake, and where this variation is unwarranted.

4. Affordability Mechanism

Summary

- 4.1 Chapter 4 summarises the affordability mechanism used within the Voluntary Scheme. This is designed to cap branded medicines' Sales at an agreed level of growth. Any growth in Sales above this level results in payments made by Scheme Members, determined as a percentage of Sales. This Chapter 4 and the associated Annexes 3 to 5 set out the mechanism for calculating growth and determining the associated Payment Percentage. 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. Arrangements for companies that make HCPs (as agreed under previous schemes) are set out in this Chapter 4 (and Annexes 11 to 13), including the option to make a one-off payment in settlement.

Introduction

- 4.2 The main objective of the affordability mechanism is to limit growth in the overall cost of Branded Health Service Medicines. This is to be achieved through an allowed growth rate on sales of Branded Health Service Medicines. Growth in sales above the allowed growth rate results in payments made by Scheme Members. The Voluntary Scheme remains a portfolio-wide profit control scheme.
- 4.3 A summary of the affordability mechanism is set out in paragraphs 4.5 to 4.15 (Affordability Mechanism). The key terms used to describe the Affordability Mechanism are set out in the Glossary and the detailed provisions for calculating and making the Scheme Payments payable by each Scheme Member are set out in paragraphs 4.16 to 4.48 and Annexes 3 to 5.
- 4.4 The provisions of this Chapter 4 are to be read as a whole together with the greater detail on the working of the Affordability Mechanism contained in Annexes 3 to 5 (the Technical Annexes) and the defined terms used in Chapter 4 and the Technical Annexes set out in the Glossary (the Affordability Mechanism Definitions). In relation to the interpretation of any provision of the Affordability Mechanism, the greater detail contained in the Technical Annexes will take priority over any less detailed text contained in Chapter 4 and the Affordability Mechanism Definitions unless there is a clear conflict or inconsistency between a specific statement in Chapter 4 or the Affordability Mechanism Definitions and any of the

detail contained in the Technical Annexes. In that case, the text of Chapter 4 or the Affordability Mechanism Definitions will prevail and the Department and the ABPI will negotiate appropriate amendments to the Technical Annexes to remove the conflict or inconsistency.

Summary of Affordability Mechanism

4.5 In outline, Scheme Members will make payments to the Department (Scheme Payments) of a percentage of their net sales of certain health service medicines (Eligible Sales). That percentage (Payment Percentage) is derived from the difference between allowed growth and forecast growth in sales to the NHS of Branded Health Service Medicines (Measured Sales) during the five (5) years of the Voluntary Scheme. In order to improve stability, predictability and accuracy, Measured Sales and therefore the calculation of the Payment Percentage will include sales of Scheme Products by Scheme Members and companies subject to the Statutory Scheme and Parallel Import Sales (set out in the Glossary) and exclude certain exemptions. These Exemptions from Measured Sales 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; and
- Low Value Sales.

Definitions of these terms are in the Glossary.

4.6 Therefore, in respect of Sales made during each calendar year of the Voluntary Scheme, Scheme Members will make Scheme Payments calculated as follows:

Scheme Payment	=	Eligible Sales by the relevant Scheme Member	X	Payment Percentage for that calendar year
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4.7 The Voluntary Scheme sets out the Allowed Growth Rate for each calendar year of the Voluntary Scheme and through applying the Allowed Growth Rate to the agreed baseline of Measured Sales in 2018 net of payments made in respect of 2018 under the 2014 PPRS and under Regulation 3 of the Statutory Scheme, a

profile of Allowed Sales (see Glossary for definition) is derived over the lifetime of the Voluntary Scheme.

4.8 The difference between forecast Measured Sales for a given calendar year and the Allowed Sales for that calendar year (Calculated Total Payment) (if forecast Measured Sales exceed Allowed Sales) is multiplied by forecast Voluntary Scheme Measured Sales as a percentage of Measured Sales for that calendar year. This amount (Calculated Scheme Payment) is then adjusted to reflect any Under Payments or Over Payments (as defined in paragraph 4.10), and divided by forecast Eligible Sales to calculate the Payment Percentage for that calendar year.

4.9 Some Sales are exempt from Eligible Sales and these Exemptions from Eligible Sales 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; and
- Low Value Sales.

Definitions of these terms are set out in the Glossary.

Of these, the following are exempt from Eligible Sales but are not exempt from Measured Sales:

- NAS Sales; and
- Medium Sized Company Sales.

Where Measured Sales have exceeded the Allowed Sales, the payment accruing from Sales that are exempt from Eligible Sales but not exempt from Measured Sales will be borne through the Payment Percentage applied to all Eligible Sales across all Scheme Members.

4.10 The Payment Percentage for the first calendar year (9.6%) is based on the initial Measured Sales forecast at the start of the Voluntary Scheme and this will not change. In the final Quarter of the first calendar year, the forecast of Measured

Sales and the forecast percentage of Voluntary Scheme Measured Sales exempt from Eligible Sales for the second and each subsequent calendar year will be reviewed against the initial forecasts upon which the Payment Percentage for the first calendar year was based and 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 Allowed Sales profile based on actuals for the baseline calendar year;
- adjustment of the forecast growth rate of Measured Sales going forward based on the cumulative deviation of outturn from initial forecast to date (including the difference between unaudited and Audited Sales Reports);
- the calculation of any cumulative under or over payments in respect of preceding calendar years in the Voluntary Scheme resulting from the difference in the Payment Percentage when calculated on the basis of outturn, rather than forecast, Measured Sales (Under Payments or Over Payments);
- a smoothed uplift or reduction (depending on the direction of the change) to future Payment Percentages to spread the impact of the resulting Under Payments or Over Payments for preceding calendar years over the remaining duration of the Voluntary Scheme.

4.11 The revised Allowed Sales will then be compared to the adjusted forecasts of Measured Sales, Voluntary Scheme Measured Sales, and Eligible Sales to calculate the Payment Percentage for the second calendar year. An equivalent process will be undertaken at the end 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.

4.12 The Department does not expect to receive a payment on Parallel Import Sales through either the Voluntary Scheme or the Statutory Scheme and therefore anticipates that growth of Measured Sales net of Scheme Payments and payments under Regulation 3 of the Statutory Scheme will exceed the Allowed Growth Rate.

4.13 The initial forecast growth rate of Measured Sales is set out below:

2019	2020	2021	2022	2023
5.72%	6.84%	8.57%	9.21%	8.76%

An adjusted forecast will be calculated under the process outlined in paragraph 4.10 during the period of the Voluntary Scheme which reflects actual growth in Measured Sales.

This is the forecast growth rate for gross Measured Sales i.e. excluding any payments under either the 2014 PPRS, the Voluntary Scheme or the Statutory Scheme. Allowed Sales in each calendar year of the Voluntary Scheme will be calculated from a baseline position of net Measured Sales i.e. 2018 Measured Sales post payments made in respect of the year 2018 under the 2014 PPRS and Regulation 3 of the Statutory Scheme. Individual component forecasts can be found in Annex 3.

- 4.14 Following the end of the first calendar year of the Voluntary Scheme, and then on an annual basis, the automatic adjustment under the process outlined in paragraph 4.10 of forecast Measured Sales will be reviewed. Following this review, amendments to the initial forecast growth rate of Measured Sales can be made by agreement between the Department and the ABPI.
- 4.15 To reflect the fact that final Audited Annual Sales Reports for all Scheme Members will not be received until 2025, there will be a two phase Voluntary Scheme-end reconciliation in 2024 and 2025 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 2024 and 2025, the 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 2025 and 2026 following the immediately preceding recalculation of the Payment Percentage for the fifth calendar year. Following the recalculation of the Payment Percentage in the final Quarter of 2025, the Payment Percentage for the fifth calendar year will be final and will not change.

Arrangements for Making Scheme Payments

- 4.16 Scheme Payments must be paid in Quarterly instalments by individual Scheme Members at the same time as the Quarterly Sales Reports are submitted.

Sales Reports

- 4.17 Quarterly Sales Reports must be submitted by the Scheme Member via the relevant portal designated by the Department and notified by the Department to the 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).

- 4.18 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 4.26 to 4.31. 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.
- 4.19 Annex 6 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);
 - a Company Declaration for the Sales Reports (Appendix 2); and
 - the Audit Report on the Audited Annual Sales Reports (Appendix 4).
- 4.20 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 Company Declaration at Annex 8. This is to allow the Department to compare Scheme Member sales data with administrative data on spend on Branded Health Service Medicines. This does not itself need to be Audited but the data should reconcile with the relevant Quarterly Sales Reports. For the purpose of completing Annex 7 the following data should be included:
- Under Primary Care Sales: those presentations which are dispensed by community pharmacists or dispensing doctors;
 - Under Homecare Sales: those presentations that are sold direct to homecare providers; and
 - Under All Other Customers: all other presentations (including wholesaler sales to homecare providers).

- 4.21 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 Voluntary Scheme.
- 4.22 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 ABPI (such appointment subject to the Department's reasonable right of veto) and details of whom have been confirmed to Scheme Members.
- 4.23 Scheme Members with a Financial Year that does not end on the last calendar day of a Quarter will be required to provide two unaudited returns in place of the Quarterly Sales Report for the Quarter that overlaps the Scheme Member's Financial Year end. The unaudited returns must comply with the requirements of the Quarterly Sales Reports in terms of content and it is acknowledged that, while the content of each unaudited return may only cover a portion of the period of the relevant Quarter, together the two unaudited returns must cover the whole of the period of the relevant Quarter. Scheme Members with a Financial Year that does not end on the last calendar day of a Quarter are still required to submit one Audited Annual Sales Return relating to the relevant calendar year.
- 4.24 Where a sale of an item of 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 Presentation.
- 4.25 If there are reasonable and objective grounds for the Department to believe that the exclusion of sales of items of 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 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 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 Presentation made by

the Scheme Member and the company (or companies) in the same Group as the Scheme Member.

Audit Arrangements

- 4.26 The following arrangements for Auditing Scheme Members' Audited Annual Sales Reports for the Scheme Payments will apply.
- 4.27 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.
- 4.28 The Audited Annual Sales Report must be Audited by an Auditor. Any resulting cost will be met by the Scheme Member.
- 4.29 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 805 (Revised) and reported for each calendar year of sales applicable to the Voluntary Scheme including the baseline calendar year sales (2018) against which the 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.
- 4.30 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.
- 4.31 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.

Smaller Companies

- 4.32 Scheme Members with Sales of Scheme Products of less than £5 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 £1m in the calendar year 2018, eligibility for the exemption will be

established at the start of the Voluntary Scheme and will continue throughout the period of the Voluntary Scheme provided that annual Sales of Scheme Products do not grow above £1m.

- 4.33 For Scheme Members with Sales of Scheme Products of £1m or over but under £5m, 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.
- 4.34 Scheme Members with Sales of Scheme Products of less than £1m must submit a Company Declaration on the value of their Sales in the calendar year 2018 by 31 March 2019 using the Company Declaration at Annex 9. These Scheme Members will continue to be exempt for the period of the 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 Voluntary Scheme and the value of those Sales as stated in the relevant Company Declaration remaining below £1m. If the value of those sales as stated in the relevant Company Declaration reaches or exceeds £5m, the exemption will cease to apply for the whole of the following calendar year.
- 4.35 Scheme Members with Sales of Scheme Products of more than £1m and less than £5m in the calendar year 2018 must submit an unaudited Annual Sales Report of Sales of Scheme Products for the calendar year 2018 by 31 March 2019 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 2018 are less than £5m 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 2019. Thereafter, Scheme Members with Sales of Scheme Products of more than £1m and less than £5m 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 Voluntary Scheme by 31 March of the following calendar year.
- 4.36 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 £5m 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 2019 submitted by 31 March 2020 shows that the Scheme

Member's Sales of Scheme Products in the calendar year 2019 were £5m or greater, then the Department will require the Scheme Member to make Scheme Payments for the whole of the calendar year 2020, submitting the Quarterly Sales Reports and Scheme Payments and an Audited Annual Sales Report for 2020 according to the same procedure as other Scheme Members.

- 4.37 If a Scheme Member has been making Scheme Payments because its Sales of Scheme Products were £5m or higher in the previous calendar year, but during the calendar year its Sales of Scheme Products (gross of the Scheme Payment) fall below the £5m 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 £5m threshold according to its Sales of Scheme Products for the calendar year 2019 and made Scheme Payments for 2020, but the Scheme Member's Sales of Scheme Products gross of the Scheme Payment in the calendar year 2020 fell below the £5m threshold, then it could apply for the exemption for 2021 based on an Sales Report for 2020 submitted by 31 March 2021.

Medium Sized Companies

- 4.38 Scheme Members with Sales of Scheme Products of £5m or over but under £25m will have their first £5m of Sales of Scheme Products (excluding NAS Sales) exempt from the assessment of Eligible Sales. 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 £5m or more and less than £25m in 2018 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).
- 4.39 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 4.18 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 Percentage in the calendar year for which the exemption was given multiplied by £5m. So, for example, if the unaudited sales total for 2019 submitted by 31 March

2020 shows that the Scheme Member's Sales of Scheme Products in 2019 were less than £25m, that company would make Scheme Payments in 2020 exempting £5m of 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 2019 were actually £25m or greater, that Scheme Member would be required to pay the Department the additional payment on the £5m of Sales of Scheme Products that was originally exempt from the assessment of their Eligible Sales in 2020. 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 £5m of their Sales of Scheme Products in that subsequent calendar year.

- 4.40 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 £25m 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 2019 submitted by 31 March 2020 shows that the Scheme Member's Sales of Scheme Products in 2019 were £25m or greater, then the Department will require the Scheme Member to make Scheme Payments for the whole of 2020 without exempting £5m of sales from the assessment of Eligible Sales and submitting the Quarterly Sales Reports and Scheme Payments and an Audited Annual Sales Report for 2020 according to the same procedure as other Scheme Members not eligible for the exemption.
- 4.41 If a Scheme Member has been making Scheme Payments without exempting £5m of sales from the assessment of Eligible Sales because its Sales of Scheme Products were £25m or higher in the previous calendar year, but during the calendar year its Sales of Scheme Products (gross of the Scheme Payment) fall below the £25m 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 £25m threshold according to its Sales of Scheme Products for 2018 and made Scheme Payments for 2019 without exempting £5m of sales from the assessment of Eligible Sales, but the Scheme Member's Sales of Scheme Products gross of the Scheme Payment in 2019 fell below the £25m threshold, then it could apply for the exemption for 2020 based on an Sales Report for 2019 submitted by 31 March 2020. The Scheme Member will be subject to the same reporting requirements set out in paragraphs 4.38 and 4.39.

Historic Cash Payments

- 4.42 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 Historic 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 2017 by a factor of three (3).
- 4.43 Scheme Members opting to make a one-off payment, must give notice to the Department by 31 March 2019 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.
- 4.44 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 4.45 to 4.48.
- 4.45 The historic cash payment percentage set for HCP Scheme Members under the 2014 PPRS (Historic Cash Payment Percentage) will continue at the same level under the Voluntary Scheme.
- 4.46 For 1 January to 31 December for each calendar year of the Voluntary Scheme, HCP Scheme Members must complete an Historic Cash Payment Form (Annex 11), annotating it appropriately so that sales against which the Historic 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 Presentations annotated must be those that were on the market on 31 December 2008 (and any subsequent Line Extensions of those Presentations) and that continue to be sold by the HCP Scheme Member. The total Sales at NHS list prices of these Presentations will be known as annual Historic Cash Payment sales (Annual Historic Cash Payment Sales).
- 4.47 The HCP for each calendar year of the Voluntary Scheme will be calculated by applying the Historic Cash Payment Percentage against the respective calendar year's Annual Historic Cash Payment Sales.
- 4.48 HCP Scheme Members must estimate the HCP in advance of each calendar year of the 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 Historic Cash Payment Sales must be made in the Quarter following the issue of the Department's assessment.

Amendments to the Statutory Scheme

4.49 There are various provisions of the Affordability Mechanism which refer to provisions of or calculations made in relation to the Statutory Scheme. In the event of any amendments to the Statutory Scheme made after 1 January 2019, the following provisions will apply, unless otherwise agreed with the ABPI, in relation to the relevant terms used in the Affordability Mechanism referred to below.

Allowed Sales	means, in the first calendar year, the amount of Measured Sales in the calendar year 2018 less payments made in respect of the calendar year 2018 under the 2014 PPRS and under Regulation 3 of the Statutory Scheme, as amended, increased by the Allowed Growth Rate and compounded by the Allowed Growth Rate for each subsequent calendar year.
Auditor	means a qualified independent auditor (as defined in the Statutory Scheme as amended) appointed by a Scheme Member.
Branded Health Service Medicine	means a relevant medicine (as defined in the Statutory Scheme as at 1 January 2019), a Branded P&GSL Medicine both covered by the Voluntary Scheme (as defined at paragraphs 2.38 to 2.41), or a Parallel Import Medicine.
Branded P&GSL Medicines	means all relevant medicines (as defined in the Statutory Scheme as at 1 January 2019) 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.
Eligible Sales	as defined in Glossary but with the definition of Scheme Products altered as stated below.
Exemptions from Eligible Sales	as defined in Glossary but with the definitions of Scheme Products and New Active Substance altered as stated below.

Exemptions from Measured Sales	as defined in Glossary but with the definition of Scheme Products altered as stated below.
Low Value Sales	as defined in Glossary but with the definition of Scheme Products altered as stated below.
Marketing Authorisation	means a marketing authorisation as defined in the Statutory Scheme as amended or a Parallel Import Licence.
Measured Sales	as defined in Glossary but with the definition of Scheme Products altered as stated below.
Medium-Sized Company	as defined in Glossary but with the definitions of Scheme Products and New Active Substance altered as stated below.
Medium-Sized Company Sales	as defined in Glossary but with the definitions of Scheme Products and New Active Substance altered as stated below.
New Active Substance	means any Presentation which satisfies the requirements of paragraph (10) of Regulation 9 of the Statutory Scheme as amended.
Parallel Import Medicine	means a Health Service Medicine which is (a) a parallel distributed presentation (as defined in the Statutory Scheme as amended); or (b) a branded medicine with a Parallel Import Licence (where “branded medicine” means branded medicine as defined in the Statutory Scheme as amended).
Parallel Import Sales	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 as amended).
Scheme Products	means all relevant medicines (as defined in the Statutory Scheme as at 1 January 2019) - 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 as amended - and Branded P&GSL Medicines both covered by the Voluntary Scheme (as defined at paragraphs 2.38 to 2.41).

Small Company	as defined in Glossary but with the definition of Scheme Products altered as stated above.
Small Company Sales	as defined in Glossary but with the definition of Scheme Products altered as stated above.
Statutory Scheme Measured Sales	means Measured Sales made by manufacturers or suppliers subject to the Statutory Scheme as amended.
Statutory Scheme Sales	<p>means:</p> <p>(a) (if the amendment to the Statutory Scheme does not relate to the definition of “relevant medicine”) the net sales income in respect of which payments are due (or forecast to be due) under Regulation 3 of the Statutory Scheme as amended 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 in accordance with Regulation 3(4)(a)(i) and (ii) of the Statutory Scheme (as amended) as reported to the Department in accordance with Regulation 21 of the Statutory Scheme (as amended);</p> <p>or</p> <p>(b) (if and to the extent that the amendment to the Statutory Scheme does relate to the definition of “relevant medicine”) the net sales income in respect of which payments would have been due or forecast to be due under Regulation 3 of the Statutory Scheme had it not been so amended plus the net sales income that would have been received (or forecast to be received) had the Statutory Scheme not been so amended by manufacturers or suppliers in respect of the total supply of presentations excluded from the calculation of net sales income in accordance with Regulation 3 of the Statutory Scheme had it not been so amended as reported to the Department in accordance with Regulation 21 of the Statutory Scheme (as amended). If any other amendment to the Statutory Scheme is made at the same time as the amendment to the definition of “relevant medicine”, that amendment shall also apply (to the extent it is relevant) to this definition.</p>
Voluntary Scheme Measured Sales	as defined in Glossary.

5. Pricing

Summary

- 5.1 Chapter 5 and Annex 14 set out the arrangements for agreeing prices of medicines, whether new or existing. Under the terms of the 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 5 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

- 5.2 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 may 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.
- 5.3 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.
- 5.4 The Department will acknowledge the submission and seek confirmation of the Marketing Authorisation status from the appropriate Licensing Authority.
- 5.5 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 5.13. Where that NHS list price is lower than the price the Scheme Member previously charged for that 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

- 5.6 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.
- 5.7 Line Extensions relating to a New Active Substance, may be priced at the discretion of the Scheme Member, as set out in paragraph 5.6, 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.
- 5.8 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.
- 5.9 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.
- 5.10 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 £20 million, 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.

5.11 If a Scheme Member considers that the rapid uptake of a new medicine will cause the Scheme Member to exceed the margin of tolerance specified in paragraph 6.15 (MOT) used in the assessment of Annual Financial Returns (AFRs) required under Chapter 6, then it must inform the Department immediately, complete an AFR if requested to do so by the Department and commit to negotiating through the methods referred to in paragraph 6.16 a reduction in profitability for the current Financial Year to the level of the MOT.

All Other Products and Their Line Extensions

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

5.13 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 five (5) Financial Years;
- 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 5.20); and
- The Scheme Member's profit over the first five (5) Financial Years.

5.14 As part of its assessment, the Department may request additional information from the Scheme Member.

5.15 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 5.13.

- 5.16 If, following discussions, agreement cannot be reached on the NHS list price of the 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.

NHS List Price Increases

- 5.17 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).
- 5.18 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.
- 5.19 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).
- 5.20 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 5.21) 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 relevant Return on Sales (ROS) target or Return on Capital (ROC) target referred to in paragraph 5.21. Where the Scheme Member's estimated and forecast profits as assessed by the Department are below 50% of the relevant ROS or ROC 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 five (5) Financial Years (inclusive of the effect of the proposed NHS list price increase) to achieve 65% of the relevant ROS or ROC target.

- 5.21 The ROS target is 6% and the ROC target is 21%. The maximum allowances for the purposes of assessing ROS or ROC in relation to a proposed price increase are:

Category of Cost	Maximum Percentage of Value of Sales of Scheme Products
Research and development	Up to 22%
Marketing	A fixed rate of £900,000 p.a. and a variable rate of up to 2%
Information	Up to 2%

Further information on the calculation of the ROS and ROC targets and these allowances and the completion of PIFRs and AFRs is set out in Annex 14.

- 5.22 The Department may additionally require the Scheme Member to submit an AFR for the current and the following Financial Year in accordance with Chapter 6 prior to making a decision on the NHS list price increase request. The AFR does not need to be Audited unless specifically required to be so by the Department. Any AFR must include forecast data including the effect of the price increase were it to be awarded. If a price increase is approved, the Scheme Member must provide an AFR for the Financial Year the price increase is awarded and an AFR for one Financial Year following the price increase. These AFRs do not need to be Audited unless specifically required to be so by the Department.
- 5.23 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.
- 5.24 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
- a Scheme Product does not qualify for a price increase (including, in the exceptional 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, and that a discontinuation would have a subsequent negative impact on patient health,

it may put a proposal to the Department for consideration on its own merit. However, any decision on such proposal will be at the Department's entire discretion.

- 5.25 A Scheme Member may request that the Department's decision on a price increase request (other than a request falling within paragraph 5.24) is referred to the DRP within fourteen (14) calendar days of the Department's final decision.

Permanent Reductions to NHS List Prices

- 5.26 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 5.17 to 5.25.

Temporary Reductions to NHS List Prices

- 5.27 Scheme Members may make temporary reductions to an NHS list price, outside the arrangements for the settlement of an AFR, 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.
- 5.28 Where temporary reductions 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 4 and Annexes 3 to 5.

Updating Dictionary of Medicines and Devices

5.29 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.

Scheme Products Sold On

5.30 The requirements set out in this paragraph 5.30 refer to the treatment of Scheme Products sold in respect of the rules on price and profit control. Accordingly, when a Scheme Product covered by the Voluntary Scheme is sold 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.

Price Modulation

5.31 Price modulation as permitted under the 2014 PPRS will cease and no new price modulation arrangements will be permitted under the Voluntary Scheme. All Scheme Products, whether currently modulated or not, will have their NHS list price set at the price sold as on 31 December 2018.

NHS List Price Increases for Branded P&GSL Medicines

5.32 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 5.32 to 5.36 in place of the approach set out in paragraphs 5.17 to

5.25. Where a Scheme Member wishes to increase the NHS list price under this paragraph 5.32 of a Branded P&GSL Medicine, 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.

5.33 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.

5.34 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 2018. If there is no NHS list price as at 31 December 2018, the reference price will be, for any new Branded P&GSL Medicine, the NHS list price agreed in line with paragraph 5.6, and for a Line Extension, a notional reference price (i.e. the price that would have been in place as at 31 December 2018 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).

5.35 Where the Department approves an increase to the NHS list price made under paragraph 5.32 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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5.36 The Department will notify the Scheme Member by the end of May 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.

Statutory Scheme

- 5.37 Where a Scheme Member has joined the 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.

6. Additional Duties and Requirements

Summary

6.1 Chapter 6 contains information on a number of additional duties and requirements relating to matters relevant to the Voluntary Scheme. The formal timescales for communications are defined. It places requirements on Scheme Members to notify the Department of changes to distribution arrangements and hospital discounts 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. Finally, the arrangements for AFRs, which may be required under certain circumstances, are set out.

Communications

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

6.3 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.

This paragraph 6.3 shall not apply to the service of any proceedings or other documents in any legal action.

Distribution Margin

- 6.4 One of the objectives of the 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.
- 6.5 Any Scheme Member that intends to change its overall distribution arrangements during the duration of the 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.
- 6.6 The Department will collect information on sales to retail pharmacy from Scheme Members annually and monitor any changes in the supply chain as per this paragraph 6.6. Information is required from Scheme Members with Sales of Scheme Products to the NHS of £5 million or more a calendar year in the form of the unaudited Annual Presentation Level Sales Report. This information should be sent to the Department in electronic format using the form set out at Annex 7 submitted via the portal designated by the Department and notified by the Department to the Scheme Members from time to time within three (3) months of the Scheme Member's Financial Year end. A Company Declaration (in the form set out at Annex 8) should accompany the data submitted.
- 6.7 If there are reasonable and objective grounds to believe that changes made during the duration of the 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.
- 6.8 Paragraph 6.7 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.

Hospital Discounts

- 6.9 The Department accepts fully the right of Scheme Members to change discounts allowed on sales to hospitals, subject to the conditions of any commercial arrangements in place with respect to individual Scheme Products. When doing so, Scheme Members will inform NHS England or equivalents in Scotland, Wales and Northern Ireland in accordance with the terms of any existing commercial arrangement for that Scheme Product and at least twenty eight (28) calendar days before the date of any change.

Patent Expiry and Generic Market Entry

- 6.10 As products near the end of their patent lives, Scheme Members should not take any unreasonable or anti-competitive action to delay or discourage generic entry to the market.

AFRs

- 6.11 The Voluntary Scheme provides a framework for determining reasonable limits to the profits to be made from the supply of Branded Health Service Medicines to the NHS. In keeping with the principles set out in the introduction to the Voluntary Scheme, there is encouragement for the research and development (R&D) of new medicines, and a commitment to a minimum of interference with Scheme Members' freedom to succeed in that activity.
- 6.12 Any Scheme Member will, if so required by the Department, provide a full, Audited AFR, together with supporting information (see specimen in Annex 14), which must be completed and submitted to the Department not later than three (3) months following notification of the Department's request for an AFR.
- 6.13 The allowable ROS that may be earned by individual Scheme Members from UK sales of Branded Health Service Medicines will be 6% of sales a Financial Year.
- 6.14 The allowable ROC that may be earned by individual Scheme Members from UK sales of Branded Health Service Medicines will be 21% a Financial Year.
- 6.15 The allowable returns referred to in paragraphs 6.13 and 6.14 will be subject to a margin of tolerance (MOT) and Scheme Members will be able to retain profits in any Financial Year of up to 150% of the relevant ROS/ROC target for that Financial Year.

6.16 If the Department's assessment of an AFR shows profits in excess of the MOT, the Scheme Member must commit to negotiating with the Department in good faith to achieve one or more of the following:

- repayments of that amount of profits which exceed the MOT;
- price reductions, during the Financial Year following that covered by the AFR, to bring prospective profits during that following Financial Year down to an acceptable level, on the basis of available forecasts; and/or
- a delay or restriction of price increases agreed for the Scheme Member or both.

Any negotiations under this paragraph 6.16 must begin no later than one (1) month after the date that the Department notifies the Scheme Member of the completion of its assessment of the AFR. Any repayments agreed must be paid no later than one (1) month after the date of completion of the negotiations.

7. Dispute Resolution

Summary

- 7.1 Chapter 7 summarises the dispute resolution procedure that applies to all parts of the Voluntary Scheme except Chapter 3 (Access, Uptake and Outcomes). It is agreed by all Scheme Members, the Department and ABPI that early discussion should be used to address any potential Disputes without recourse to the formal procedure. This Chapter 7, 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 DRP, and the arrangements for responding to any decision, including amendment of the Voluntary Scheme, withdrawal of membership of the Voluntary Scheme and enforcement are described.

Introduction

- 7.2 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 7. 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 7.
- 7.3 For the purposes of this Chapter 7 and Annex 15, except as otherwise provided, the Department and each Scheme Member are each a Party and together the Parties.
- 7.4 The provisions of this Chapter 7 and Annex 15 shall not apply to any dispute, difference or question of interpretation arising out of or in connection with Chapter 3.
- 7.5 A diagrammatical representation of the process described in this Chapter 7 is set out at paragraph 7.10.

Early Discussion

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

7.7 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: the Head of Branded Medicines Pricing Operations; or
- for the Scheme Member, such Director (or equivalent) as the Scheme Member shall notify the Department of,

for resolution. In attempting to resolve the Dispute, if possible, the Head of Branded Medicines Pricing Operations and the Director (or equivalent) must meet in person 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

7.8 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.

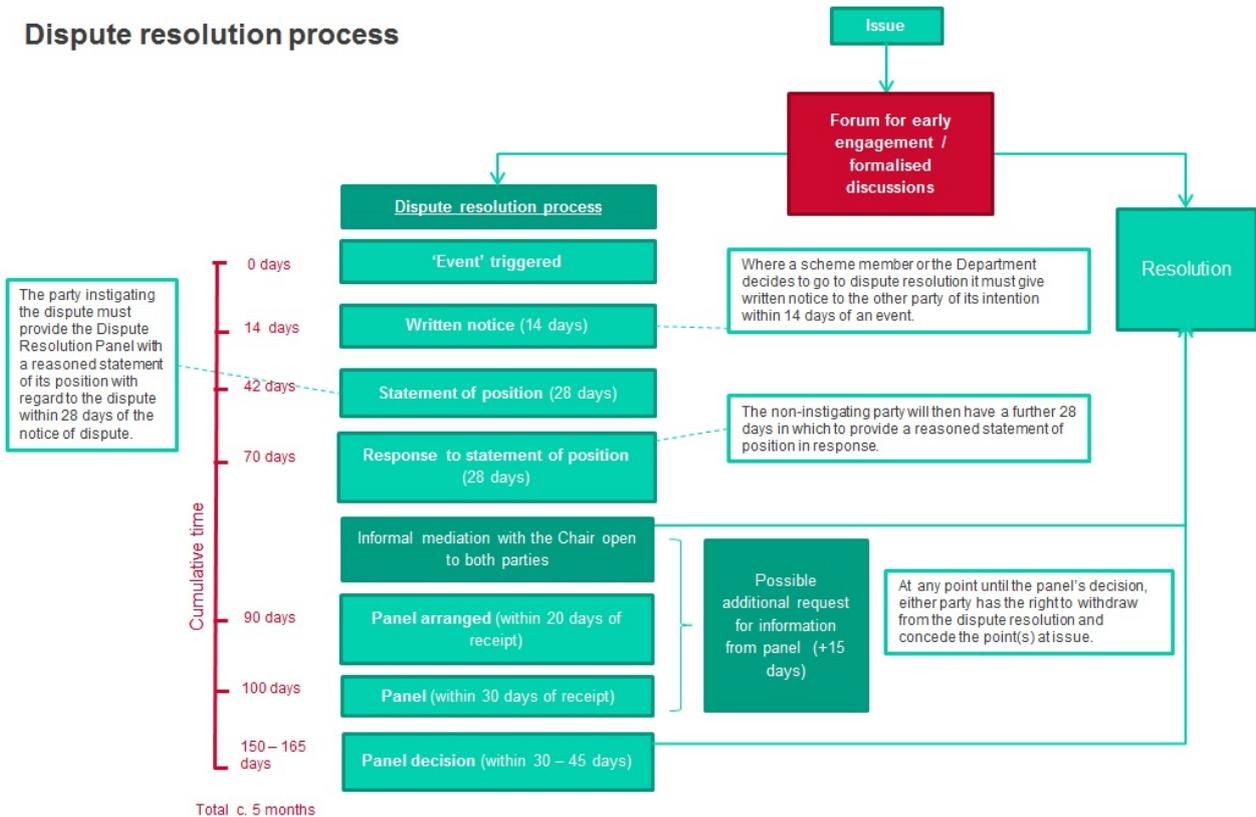
If neither Party refers the Dispute to the DRP within fourteen (14) calendar days of the Event, the Dispute Notice will automatically be deemed to have been withdrawn and neither Party may then refer the Dispute to the DRP.

7.9 Neither Party may refer the Dispute to the DRP until the procedure set out at paragraphs 7.6 and 7.8 has been followed and an Event has occurred.

Dispute Resolution Procedure

7.10 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

7.11 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,

(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.

7.12 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.

7.13 Where the ABPI Dispute is referred to the DRP for resolution in accordance with the timescales specified in paragraph 7.12:

- 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

7.14 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

7.15 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).

7.16 Where, as part of the DRP Decision, the DRP has made a determination on a question of interpretation of the Voluntary Scheme, the ABPI and the Department shall amend the provisions of the Voluntary Scheme to reflect such determination and/or DRP Decision and to clarify the interpretation of the 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.

- 7.17 The Secretary of State may use any of his/her 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 7 shall prevent the Secretary of State from using any of his/her powers (including without limit those under the NHS Act) in circumstances where a DRP Decision has not been made.
- 7.18 The DRP Decision shall not give rise to any action under the Arbitration Act 1996.
- 7.19 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 Voluntary Scheme

- 7.20 Where the Scheme Member serves notice under paragraph 2.32 to leave the Voluntary Scheme and an Event occurs before or on the date on which that Scheme Member ceases to be a member of the 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 7.8; and
 - the Secretary of State may, at any time, use any of his/her powers (including without limit those under the NHS Act) in relation to the manufacturer or supplier.
- 7.21 Where the Scheme Member serves notice under paragraph 2.32 to leave the Voluntary Scheme and a Dispute arises after the date on which that Member ceases to be a member of the 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 his/her powers (including without limit those under the NHS Act) in relation to the manufacturer or supplier.

Enforcement

- 7.22 The Parties agree that the Secretary of State may exercise any of his/her 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 7.8 but monies remain unpaid by the manufacturer or supplier.

Continued Obligations

- 7.23 Notwithstanding the Scheme Member leaving the Voluntary Scheme under paragraph 2.32, the disapplication of the Voluntary Scheme in relation to the Scheme Member under paragraph 2.35 or expiry of the 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 his/her powers (including without limit those under the NHS Act) in relation to such manufacturer or supplier.

Glossary

Subject to paragraph 4.4, in the event of a conflict between the meanings of defined terms set out in the Chapters and/or Annexes to the 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.

2014 PPRS	means the Pharmaceutical Price Regulation Scheme 2014 made between the Department and the ABPI dated 3 December 2013 as varied on 17 December 2013, 23 December 2016 and on 1 January 2018
ABPI	shall have the meaning given to it in paragraph 1.2
ABPI Dispute	means either: (a) 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 (b) a dispute between the Department and the ABPI out of or in connection with the Voluntary Scheme with the exception of Chapter 3
Accounting Reference Period	shall have the meaning given to it under section 391 of the Companies Act 2006
Affordability Mechanism	means the affordability mechanism as described in paragraph 4.3
Annual Financial Return or AFR	means an Annual Financial Return required to be submitted by a Scheme Member in accordance with Chapter 5
Annual Historic Cash Payment Sales	shall have the meaning given to it in paragraph 4.46
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
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 Rate	means two per cent (2%) per annum (nominal) in each calendar year of the Voluntary Scheme
Allowed Sales	means, in the first calendar year, the amount of Measured Sales in the calendar year 2018 less payments made in respect of the calendar year 2018 under the 2014 PPRS and under Regulation 3 of the Statutory Scheme, increased by the Allowed Growth Rate and compounded by the Allowed Growth Rate for each subsequent calendar year
Annual Presentation Level Sales Report	means the report referred to in paragraph 4.20
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 4.18
Auditor	means a qualified independent auditor (as defined in the Statutory Scheme) appointed by a Scheme Member
Audit Report	means the report referred to in paragraph 4.29
Biological Medicinal Products	as defined in Regulation 8(1) of the Human Medicines Regulations 2012
BIT	means the Budget Impact Test referred to in paragraph 3.23
Branded Health Service Medicine	means a relevant medicine (as defined in the Statutory Scheme as at 1 January 2019), a Branded P&GSL Medicine both covered by the Voluntary Scheme (as defined at paragraphs 2.38 to 2.41), or a Parallel Import Medicine
Branded P&GSL Medicines	means all relevant medicines (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

Calculated Scheme Payment	means, in respect of each calendar year, the Calculated Total Payment multiplied by the share of Measured Sales accounted for by Voluntary Scheme Measured Sales.
Calculated Total Payment	means, in respect of each calendar year, the difference between Allowed Sales and Measured Sales, where Measured Sales is greater than or equal to Allowed Sales. If Measured Sales is less than Allowed Sales, the Calculated Total Payment will be zero.
CDF	means the Cancer Drugs Fund as referred to in paragraph 3.23
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	means vaccines procured by a Central Government Body for national immunisation programmes that are approved by the Joint Committee on Vaccination and Immunisation (JCVI) and managed by Public Health England (or any successor body)
Chair	shall have the meaning given to it in paragraph 7 of Annex 15
CMA	means the Competition and Markets Authority
Department	means the Secretary of State for Health and Social Care acting through the Department of Health and Social Care
Department Representative	Deputy Director: Medicines Pricing and Supply (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 arising out of or in connection with the Voluntary Scheme with the exception of Chapter 3

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 7.10 and Annex 15
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 but excluding Exemptions from Eligible Sales
Event	shall have the meaning given to it in paragraph 7.8
Exceptional Central Procurements	means exceptional procurements conducted by a Central Government Body and managed by Public Health England (or any successor body) for the purposes of emergency preparedness (such as national stockpiles for the security of the nation or pandemic preparation)
Exemptions from Eligible Sales	means: (a) Sales of Scheme Products by a Scheme Member relating to Exceptional Central Procurements; (b) Sales of Scheme Products by a Scheme Member relating to Centrally Procured Vaccines; (c) NAS Sales; (d) Small Company Sales; (e) Medium Sized Company Sales; and (f) Low Value Sales
Exemptions from Measured Sales	means:

	<p>(a) Sales of Scheme Products by a Scheme Member relating to Exceptional Central Procurements;</p> <p>(b) Sales of Scheme Products by a Scheme Member relating to Centrally Procured Vaccines;</p> <p>(c) Small Company Sales; and</p> <p>(d) Low Value Sales</p>
Financial Year	means, in relation to a Scheme Member, the financial year of that Scheme Member as determined in accordance with s390 of the Companies Act 2006
FOIA	means the Freedom of Information Act 2000
GIRFT	means the Getting It Right First Time programme referred to in paragraph 3.53
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
HCP Scheme Member	shall have the meaning given to it under paragraph 4.42
health service in England	means the health services 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
Historic Cash Payment or HCP	shall have the meaning given to it under paragraph 4.42
Historic Cash Payment Percentage	shall have the meaning given to it under paragraph 4.45
Homecare Sales	means Sales of Presentations that are sold directly to homecare providers
HST	means Highly Specialised Technology referred to in paragraph 3.21
Launch	means place for sale on the UK market

Lead Company	shall have the meaning given to it in paragraph 2.27
Licensing Authority	the Medicines and Healthcare products Regulatory Agency or the European Medicines Agency (or any statutory successor) as the case may be
Line Extensions	means a new Presentation of a known active substance marketed under the same brand name by the same manufacturer as an existing Presentation
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 Holder	means the Marketing Authorisation holder
Marketing Allowance	shall have the meaning given to it in Annex 14
Marketing Authorisation	means a marketing authorisation as defined in the Statutory Scheme or 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
Medium Sized Company	means a Scheme Member whose total Sales of Scheme Products (including NAS Sales) are £5m or more but less than £25m in the calendar year preceding the relevant calendar year
Medium Sized Company Sales	means the first £5m of Sales (excluding NAS Sales) of Scheme Products by a Medium Sized Company as further detailed at paragraph 4.38
Month (or month)	means a calendar month except where otherwise stated
MOT	means the margin of tolerance specified in paragraph 6.15
NAS Sales	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 2018). 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

	<p>that Marketing Authorisation was granted on or after 1st January 2018). 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 Voluntary Scheme:</p> <p>(a) where a manufacturer or supplier Launches the same active substance but under a 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> <p>(b) 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 2018)</p>
New Active Substance	means any Presentation which satisfies the requirements of paragraph (10) of Regulation 9 of the Statutory Scheme
New Manufacturer or Supplier	means a manufacturer or supplier that is within its first Accounting Reference Period
NHS	<p>means the health services:</p> <p>(a) continued under section 1(1) of the NHS Act;</p> <p>(b) provided by virtue of Health and Social Care (Reform) Act (Northern Ireland) 2009;</p> <p>(c) within the meaning of the National Health Service (Scotland) Act 1978; and</p> <p>(d) continued under section 1(1) of the National Health Service (Wales) Act 2006</p>
NHS Act	means the National Health Service Act 2006

NHS England	means the National Health Service Commissioning Board
NICE	means the National Institute for Health and Care Excellence
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
Other Company or Other Companies	shall have the meaning given to it in paragraph 2.26
Parallel Import Licence	means a parallel import licence (as defined in Regulation 172 of the Human Medicines Regulations 2012)
Parallel Import Medicine	means a Health Service Medicine which is (a) a parallel distributed presentation (as defined in the Statutory Scheme); or (b) a branded medicine with a Parallel Import Licence (where “branded medicine” means branded medicine as defined in the Statutory Scheme)
Parallel Import Sales	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)
Party and/or Parties	means the Department, NHS England, ABPI and Scheme Members
PAS	means Patient Access Schemes as referred to in paragraph 3.23
Payment Percentage	means 9.6% in the first calendar year and, in the second and each subsequent calendar year, a percentage calculated in accordance with Annexes 3 to 5
PCA data	means Prescription Cost Analysis data which is published regularly by the NHS Business Services Authority
Pharmacy or General Sale List Medicine	means a pharmacy medicine or a medicinal product subject to general sale both as defined in the Human Medicines Regulations 2012

Presentation	means a particular form 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
Price Increase Financial Return	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 Voluntary Scheme
Referring Party	shall have the meaning given to it in paragraph 7 of Annex 15
Referring Party Documents	shall have the meaning given to it in paragraph 7 of Annex 15
Return	shall have the meaning given to it in paragraph 12 of Annex 14
Return on Capital or ROC	shall have the meaning given to it in paragraph 5.20
Return on Sales or ROS	shall have the meaning given to it in paragraph 5.20
Sales	means income from sales of Presentations made on or after 1st January 2019, 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 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 Voluntary Scheme
Scheme Member Representative	means the Scheme Member's UK General Manager or equivalent
Scheme Payment	means a payment due under paragraph 4.5 and calculated in accordance with paragraph 4.6
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 Voluntary Scheme (as defined at paragraphs 2.38 to 2.41)
Small Company	means a Scheme Member whose total Sales of Scheme Products are less than £5m in the calendar year preceding the relevant calendar year
Small Company Sales	means Sales of Scheme Products by a Small Company
Statutory Scheme	means the statutory scheme for branded health service medicines established under The Branded Health Service Medicines (Costs) Regulations 2018
Statutory Scheme Measured Sales	means Measured Sales made by manufacturers or suppliers subject to the Statutory Scheme
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 in accordance with Regulation 3(4)(a)(i) and (ii) of the Statutory Scheme 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

TAP	means the Technology Appraisal Programme operated by NICE referred to in paragraph 3.19
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
Voluntary Scheme	means the 2019 voluntary scheme for branded medicines pricing and access
Voluntary Scheme Measured Sales	means Measured Sales made by Scheme Members

Except as stated in paragraph 4.49, 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. In paragraph 4.49, “amended” includes any update, supplement, extension, re-enactment or replacement and “amendment” shall be construed accordingly.

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