



Understanding the 2014 Pharmaceutical Price Regulation Scheme

The Pharmaceutical Price Regulation Scheme - introduction

The Pharmaceutical Price Regulation Scheme (PPRS) has existed in various forms since 1957. It is a voluntary agreement between the Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI) regarding the supply of branded medicines to the National Health Service (NHS) across the four nations of the United Kingdom. It is negotiated by the ABPI with the DH on behalf of companies supplying branded medicines to the NHS. All such companies have the option to participate in the PPRS, irrespective of whether they are ABPI members, large or small companies, or their country of domicile.

The PPRS covers all branded medicines supplied to the NHS, whether or not they are still subject to a patent or have lost exclusivity. It does not apply to

unbranded generic medicines, which are subject to different arrangements.

The 2014 PPRS came into effect on 1 January 2014. It can be found on the [gov.uk website](http://gov.uk).

Companies that choose not to join the PPRS are covered by the statutory scheme (see page 7).

The PPRS agreement sets out in detail the objectives and operation of the scheme. This summary is intended as a general guide both for industry and other stakeholders but does not contain all the information included in the agreement. This guide summarises the key points and themes in the chapters.

PPRS overview and summary

The PPRS is an integrated, holistic agreement encompassing all major issues determining the relationship between the research-based pharmaceutical industry and the UK government. It is particularly relevant to the commercial environment and is unique globally in several important respects.

1. It is negotiated – not imposed – and is intended to achieve a balance between reasonable prices for medicines prescribed for NHS patients, and recognising the role of the pharmaceutical industry in the UK as a leading employer and investor in research and development.
2. It is normally negotiated for a period of five years. It has often lasted for longer than five years and has only once been terminated early. This is important since it gives industry the predictability and stability needed for investment planning, whilst also providing stability and predictability to government and the NHS for planning purposes. Stability of the UK environment is one of the features that attracted pharmaceutical investment to the UK in the past.

The 2014 PPRS is agreed for a fixed five year period and will terminate on 31 December 2018. This was agreed due to the current global economic circumstances. The UK has amongst the lowest prices for branded medicines in Europe (source: DH report to Parliament, February 2012). However, a fixed term enabled industry to make a

time limited cost concession to ensure patients can continue to obtain the medicines they need during this period of austerity.

3. It regulates the profit that companies can achieve on sales to the NHS, rather than regulating prices directly. However, it does not guarantee profit. Instead, it is based on a range of maximum allowances covering R&D, manufacturing costs, information, sales and marketing, and general administrative costs. These are then subject to a maximum percentage profit. The underlying assessment of profit remains the core basis of the 2014 PPRS.
4. Companies are permitted to introduce new medicines to the UK at a price determined by the manufacturer. This avoids patient access delays which arise in countries where prices are negotiated prior to patient availability. However, price is not without restraint. If the price is too high the company may exceed its profit ceiling; NHS prescribers are subject to indicative budgets for medicines and will prescribe medicines that are both effective and cost effective for patients.

Finally, since 1999 the National Institute for Health and Care Excellence (NICE) has assessed many new medicines for cost effectiveness which provides a further restraint on pricing. If NICE does not consider a new medicine to be cost-effective, it does not recommend it for use in the NHS.

UK branded pharmaceutical prices are amongst the lowest in developed countries

Position of the UK in the ranking of branded pharmaceutical prices by year

2003		2004		2007		2008		2010		2011	
USA	190	USA	176	USA	183	USA	252	USA	281	USA	331
Germany	102	Germany	106	Germany	113	Germany	142	Germany	155	Germany	153
UK	100	UK	100	Ireland	112	Ireland	134	Australia	139	Australia	143
Finland	98	Ireland	99	Sweden	105	Belgium	122	Ireland	133	Sweden	134
Austria	94	Finland	96	Belgium	101	Finland	119	Sweden	130	Belgium	123
Netherlands	93	Austria	94	UK	100	Sweden	116	Belgium	122	Ireland	123
Belgium	91	Netherlands	92	Finland	99	Netherlands	115	Austria	117	Netherlands	117
France	91	Belgium	90	Netherlands	99	Austria	111	Italy	113	Austria	115
Italy	90	Italy	90	Austria	96	Spain	109	Spain	106	France	104
Spain	81	France	84	Australia	94	France	108	Finland	105	Finland	103
Australia	-	Spain	80	France	92	Italy	101	France	104	Italy	101
Ireland	-	Australia	-	Spain	88	UK	100	UK	100	Spain	101
Sweden	-	Sweden	-	Italy	83	Australia	94	Netherlands	-	UK	100

Based on DH 11th Report to Parliament on PPRS (2004-2010); DH 5th Report to Parliament on PPRS (2000 - 2003); 2011: OHE calculations based on IMS and PCA data

Note: blank cell = Not available

Notes: Table includes the years prior to PPRS negotiations (2003/2004; 2007/2008) as well as for 2010 and 2011

Exchange rate used: Average of Q4 of every year.

Overall the scheme allows companies to make a reasonable profit recognising the high cost of R&D, to enable companies to continue to invest in the development of new medicines for patients in the future. At the same time, setting a limit on allowed

profit helps secure value for money for the NHS. The aim is to provide a balance between the need for new medicines in the future, patient access to medicines, and the need for government to manage expenditure wisely.

PPRS 2014 content

The PPRS consists of 11 chapters covering:

1. Purpose, Principles and Objectives
2. Introduction
3. Status and Membership of the Scheme
4. Access and Outcomes
5. Value and Pricing: Flexible Pricing and Patient Access Schemes
6. PPRS Payment Mechanism
7. Pricing
8. Levels of Return and Allowances
9. Information Requirements for Annual Financial Returns (AFR)
10. Other Matters
11. Dispute Resolution

Chapters 1-2: Recognition of the importance of the pharmaceutical industry for economic growth

The PPRS recognises the importance of striking a balance to promote the common interests of patients, the NHS, the industry and the taxpayer.

The research-based pharmaceutical industry is a key contributor to the UK economy. It is consistently the greatest contributor to R&D in the UK, and for many years has been in the top three in the economy for balance of trade. Key aspects of the commercial environment have been fundamental over many years to encouraging investment in the UK, and enabling the UK to become an important springboard for international competitiveness and success.

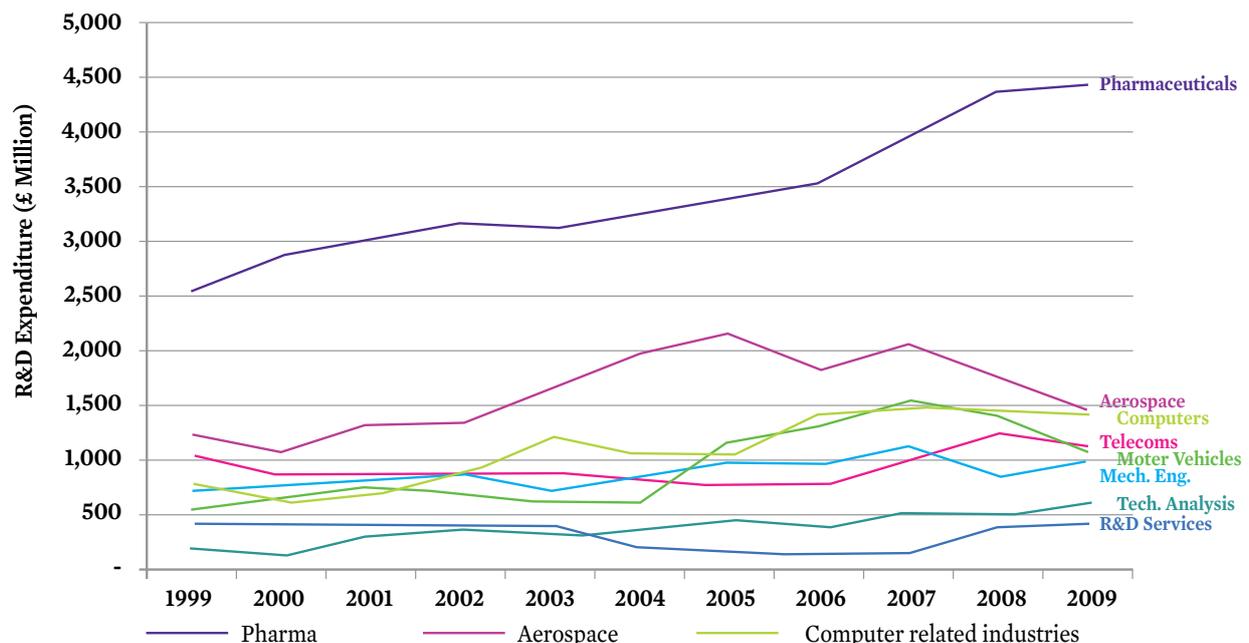
The government and the ABPI are committed to strengthening the UK environment for life sciences. The government has set out a broad range of policy initiatives, which are referred to in the PPRS, including the Life Sciences Strategy, to support a sustainable industry based on innovation. The Innovation, Health and Wealth initiative also addresses the importance of early adoption and diffusion of clinically and cost effective innovative medicines for patients in the NHS.

Objectives of the scheme include the promotion of a strong and profitable pharmaceutical industry that is capable of and willing to invest in sustained research and development. It is also an objective to reduce bureaucracy and duplication, and avoid unforeseen burdens on either party over the coming years.

In recognition of the balance intended by the scheme, the PPRS also commits government and the ABPI to continue to work together through the Ministerial Industry Strategy Group (MISG) in a programme of action aimed at supporting the objectives of the scheme and the industry's global competitiveness. MISG brings together ministers from the DH, the Department for Business, Innovation and Skills and Her Majesty's Treasury, with senior industry executives, and usually meets twice each year.

These commitments are mostly incorporated in Chapters 1 and 2 of the scheme, although important details are reflected in the overall structure of the PPRS including the assessment of profit rather than price-fixing, rapid patient access in the market, and the right for manufacturers to determine prices at launch.

No other industrial sector invests more in R&D



Data source: ONS UK Business Enterprise Research and Development, 2007 and 2009 report

Chapters 1-2: UK-wide scheme, tendering and procurement

The scheme is explicit that it is the single, holistic UK pricing agreement across the UK, including the health departments of England, Wales, Scotland and Northern Ireland. The four health departments do not support additional or alternative initiatives by NHS organisations in respect of the pricing of branded, licensed NHS medicines in primary care. In secondary care, NHS bodies must comply with UK and EU 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.

NHS England will seek to end initiatives by NHS bodies to seek rebates for positive NICE appraised medicines.

The health departments of England, Wales, Scotland and Northern Ireland have committed to ensure the scheme is fully implemented and sustained throughout the NHS during the lifetime of the scheme.

Chapter 3: Status and membership

The scheme is voluntary and non-contractual. Companies can elect to join the 2014 PPRS. Any company not joining the scheme is automatically subject to the alternative statutory scheme, but the statutory scheme cannot be applied to any member of the voluntary PPRS.

Chapter 3 and related annexes set out the process for companies who wish to join the scheme or withdraw from it. The Secretary of State may also serve notice on a company where a member significantly fails to comply with the requirements of the scheme. In such circumstances, the company can appeal to the Dispute Resolution Panel.

The scheme applies to all branded, licensed health service medicines supplied by members for health service use, but does not apply to sales of medicines for supply on private prescription or other use outside the health service. It also does not apply to any medicine which cannot be prescribed in NHS primary care, or to dental anaesthetics or over the counter sales.

It does, however, apply to branded generics, vaccines, in vivo diagnostics, blood products, dialysis fluids, products supplied through tenders or central contracts, biotechnology products and biosimilars.

Chapter 4: Patient access and outcomes

A fundamental objective of the scheme is to improve outcomes for patients by improving access to and appropriate use of clinically and cost effective medicines. This is a commitment from the health departments of England, Wales, Scotland and Northern Ireland. There is a specific objective for England to encourage the NHS to promote the rapid adoption and diffusion of innovative medicines and treatments recommended by NICE.

The PPRS also reinforces commitments that exist already and other important commitments to help ensure patients can be prescribed innovative medicines.

The NHS Constitution 2012 gives patients the legal right to have access to medicines recommended

by NICE, and there is a statutory three month funding requirement for NHS implementation of NICE technology appraisal and Highly Specialised Technology (HST) guidance.

National guidance in NICE technology appraisals and HST evaluations takes precedence in full over regional or local guidance. The NHS will not seek to duplicate this activity, and there will be no further qualification, reinterpretation or modifications made to national guidance. The absence of NICE guidance is not in itself a reason for refusing funding.

NHS England has renewed its commitment to implementation of Innovation, Health and Wealth.

This seeks to improve NHS use of innovative medicines for the benefit of patients, including:

- Supporting the prompt implementation of NICE guidance
- Establishment with industry and other stakeholders of a NICE implementation collaborative
- Requiring that all NICE technology appraisal recommendations are incorporated into local formularies in a planned way within the required 90 days
- Publishing on a regular basis the Innovation Scorecard to track adoption of NICE technology appraisals at a local level

The DH also supports the establishment of written bilateral working agreements between the ABPI and both NICE and NHS England, along with a NICE Industry Council and an NHS England Industry Council.

The government holds NHS England to account for its commitment to innovation in the NHS England Mandate. This includes its support for research and development, and its success in promoting the rapid adoption and diffusion of innovative medicines, and to other commitments in the scheme.

These commitments are set out in Chapter 4 of the scheme, to which reference should be made for further information.

Chapter 5: Value based assessment

Background

The Office of Fair Trading proposed an evolution towards more value based pricing in 2007. Subsequently, the 2009 PPRS included steps to evolve the agreement in this direction. The 2014 scheme further embeds value assessment, together with additional initiatives for NICE to undertake a broader assessment of value in reviewing new medicines.

Under the Health and Social Care Act 2012, NICE is now established at arms length from the DH as a non-departmental public body. This means that ministers can set the framework and objectives for the work of NICE, including the scope of its activities. However, NICE is responsible in most instances for determining its methods and processes for implementing the framework determined by government.

In June 2013, NICE was given new Terms of Reference to implement value based assessment further by introducing a broader definition of value. Sometimes called the 'blue print'. This can be found on the [NICE website](#).

Under these terms of reference, NICE has been asked to include a broader definition of value incorporating both Burden of Illness and Wider Societal Benefits in its assessments. In line with its constitution, NICE is consulting with stakeholders on how to implement this new mandate for England and Wales. The new approach is expected to be implemented in revised methods and processes after public consultation in autumn 2014.

Until now, the primary systematic criterion for NICE assessment of value was an economic approach known as 'Quality Adjusted Life Years' (QALY). The QALY range ('threshold') was indicatively set at £20,000-30,000 per QALY, although this could be adjusted informally with judgement on other aspects and explicitly in the case of an uplift reflecting End of Life considerations. The new approach is expected to make Burden of Illness, Wider Societal Benefits and related considerations more transparent, systematic, consistent and predictable.

The indicative QALY range has not been increased, even for inflation, since the inception of NICE in 1999. **The 2014 PPRS commits to maintaining the QALY threshold range unchanged for the full five year duration of the new agreement.**

The 2014 PPRS is explicit that NICE will not negotiate or publicly set or publicly indicate prices.

There is also an explicit agreement for NICE, the DH and the ABPI to work together further to consider issues concerning the constitution and functioning of Evidence Review Groups, and the use by NICE of unlicensed medicines or indications as comparators in its assessment of new medicines.

Flexible Pricing and Patient Access Schemes

The new scheme retains the option for companies to propose Flexible Pricing or a Patient Access Scheme.

Flexible Pricing is where a scheme member can apply for an increase or decrease to a medicine's original list price in light of new evidence or a different indication for use being developed.

Patient Access Schemes are proposals that can facilitate patient access to a new medicine where

NICE's assessment of value, on the current evidence base, is unlikely to support the company's proposed list price. A Patient Access Scheme can only be proposed by the company, and there are both simple and complex schemes. Complex schemes may include, for example, free stock, dose capping or schemes based on patient outcomes.

Full details of the principles agreed for such schemes are set out in Chapter 5.

Chapter 6 & Annexes: PPRS Payment Mechanism

Recognising the current state of the global economy and the financial challenges facing the NHS, the DH and the ABPI have agreed to introduce a limit on growth in the overall cost of the branded medicines purchased by the NHS from members of the scheme during 2014-2018. This provides government surety on the level of NHS expenditure during this period of austerity.

In outline, industry has agreed to hold the branded medicines bill (as measured by scheme members' sales) flat for 2014 and 2015. Permitted growth in the last three years of the scheme is 1.8%, 1.8% and 1.9%. These growth levels are fixed. Retrospective quarterly cash payments will be paid to the DH if expenditure exceeds the permitted level.

The DH and the ABPI have agreed a joint forecast of expected growth in the branded medicines bill and new products launched after January 2014. From this the estimated growth rate above the agreed levels can be estimated. This is converted into percentage payments for each company. For 2014,

companies will make quarterly payments of 3.74%. In subsequent years, the actual percentage growth will be reviewed versus the forecast, and the initial estimates of payment percentages for the future years will be adjusted to reflect actual percentage growth, actual use of new products, any over or underpayment from the previous year, and a revised forecast percentage growth for the following years. Scheme members will be advised of the percentage payment for the following year in the fourth quarter of the previous year, for planning purposes.

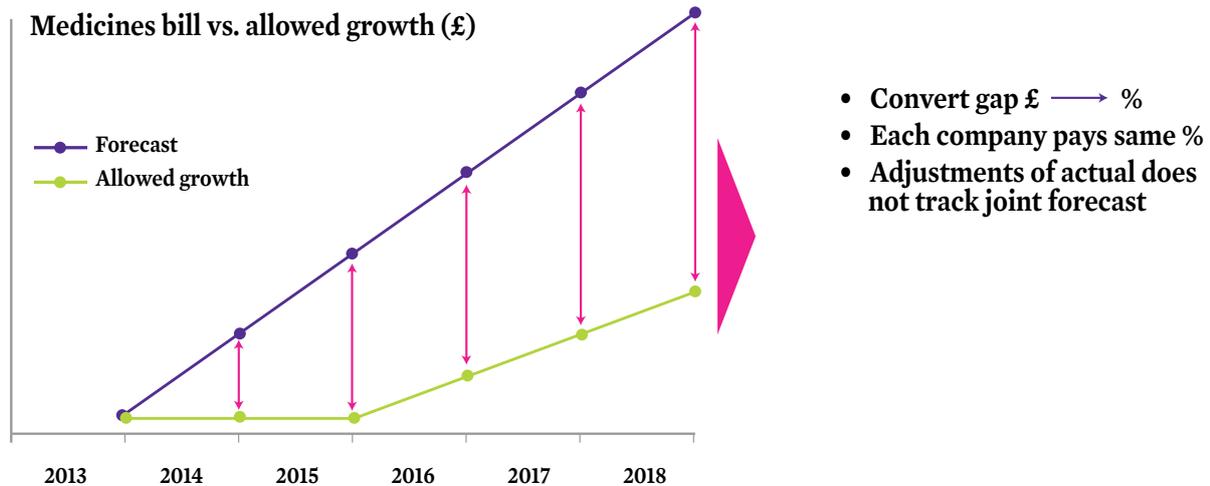
The percentage payments apply to products on the market at 31 December 2013, with some exemptions. This means that new products launched after 1 January 2014 are not subject to PPRS payments. All companies will pay the same percentage payment.

In the last year of the scheme (2018), the payment percentage will be based on the forecast percentage growth calculated at the end of the previous year, and there will be no adjustment and/or payment to reflect the actual percentage growth in the last year. In this

In recognition of austerity a payment scheme has been agreed

	2014	2015	2015	2017	2018
Allowed growth (YoY growth %)	0%	0%	1.8%	1.8%	1.9%
Agreed joint forecast (YoY growth %)	3.87%	3.52%	3.85%	2.14%	3.09%
Estimated payment percentage	3.74%	e 7.13%	e 9.92%		
		(depending on actual med bills growth)			

Illustration of the mechanism



way, both industry and the DH share the risk of over or underpayment in the final year, and this avoids a long ‘hangover’ effect at the end of the scheme.

Quarterly payments by companies are made on net sales to the NHS of branded medicines, ie. after any other discounts already given. Following the end of the calendar year, there will be an independent audit of each company’s audited annual sales report for that year.

Sales subject to payments include most central procurements. Exceptional central procurements outwith the normal annual pattern of NHS prescribing – such as national stockpiles for the security of the nation, or pandemic preparation – will not be included in calculations for growth in branded medicines expenditure. Procurements of centrally supplied vaccines are also excluded from growth calculations. Parallel imports are not included in measurement of sales since they are not supplied to the NHS by the scheme member.

Smaller companies with sales to the NHS of less than £5m in the previous calendar year are exempt from payments, and this cost will be absorbed by the DH.

All these matters are set out in detail in Chapter 6 of the scheme and annexes.

Industry does not consider this arrangement to be comparable with ‘cap and rebate’ systems operating in some EU countries for several reasons: this is a five year agreement with permitted growth levels fixed for the full five years, securing a level of predictability not reflected elsewhere; new products introduced after 1 January 2014 are exempt from payments consistent with UK objectives to support innovation; there are exemptions for smaller companies; and unpredictable

medicines bill expenditure – such as parallel imports and certain central procurements – are excluded from measurement and payment.

Statutory scheme

The PPRS payment mechanism summarised above applies only to members of the 2014 PPRS. Any company not in membership of the PPRS is automatically subject to the reserve statutory powers, ie. the statutory scheme. This is cited as the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013, Statutory Instrument No 2881. It can be found on the [legislation.gov.uk website](http://legislation.gov.uk).

There is no direct comparison between the voluntary and statutory schemes. The statutory scheme is a method of price control, not profit control. It does not provide five years’ stability since it can be revised by government at any time.

The current statutory scheme imposes a list price cut of 15% on products and companies covered by this scheme. There is no option for companies to modulate prices, and the price cut applies to each presentation (pack/strength etc) of the medicine. There is, however, an exemption for very low cost presentations where the list price is less than £2.00. There is also an exemption for companies with sales to the NHS of less than £5m.

The current statutory scheme price adjustment is a list price cut, not a net price cut. The DH has indicated its intention to review this matter with a view to imposing a net price cut.

The statutory scheme does not apply in any circumstances to members of the PPRS scheme.

Chapters 7-9: Pricing and profit regulation

The underlying basis of the PPRS has been established for over 50 years and, as a result, three chapters of the 2014 PPRS have not changed much.

Chapter 7 of the 2014 PPRS relates to overall pricing matters. Chapter 8 relates to levels of allowances permitted on levels of expenditure by companies which are included in assessment of profit achieved on sales to the NHS of branded medicines, and Chapter 9 relates to information required and assessment of such information.

The basis of the PPRS is a limit on the level of profit which companies can make on sales of branded medicines to the NHS. In recent years, the profit limit has been set in line with comparable research-intensive industries. This is a permitted return of 21% on capital employed at historic net book value, Return on Capital (ROC) and is unchanged in the 2014 scheme. Companies can alternatively choose to be measured by Return on Sales (ROS), at a level intended to be directly comparable to the ROC limit. In fact, the majority of companies in the PPRS choose to be measured by Return on Sales.

Within either limit, companies are permitted to determine or change prices in line with commercial considerations, including pricing of competitors, or assessment of value by NICE. Companies are also free to offer or withdraw discounts at any time subject, in certain circumstances, to agreement by the DH. This is a positive traditional strength of the PPRS: measuring profit retrospectively maximises commercial and competitive behaviour by companies, but does not guarantee profit.

Regarding discounts, companies are required to notify the DH if they intend to reduce or remove discounts to hospitals as a change in policy in all or the majority of the UK other than discounts that result from a competitive tender. Companies are also required to discuss with the DH any change to overall discounts available in primary care by a change in distribution practice.

Allowances

The DH sets a limit on what costs will be allowed for the purposes of assessing profit. There are fixed percentages for what will be allowed in expenditure for purposes of profit assessment on: R&D, manufacturing costs, costs for information provision including statutory information requirements, costs for promotion (sales, marketing) and costs for general administration. These allowances have not been changed in the 2014 PPRS.

Profit target

Since the PPRS is not a guaranteed profit scheme, companies should not be penalised if they introduce a new, clinically and cost effective medicine which finds high acceptance by patients and prescribers. Equally, companies are not guaranteed a continuing profit level if sales decline under normal commercial circumstances. In recognition of this, the PPRS provides an element of flexibility in assessing company profitability. This is called the Margin of Tolerance (MOT).

The 2014 scheme builds on previous measures in this regard. A company may be permitted to retain up to 50% additional profit before making additional payments to the government for excessive profits. In turn, no company will be permitted any price increase to address lack of profitability unless its profits have fallen below 50% of allowable profit.

Pricing of new medicines

New medicines launched in the UK following the granting of an EU or UK new active substance marketing authorisation may be priced at the discretion of the company on entering the market. Line extensions relating to such medicines, granted on the basis of an abridged application, may also be priced at the discretion of the company provided that the application to market the line extension has been submitted to the appropriate licensing authority within five years of the grant of the original authorisation.

Modulation

The PPRS allows price neutral modulation across the portfolio from 1 March 2014 of presentations on the market on 31 December 2013. This means that companies may adjust NHS list prices up or down to respond to commercial needs as long as the overall effect is neutral.

There are certain restrictions on the opportunity to modulate or remodulate prices which are set out in Chapter 7. There are also information and monitoring processes which apply to companies which opt to modulate NHS list prices.

Annual financial return

In the 2014 PPRS, there are already quarterly sales reporting requirements for companies with NHS sales in excess of £5m per annum subject to the PPRS Payment Mechanism.

For monitoring profit assessment, companies are also required to submit an Annual Financial Return (AFR) to the DH. This applies to companies with NHS home sales in excess of £50m per annum. This threshold for smaller companies to be exempt from annual reporting represents an uplift from £35m in the 2009 PPRS.

Chapter 10: Other matters

Companies are expected to follow good commercial practice in the distribution of their products. Members may offer or withdraw competitive trade discounts at any time, and may determine individually how to distribute their products.

However, any company that intends to change its overall distribution arrangements will notify the DH at least four months in advance. The DH will

also collect information on sales to retail pharmacy and monitor any changes to the supply chain. If any changes have an adverse net effect on NHS expenditure, then the DH and the company will discuss and agree adjustments.

This chapter also refers to best practice in the notification of product discontinuations, and the notification and management of medicines shortages.

Chapter 11: Dispute Resolution

It is intended that the DH and individual scheme members will seek to resolve issues by discussion. Nevertheless, significant issues may be referred to the dispute resolution procedure by either the company or the DH.

The Dispute Resolution Panel comprises of three members: A chairman appointed by the Secretary of State who should ideally be a solicitor or barrister, or a person with experience of mediation or dispute

resolution, and two additional members, one appointed by the Secretary of State and the other by the ABPI.

The process and timelines for dispute resolution are set out in Chapter 11.

Next steps

Whilst the 2014 PPRS has many similarities to previous schemes, the payment mechanism is new and very different. Companies will submit quarterly sales reports to a third party at the same time as the reports go to the DH. The third party will report aggregated data to the ABPI. This will allow the ABPI to report back to companies the total growth rates in the branded medicines bill and whether they are tracking to the forecast.

The agreement to manage the branded medicines' bill of scheme members in this way provides an opportunity to tackle the issues in the UK system. These include enhancing the value assessment

process used by NICE to reflect value better and improve the level of recommendations by NICE, to improve the low and slow patient access to newer medicines in the NHS, and also to address inconsistency in use of clinically and cost effective medicines in the NHS (so called postcode prescribing).

The next five years provides an opportunity to address these challenges, so that patients can benefit from greater use of newer medicines and clinicians are enabled to prescribe the medicines they believe to be best for their patients.

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