

Spotlight on pharmaceutical pricing regulation

The UK pharmaceutical pricing landscape

At a time of extreme financial pressure on the health service, the tension between providing medicines at an affordable cost and the need to fund the development of innovative and increasingly sophisticated medicines is particularly acute. In this series of notes we look at the current state of pharmaceutical pricing regulation in the UK and consider changes on the horizon.

There are a number of strands to the regulation of pharmaceutical pricing in the UK.

- The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary scheme negotiated between the Government and the Association of the British Pharmaceutical Industry (ABPI) and covering by far the majority of branded medicines sold to the National Health Service.
- In parallel to this, there is an alternative, statutory scheme, also focusing on branded medicines. Manufacturers and suppliers of branded medicines to the NHS are obliged to participate in this statutory scheme if they do not wish to participate in the PPRS.
- Competition law applies to both generic and branded medicines.
- The control of generic pricing, has traditionally – and most would say very successfully – been left to the market, subject to competition law controls. Recent headline cases involving dramatic increases in some generic prices have, however, prompted the Government to develop new plans for generic price regulation.

Our ‘Spotlight on pharmaceutical pricing regulation’ series examines each of these strands and discusses expected future developments.

Contents

The Pharmaceutical Price Regulation Scheme

The statutory pharmaceutical price regulation scheme

Generic prices

The impact of competition law on pricing

Focus on future developments

Further information

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The Pharmaceutical Price Regulation Scheme

The Pharmaceutical Price Regulation Scheme (PPRS) is a self-regulatory scheme covering branded medicines supplied to the National Health Service (NHS). Companies in the scheme account for about 90% of branded medicines supplied to the NHS. The PPRS sets out to cap the NHS branded medicines bill at a time of severe financial pressure on the health service. It does this principally by requiring life sciences companies to make payments 'back' to the NHS if growth in NHS spend on branded medicines supplied by PPRS members exceeds an agreed percentage. This is combined with price and profit restraints. The PPRS's stated aim is to strike a balance between keeping the NHS drugs bill affordable and encouraging investment in research and innovation. Members therefore have more freedom of pricing in relation to products containing new active substances (although they are expected to follow NICE guidelines), and sales of products containing new active substances are excluded from the sales on which the payment back is calculated. The current PPRS runs from 01.01.2014 to 31.12.2018 and supersedes all previous PPRS schemes. It differs substantially from previous schemes, which imposed price adjustments but did not include a payment mechanism of the kind described above. The PPRS has not been as successful as the Government hoped in delivering savings to the NHS, and it is now legislating to address this issue (please see our note: [Focus on future developments](#)).

A voluntary scheme

The PPRS is negotiated between the Department of Health (the Department) and the Association of the British Pharmaceutical Industry (ABPI), representing the innovative biopharmaceutical industries, but it is also open to non-ABPI members. Members join by consent and may leave by giving three months' notice. Although it is a voluntary, non-contractual scheme, members are subject to directions and regulations issued by the Secretary of State, who may exclude a member from the PPRS, for example if it has entered into arrangements designed to reduce the amount of sales subject to the scheme or has otherwise failed to comply. The PPRS is currently reported as having about 160 members.

Medicines covered

The PPRS applies to branded health service medicines supplied by scheme members. 'Health service medicine' refers to any medicinal product used to any extent for the purposes of the NHS in any part of the UK, including services provided pursuant to the public health functions of the Secretary of State. This includes, for example, medicines prescribed by GPs, medicines used in hospitals and medicines used in vaccination and screening services. A 'branded' medicine is an authorised medicine which has a brand name that identifies the product without reference to the generic title, INN or equivalent and includes, for example, branded generics. Exclusions include private prescriptions and other non-health service use, dental anaesthetics and over-the-counter (OTC) products except where OTC products are prescribed on the NHS.

The PPRS payment mechanism

The PPRS payment mechanism is at the heart of the PPRS scheme. It aims to ensure that growth in NHS spend on branded medicines supplied by PPRS members does not exceed an agreed percentage (the 'allowed growth rate') in each year of the PPRS. It does this by requiring PPRS members collectively to pay an amount corresponding to the excess back to the Department.

The allowed growth rates for each year were agreed at the outset and will not change (see table).

Allowed growth rates:

| 2014 | 2015 | 2016 | 2017 | 2018 |
|------|------|------|------|------|
| 0% | 0% | 1.8% | 1.8% | 1.9% |

Calculating each member's payment back

Based on data from PPRS members, actual NHS spend on qualifying medicines within the PPRS scheme is measured (Measured Spend). Measured Spend includes both products that were on the market at the start of the current PPRS on 01.01.2014 and also new products launched on or after that date.

The intention is that, in any year, the total of the payments back by all PPRS members should add up to the difference between the allowed spend and the actual Measured Spend. The Department publishes a percentage figure (the PPRS Percentage), which each PPRS member must apply to its own sales to calculate the amount it must pay back (its PPRS Payment). However, in order to encourage innovation, products containing new active substances introduced after 31.12.2013 are excluded from the sales on which a member's PPRS Payment is based – i.e. members exclude sales of products containing new active substances when applying the PPRS Percentage.

It can be seen from the above that the PPRS Percentage is applied uniformly to each individual PPRS member's relevant sales regardless of the actual growth (or indeed decrease) in their own sales. Companies which do not have many products containing new active substances bear a greater burden.

Forecasts and adjustments

In practice, PPRS members pay on the basis of forecasts which are then revised in the next year, resulting in adjustments. No adjustment will be made at the end of the final year.

Current PPRS Percentages

The table below shows the PPRS Percentages for 2014, 2015, 2016 and 2017 and the range within which it is expected to fall in 2018. These figures incorporate revisions agreed between the Secretary of State and the ABPI in December 2016 clarifying the way in which spending under the Cancer Drugs Fund is treated by the Scheme:

| 2014 | 2015 | 2016 | 2017 | 2018 |
|-------|--------|-------|-------|-------------|
| 3.74% | 10.36% | 7.80% | 4.75% | 2.38%-7.80% |

It can be seen from these figures that the percentages are falling whereas the initial estimates suggested that these percentages would rise steadily as an increasing proportion of Measured Spend was accounted for by new products in the later years.

Pricing of products

The PPRS also includes a wide range of specific rules about the pricing of individual products. PPRS members may not generally increase the NHS list price of a PPRS product without Department approval, which will only be given if the member's profits are below certain thresholds. The main exceptions to the need for approval are the 'flexible pricing' and modulation options (described in our more detailed review of the PPRS [click here](#)). By contrast, members may price new active substances as they wish, although it is assumed that they will keep to NICE guidelines. Such 'freedom of pricing' also applies to line extensions of new substances based on abridged applications submitted within five years of the grant of the original marketing authority. The price of other new products requires Department approval.

Information requirements

Any PPRS member with total home sales of NHS medicines of £50 million or more in its financial year must provide an Annual Financial Return (AFR) to the Department detailing sales, pricing and other financial information. The Department selects 20% of qualifying PPRS members for submission of a full, independently reviewed AFR; others are required to provide short form data.

Enforcement

Fines are payable for contravention of the directions and regulations issued under the voluntary scheme.

Future developments

The PPRS has not been as successful as hoped in delivering savings to the NHS and the Government is now legislating to address this issue. The legislation will enable it to amend the alternative statutory scheme to 'level the playing field' between this statutory scheme and the PPRS in a bid to try to stop companies moving out of the PPRS and into the statutory scheme. (Please see our notes: [The statutory pharmaceutical price regulation scheme](#) and [Focus on future developments](#).)

[Click here](#) to read our more detailed review of the PPRS.

The statutory pharmaceutical price regulation scheme

The statutory pharmaceutical price regulation scheme runs in parallel to the better-known Pharmaceutical Pricing Regulation Scheme (PPRS) (see our note on the PPRS). Both schemes relate to the regulation of branded medicines supplied to the health service, but whereas the PPRS is a voluntary scheme agreed between the Government and the pharmaceutical industry the statutory scheme is for those manufacturers and suppliers which choose not to participate in the PPRS. These manufacturers and suppliers are obliged to comply with the statutory scheme. The regulations governing the statutory scheme are set out in the Health Service Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008/3258.

Medicines covered

The statutory scheme applies to prescription-only, branded medicines.

Price control

The statutory scheme currently provides for a fixed 15% cut on list price coupled with a price freeze based on sales prices as at 01.12.2013.

Exclusions

The 15% cut does not apply to manufacturers and suppliers with sales of branded health service medicines of less than £5 million in the previous calendar year or to products supplied under certain framework agreements under the Public Contracts Regulations 2006. Products priced at less than £2 on 01.12.2013 are also not subject to the cut.

The Secretary of State may exempt a product from the price restrictions for a period if he considers this is necessary to ensure adequate supplies of the product to the health service. He may also increase the maximum price permitted for a particular product either on his own initiative or on application by the manufacturer or supplier. Such an application must be accompanied by sales figures and other financial information including promotional and research and development costs and profits.

New products

In the case of new products – which had no price on 01.12.2013 – the Secretary of State can prescribe a maximum price taking a range of factors into account. A new product includes any new presentation of a product, for example where there are changes in the strength or excipients, different pack sizes or types of packaging, new clinical indications or methods of administration or formulation. The factors to be taken into account when prescribing the maximum price include the cost of therapeutically equivalent medicines, the cost of manufacture and prices elsewhere in the world, research and development costs, and whether the medicine contains a new active substance.

Information requirements

Members of the statutory scheme which make UK sales income on branded health service medicines in any year must also provide sales and pricing information about the products sold to the Secretary of State.

Enforcement

Fines are payable for contravention of the directions and regulations issued by the Secretary of State under the statutory scheme.

The future of the statutory scheme

A consultation on changes to the statutory scheme published by the Department in September 2015 indicated that the statutory scheme produces lower savings for the health service than the PPRS and that the gap is expected to widen. Relevant factors here include that the statutory scheme does not include a payment mechanism similar to that in the PPRS and that the list price to which the 15% cut is applied does not take discounts into account. In addition, the consultation points out that no savings are made in the statutory scheme on new products launched post December 2013 whereas spend on new products is included within the calculation of the PPRS Percentage. It appears that some companies are choosing to join the statutory scheme in order to make savings; the Government's response to the consultation indicates that since the PPRS began, a total of £157m of sales have moved from the PPRS to the statutory scheme. The current forecast for the income for England from the PPRS for 2016/7 is £440 million, revised down from a forecast of £518 million. Income for 2015/16 was £629 million.

The Government wishes to level the playing field between the two schemes to discourage companies from moving out of the PPRS and intends to introduce a payment percentage similar to that in the PPRS into the statutory scheme; it believes this will deliver the largest savings for the NHS. The industry had questioned the Secretary of State's powers to introduce such a statutory payment mechanism, and this point is now being clarified through legislation. The Government has published draft regulations on an amended statutory scheme and intends to carry out a further consultation on the level of the payment percentage in the new statutory scheme before detailed regulations are adopted. It also indicates that in a new statutory scheme the PPRS Percentage would be applied to both old and new products. It expects the changes to take effect during 2017/18 at the earliest.

A further potential issue here is that if the PPRS and statutory schemes become very similar then a question inevitably arises about whether it is worth having two schemes at all; statements by the Government during the parliamentary debates have suggested that this issue may be considered later raising the possibility that potentially the PPRS may be phased out in favour of statutory regulation at a future date.

Generic prices

The prices of branded medicines supplied to the National Health Service are specifically regulated under the voluntary Pharmaceutical Price Regulation Scheme (PPRS) and the parallel statutory scheme (Please see our notes: [The PPRS](#) and [The statutory pharmaceutical price regulation scheme](#)). Generic medicines (other than 'branded generics') are not included in these schemes.

The price paid by the NHS for generic medicines under the NHS Drug Tariff is usually set by reference to market prices for the drug in question. Pharmacists dispensing these medicines to fulfil NHS prescriptions buy them in the market and are reimbursed under the Drug Tariff. This results in price competition as pharmacists look for the best price. The Department relies on this market competition to keep generic prices down.

Recent focus on increases in generic prices

Recently, however, there has been increasing media and government focus on cases where generic suppliers have 'hiked' the price of older generic drugs for which there appears to be little competition in the market. A study by academics at the London School of Hygiene and Tropical Medicine and Liverpool University also suggested that the price of some generic drugs has been steadily rising over recent years. A recent headline example was that of Pfizer and its UK distributor, Flynn Pharma, relating to price increases for the generic anti-epilepsy drug, phenytoin sodium. The drug, which was previously sold under the brand name Epanutin and is reported to have been loss making, was 'de-branded' meaning that it fell outside the PPRS and statutory schemes described above, and enabling significant price increases (of reportedly up to 2600%) to be made. In December 2016 the UK Competition and Markets Authority (CMA) held that Pfizer and Flynn had abused a dominant position on the market for phenytoin by charging "unfair and excessive" prices; it issued its biggest fine ever (£84.2m) against Pfizer and a further fine of £5.2 million against Flynn. The case is currently on appeal to the Competition Appeal Tribunal, but similar cases relating to other generics are in the pipeline at the CMA. In cases where market forces are not effective, competition law in relation to excessive pricing currently provides the only real mechanism for restraining prices. However, CMA cases can take a significant period to resolve, and involve uncertainty.

New legislation to address the issue of generic pricing

In response to this the Government is now legislating to enable the Secretary of State to limit the prices of unbranded generic medicines across the board: this closes a 'loophole' in the current arrangements whereby it is unable to control unbranded generic prices of companies which are members of the voluntary PPRS. The feeling is that high profile cases such as Pfizer and Flynn, where companies have been able to 'hike' the price of some generic medicines outside the PPRS have shown that the current arrangement whereby unbranded generic prices are basically controlled by the market and by competition law is not effective to keep down prices. The Bill paves the way for the Government to take direct action in relation to excessive price increases on unbranded generics. It has said that it intends to use this power only where there is no competition in the market and companies are charging the NHS an unreasonable price.

Information requirements

The Government collects pricing information about some generic medicines on a voluntary basis for use in setting the reimbursement price. However, not all manufacturers, wholesalers and suppliers participate so that the information does not cover all sales of generic medicines. The Government is now legislating to require all parts of the supply chain to keep, and supply to the Secretary of State on request, information on sales and purchases of health service medicines (please see or note [Focus on future developments](#)). This is to enable more informed decisions on reimbursement to be made and to help in evaluating the efficiency of health service medicines supply pricing arrangements.

Competition law

The enforcement of competition law in respect of pharmaceutical pricing has never been more prevalent in the UK and EU than it is now. It is therefore important that businesses take competition law into account when assessing prices, whether for branded or generic products.

Competition law broadly prohibits anti-competitive pricing practices, but whether or not pricing is anti-competitive in any particular circumstances can be a little (and sometimes very) difficult to ascertain. A simplistic set of questions that businesses should ask themselves when setting prices are as follows:

- Am I independently setting my own price?
- Am I dominant in the market for the pharmaceutical product in question and if so:
 - Is my price too low?
 - Is my price too high?
 - Is my price structure appropriate?

We look at each of these questions in turn.

Am I independently setting my price?

This question touches on at least two types of competition law infringement:

- cartelisation/information exchange; and
- resale price maintenance.

Agreeing prices with competitors, or exchanging price information in such a way that prices might ultimately be deemed to be the result of collusion with competitors should absolutely be avoided, with almost no exception. Do not do it, and if you are thinking of doing it or have done it, ensure you seek advice immediately.

Resale price maintenance, which as the name suggests is fixing a price or a price floor for onward sales of product by resellers should also be avoided. An infringement can give rise to liability both on the part of the manufacturer mandating the price and the reseller which acquiesces to such price fixing.

Am I dominant in the market for the pharmaceutical product?

Aside from the price fixing elements above, competition law tends not to bite on the pricing decisions of entities that are not dominant in a market. The assumption in cases where an entity is not dominant is that the process of competing will tend to ensure a market price is charged. A key stage in deciding whether further deliberation from a competition law perspective is required is whether an entity is dominant. In pharmaceutical cases this will tend to focus initially on the therapeutic substitutability of the product in question with other products, but will typically then progress to involve an assessment of myriad factors including prescribing patterns, potential entry and exit and any arguments in relation to countervailing buyer power.

It would be prudent to exercise caution, and to take into account the following risks when setting prices for any product that has a strong market position/is subject to weak competition constraints.

Is my price too low?

If you are dominant it is unlawful to engage in so called 'predatory' pricing practices. These are prices so low that the only credible rationale for them is to drive competitors from the market. Although actually establishing whether a cost is predatory can be difficult depending on the circumstances, the crux of the test focuses on whether the entity in question is selling at below cost and/or whether there is some demonstrable anti-competitive intention.

Is my price too high?

Excessive pricing was a relatively infrequently cited competition law infringement. But now there are at least two excessive pricing cases making their way through UK competition institutions. These will no doubt provide further helpful guidance on when a price can properly be considered excessive. Ultimately the traditional test that it is a price that "has no reasonable relation to the economic value of the product" is probably not that helpful. Certainly companies that are or may be considered dominant should exercise considerable caution and take advice if engaging in large price increases.

Is my price structure appropriate?

Here we are thinking primarily about rebates i.e. the refund of part of the price paid for a product, most often based on the volume of purchases made in a particular period. As with predatory pricing the concern here is the exclusion of competitors, in this case because of the so-called 'suction effect' that rebates can have. This is a notoriously difficult area of competition law, but as a starting point there is a three- fold test:

1. If the rebate merely reflects savings based on the volume of products purchased it is assumed to be unproblematic;
2. If the rebate is contingent on exclusivity (aka loyalty) it will be presumed to be anti-competitive; and
3. All other rebates- where the effect of the rebate on competition needs to be considered to determine whether customers are locked in by rebates in such a way that competitors may find it difficult to compete.

We might also in this context consider price discrimination, which has broadly been described as applying "dissimilar conditions to equivalent transactions". In fact unlawful price discrimination can take a number of different forms:

- exploitative practices, such as bundling and tying where popular products are sold with less popular products;
- geographic price discrimination (charging different prices in different markets) which might give rise to issues from an EU single market perspective, and

- exclusionary price discrimination, for example margin squeeze- where a low price for key inputs is charged to downstream group companies and a high price is charged to competitors of the downstream entity such that these competitors find it difficult or impossible to compete.

Conclusion

The above is no more than a whistle stop tour of the key issues that may arise from a competition law perspective when setting the price of pharmaceutical products. This is a difficult area which can give rise to very significant liabilities. While in depth knowledge of every potential infringement is far from the day job of all but experienced practitioners in this area, it is certainly worth thinking about competition law in the price setting process and listening to instincts. Typically infringers of competition law might not know the offence that is being committed but a significant proportion have at least a suspicion that their actions might be problematic. If in doubt seek advice.

Focus on future developments

New legislation will clarify and extend Government powers to regulate pricing and require the industry to disclose more comprehensive pricing information. The legislation will impact companies at all stages of the medicines supply chain.

The legislation: The Health Service Medical Supplies (Costs) Bill 2017 (the “Bill”)

What the Government hopes to achieve – branded medicines

The PPRS is not working as well as the Government had hoped

The current, voluntary Pharmaceutical Price Regulation Scheme (PPRS), which covers about 90% of branded medicines supplied to the NHS, was intended to cap the NHS branded medicines bill at a time of severe financial pressure on the NHS. Controversially, it requires participating life sciences companies to make payments ‘back’ to the NHS if growth in NHS spend on branded medicines exceeds an agreed percentage. This provides a high degree of certainty for the NHS but involves obvious risks for companies. However, it now transpires that the PPRS has not been as successful as the Government had hoped in delivering savings to the NHS. This is partly because some companies have chosen to move out of the PPRS and into the alternative statutory scheme, which does not involve such payments back and which produces lower savings for the NHS.

Closing the gap between the PPRS and the statutory scheme

The Bill will enable the Government to introduce a form of payment ‘back’ into the statutory scheme similar to that in the PPRS. The intention is to discourage companies from moving out of the PPRS. A further potential issue here is that if the PPRS and statutory schemes become very similar then a question inevitably arises about whether it is worth having two schemes at all; statements by the Government during the parliamentary debates have suggested that this issue may be considered later raising the possibility that potentially the PPRS may be phased out in favour of statutory regulation at a future date.

The Government has published draft regulations on an amended statutory scheme and will be consulting on these after the Bill has achieved Royal Assent.

What the Government hopes to achieve – generics

Recent media focus on increases in generic prices

Both the PPRS and the statutory scheme focus on branded medicines. Generic medicines (other than ‘branded generics’) fall outside these schemes. The Government relies on price competition to keep generic prices down, and this has generally worked well. Recently, however, there has been increasing media and Government attention on cases where generic suppliers are alleged to have ‘hiked’ the price of older generic drugs for which there is little competition in the market.

A recent headline example of this involved the anti-epilepsy drug phenytoin sodium; in this case the UK Competition and Markets Authority fined Pfizer (£84.2m) and Flynn Pharma (£5.2m) in respect of “unfair and excessive prices” charged for this drug. There have also been suggestions that the price of some generics has simply been steadily rising over the years without the dramatic ‘hikes’ that characterise such headline cases.

Limiting generic prices through regulation rather than competition

The new legislation will enable the Secretary of State to limit the prices of unbranded generic medicines across the board: this closes a ‘loophole’ in the current legislation whereby the Government does not have the power to regulate the unbranded generic prices of companies which are members of the voluntary PPRS. Closing this loophole paves the way for the Government to take direct action in relation to excessive price increases in unbranded generics. Again, the Government is expected to bring in regulations to achieve this after the Bill has passed.

What the Government hopes to achieve – information requirements

A new, comprehensive power

The Bill will introduce a comprehensive statutory power to require information from manufacturers, distributors and suppliers of both branded and unbranded products at all levels of the supply chain. Currently, some of this information is provided on a voluntary basis and is incomplete. The new power will, among other things, enable better market information about generic pricing to be collected in order to set a more accurate reimbursement price to pharmacies which dispense pursuant to NHS prescriptions and, potentially, to gain information needed to take action on excessive generic price increases.

Detailed and extensive information from all levels of the supply chain

The information which can be required is detailed and extensive including in relation to prices charged and paid, discounts and rebates, revenues and profits. Provision has been made for the protection of commercially sensitive information. Nevertheless, issues have been raised about whether regulations to be enacted pursuant to these provisions may prove overly burdensome and may represent an unjustifiable level of intrusion by Government. Draft regulations have been published, and the Government will be consulting on them after the Bill has received Royal Assent.

The devil in the detail?

In conclusion, the Bill is a short one and has been presented in some quarters merely as a “tidying up” measure. Life sciences companies will, however, wish to follow developments and make their views known to Government on the detail of the regulations to come.

This information is necessarily brief and is not intended to be an exhaustive statement of the law. It is essential that professional advice is sought before any decision is taken.

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