HSJ LOCAL briefing

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PRIMARY CARE REBATE SCHEMES

HSJ Local Briefing is our new in-depth analysis of the key issues facing the NHS's major health economies

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In brief

Issue Over the past three or four years, anecdotal evidence suggests a growing number of primary care trusts have been entering primary care rebate schemes with pharmaceutical companies to negotiate savings. HSJ set out to investigate the extent to which these schemes were being used, what form they took and the potential for them to contribute to savings on the primary care prescribing budget.

Context The schemes are controversial. The Department of Health is reported to have advised that they were illegal and a number of organisations have raised concerns about whether they contravene EU competition law or the Bribery Act. They could also be seen to undermine national pricing agreements between the DH and industry.

Outcome Data collected from 75 PCTs offers a snapshot of how primary care rebate schemes are being used across the country for the first time. It suggests just under a third of PCTs have such schemes in place although industry insiders insist it is closer to half. There is a widespread expectation use of this type of arrangement will increase as clinical commissioning groups look to make savings.

Introduction

Figures from the Information Centre for Health and Social Care show £8.8bn was spent on drugs prescribed in primary care in 2011, the vast majority of the NHS total spend on drugs. Unsurprisingly, the primary care prescribing budget has been a major target of the quality, innovation, productivity and prevention savings programme.

One of the ways in which primary care trusts can save money is through reaching agreements, often known as primary care rebate schemes, with pharmaceutical companies. Such schemes see the PCT receive a discount or other economic benefit when they use the company's drug.

The extent of their use and scale of savings potential is unclear while the ethical issues involved mean the deals remain controversial. A number of sources involved with PCT pharmacy have told HSJ the Department of Health has described the schemes as illegal.

More guidance on their use or otherwise could potentially emerge from ongoing negotiations between the DH and industry over the national pharmaceutical price regulation scheme and value based pricing. This briefing considers whether mounting financial pressures will mean we see more of these arrangements or ethical concerns will put pay to them once and for all.

Primary care rebate schemes: a definition

A primary care rebate scheme is an agreement between a PCT and a drug company that provides an economic benefit to the commissioner and, in theory, increases the volume sales of a company's product. Unlike national patient access schemes, which are a way of obtaining new drugs for patients more cheaply, primary care rebate schemes are for drugs already on the market that usually have a competitor product.

While national schemes are approved by the National Institute for Health and Clinical Excellence, with the backing of the DH, primary care schemes are approved locally by the organisation entering into it with no oversight. The first national scheme was set up in 2002, while local schemes first began to emerge three or four years ago.

Both local and national schemes have the effect of protecting the published price for the drug in the UK , known as the "list price", which is used as a reference by markets in other countries.

In primary care rebate schemes a PCT is charged the list price set out on the drug tariff for prescriptions, then the manufacturer provides a rebate based on an agreed discount price. Sometimes the rebate is provided only if a certain volume is used or the company achieves a specified local market share. Companies may also provide funding for resources such a specialist nurses in the disease area as part of the arrangement.

The national picture

Details on the number, type and potential of schemes are shrouded in secrecy due to the commercial confidentiality surrounding them. While companies may offer the same or similar discounts to a number of PCTs, any suggestion they were offering an NHS-wide discount could have an impact on the list price, with subsequent impact on their income around the world.

HSJ used Freedom of Information legislation to collect details from PCTs on the number of locally agreed patient access schemes they had in place.

PCTs provided information on the details of 44 schemes

- 34 per cent were best described as a rebate depending on volume use or market share.
- 63 per cent were unconditional rebates, essentially a straightforward discount.
- One scheme, operated by West Leicestershire CCG, involved the provision of a resource in the form of specialist respiratory nurses.

Of the 75 PCTs that responded, 30 per cent had such a scheme in place.

The mean saving per scheme was just over £9,000 in 2011-12.

This saving ranged from £328 for a prostate cancer drug scheme in North East Essex to £123,000 for a scheme in Hampshire.

Information on the disease area was not available for this scheme. Data on savings was unavailable from a number of PCTs either because they judged it exempt under the FoI Act or because they had not collected it. This reflects concerns that many schemes can be difficult to administer and monitor.

The large number of unconditional rebates is likely to reflect the difficulty of administering schemes which rely on market share as the data can be difficult to collect. As competition increases commissioners are likely to opt for this kind of scheme if it is available rather than a more complex alternative.

The most common disease area for schemes was cardiovascular, with a number of deals in place for atrial fibrillation, anticoagulants and stroke prevention. The responses on disease area can be viewed in a word cloud.

The South Central region had the most schemes in place, driven in large part by NHS Isle of Wight, which has 17 and is in discussions about setting up five more. Of those PCTs that did have schemes in place, three-quarters had two or three. No PCTs in London and Yorkshire and Humber, where 71 per cent and 50 per cent of commissioners responded respectively, had schemes set up.

The data obtained by HSJ presents a national snapshot of the incidence of primary care rebate schemes which appears to be the first time such information has been collected for publication.

However, some industry insiders

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believe the proportion of PCTs with rebate schemes in operation is likely to be closer to half and that the results could have been effected by different interpretations of the freedom of information request.

The controversy of such schemes

The variation between different PCTs reflects what former chair of the Primary Care Pharmacists Association Shailen Rao describes as a nervousness within some parts of the NHS about getting involved in commercial deals and a view of rebate schemes as "wheeling and dealing".

Many organisations are concerned about whether rebate schemes contravene EU competition law, procurement rules or the Bribery Act and feel guidance from the DH has been unclear.

A number of sources told HSJ the DH had described them as "illegal". The Dorset PCT cluster board agreed last September to adopt a "wait and see approach" and not to get involved in any rebate schemes for the time being due to concerns over their legality and an absence of national guidance.

Mr Rao added: "I think there is a psychological barrier and fear of falling foul of the law so someone can point the finger and say they have been unduly influenced... I think it's a lot to do with lack of commercial nous."

Mr Rao, who is managing director of consultancy firm Soar Beyond, provides advice to the NHS and pharmaceutical companies on medicines management, warned the data obtained by HSJ might not reflect the whole picture as many PCTs might not be aware of all the schemes they have in place.

Mr Rao added: "We have heard of companies sending rebates that go uncashed and when they enquire why they are told the PCT had not realised what it was for."

In London, PCTs had until late last year been advised against participating in these schemes by the NHS London Procurement Partnership. The partnership, which was set up by NHS organisations in the capital to provider procurement support, commissioned legal advice last year. This concluded that although the schemes were not unlawful, and were within the powers of both PCTs and CCGs to agree, they should be entered into with caution.

The partnership's pharmacy and medicines use and procurement lead for primary care Jas Khambh told HSJ the advice was commissioned because they had received a lot of queries on the issue from PCTs and CCGs.

She said: "With the QIPP agenda it's really difficult to ignore the savings you could achieve. Because there was no clear direction from the DH or anywhere, it was such a grey area, we decided to seek legal advice."

The partnership set out a list of principles, based on the advice from DAC Beachcroft, which commissioners are advised to abide by when entering into the schemes. These include:

Patients continue to be treated as individuals; acceptance of a scheme should not constrain existing local decision making processes or formulary development.

Before any consideration of price, the clinical need for the medicine and its place in care pathways should have been agreed by established local decision-making processes.

Ideally the rebate scheme should not be directly linked to requirements to increase market share or volume of prescribing.

The administrative burden to the NHS of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme.

Signing up to a scheme can involve switching cohorts of patients from one drug to another, the governance of which needs to be handled carefully. In the old system PCTs commissioned primary care and agreed these schemes. In the new system rebate schemes will be agreed by GP led CCGs, taking the deals a step closer to prescribers.

Ms Khambh stressed it should be the responsible officer for the statutory body signing up to the scheme, not the clinician, and agreed this conflict of interest could get more difficult to navigate with GP led CCGs.

Region	PCRS	% of PCTs that responded
South Central	20	67
East of England	13	71
North East	12	67
North West	7	50
South East Coast	7	38
West Midlands	5	41
East Midlands	2	33
South West	2	36
London	0	45
Yorkshire and Humber	0	50

However, she added: "It is likely the principles will evolve over time."

Peter Rowe, former DH QIPP lead for medicines use and procurement, agreed conflict of interest issues could be more challenging for CCGs than PCTs when they have the "prescribers on the board".

However, he said he viewed the schemes as positive, provided there was proper corporate governance, and had encouraged them while at the DH.

The national context

The fact that rebate schemes are being set up locally on an ad hoc basis and protected by commercial confidentiality makes it difficult to estimate the total savings potential.

National arrangements for the pricing of drugs in the UK are complicated. Most big firms sign up to the PPRS, which was first introduced in 1957 and essentially caps the profits they can make in the UK. The current scheme, agreed in 2009, is due to expire at the end of this year.

Negotiations between the DH and the industry for a replacement PPRS are ongoing, alongside discussions about the introduction of a value-based pricing system for new drugs. There is an opportunity for the government and industry to agree some principles on the operation of primary care rebate schemes as part of the discussions and include it in the next set of PPRS guidance.

Certainly there is a hope from some commissioners, such as Dorset, that guidance will emerge. There is a precedent in that the 2009 PPRS issued guidance on national patient access schemes for new drugs. However, the department's current position makes it unlikely this advice, if it comes, will be

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favourable.

In a statement a spokesman said: "We do not encourage these schemes. Whilst they may offer short-term savings to individual PCTs, in the longer term they can actually increase costs to the NHS as a whole.

"Making sure patients are given the most appropriate care and treatment for their individual needs is the priority. It is important the local NHS understands the potential such schemes have to distort these decisions."

In any case it would be difficult for the DH and industry to thrash out a national deal, which will likely involve some level of price cut, while explicitly supporting schemes that offer further reductions on a local level. It is in the government's interest as well as the industry's for the UK list price to remain high to maintain the profitability of UK pharmaceutical companies abroad.

Rebate schemes are also a tricky issue for the Association of British Pharmaceutical Industry which represents the sector in the negotiations but also has members who are offering primary care rebate schemes. One senior source described the attempt to maintain the UK list price as high while offering widespread discounts as a "façade".

The likelihood of more schemes in future

There is widespread expectation that the number and prevalence of these schemes will increase as primary care, like the rest of the NHS, faces a continuing financial squeeze. Ms Khambh told HSJ she had received numerous requests to share the partnership's legal advice with commissioners around the country.

A report to the Dorset PCT cluster's board last autumn noted the number of rebate schemes on offer from pharmaceutical companies was increasing. Mr Rowe, described it as a natural response "in any market where the customer is struggling" for providers to respond by lowering the price.

It would be awkward if the DH tried to block arrangements that contribute to the achievement of the centrally mandated QIPP agenda. However, its position seems unequivocal.

Whether the new PPRS guidance or value-based pricing will even address primary care rebate schemes is not clear as currently negotiations appear to be stuck on the high level issues. The easiest thing could be to avoid the issue, while the economic reality will drive a pragmatic approach, even among commissioners who have so far been reluctant to take part in rebate schemes.