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POUNDS, PILLS AND PRESSURES

WHY YOU EITHER LOVE OR LOATHE PRIMARY CARE REBATE SCHEMES

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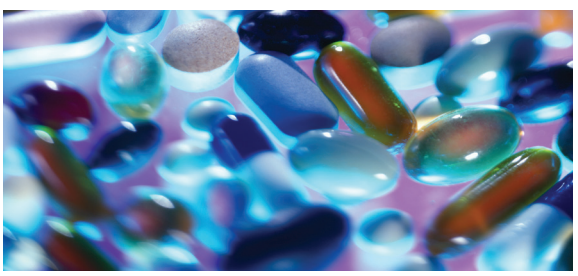

FOREWORD: SEEKING CONSENSUS

A quest for consistency

The Primary Care Rebate Scheme Consensus project has been developed to better understand attitudes to primary care rebate schemes across a variety of NHS stakeholders and define a position that is supported by the majority of respondents.

Uncertainty about primary care rebate schemes is fed by a lack of robust guidance regarding their implementation from Department of Health and the Association of the British Pharmaceutical Industry. As a consequence there are polarised approaches and a variety of implementation models seen across the UK.

Primary care rebate schemes provide an alternative method, which allows industry to deal with reference pricing, and by which costs of medicines to the primary care sector can be reduced within the constraints of the global pricing environment. They enable retrospective refunding of money back to the NHS, which can be used to invest in other aspects of patient care.

The variance in attitude towards rebates should be recognised by the DH and it is hoped that a clear definition of the consensus views of NHS professionals may provoke focus and guidance on this relevant topic.

For clinical commissioning groups, appropriate use of primary care rebates may offer a clear mechanism for the reduction of costs without compromising patient care or outcomes, in some cases allowing access to treatments that otherwise might not be affordable.

Inducement to prescribe

Adoption of rebate schemes is held back through lack of clarity and the absence of clear national guidance regarding their implementation. In addition, the practical aspect of managing a primary care rebate scheme often needs to be considered. Confusion also exists as to whether primary care rebate schemes constitute an inducement to prescribe and are therefore inappropriate.

Lack of clarity regarding current guidance leaves us in a position of confusion, with an emergent and unstructured approach to primary care rebate schemes, which may impact the equity of services around the UK.

As a consequence, PrescQIPP, the London Procurement Partnership and Greater Manchester Medicine Management Group have all set local policies regarding primary care rebate schemes, which delivers some consistency within their geographies and reduces duplication of workload.

Either the DH or the ABPI should define a framework for primary care rebate schemes. We realise the ABPI and DH will find it hard to give guidance but in the absence of this clarity, consensus among healthcare professionals may define a way forward. ●

Kevan Wind is medicines procurement specialist pharmacist, London and East of England.

THE MONEY AND THE MUDDLE IN BETWEEN

If rebate schemes have the ability to help commissioning support groups reduce costs, why aren't they all doing it? The answer, in part, is a lack of support

The NHS faces massive financial pressures over the next few years and is looking to make savings and improve care wherever it can. GP-prescribed medicines account for nearly £9bn of spending each year.

Not surprisingly, many primary care trusts and now clinical commissioning groups have devised QIPP schemes which look at reducing this cost without affecting the quality of patient care. Many see this in terms of reducing the overall volume of prescribing, restricting or discouraging the prescribing of some high cost medicines and opting for lower cost alternatives – such as generics.

But are there others ways to cut this bill without impacting on patients? Many hospitals pay less than the list price for drugs through negotiations with suppliers and the National Institute for Clinical Excellence has approved patient access schemes which allow access to medicines at a substantially lower cost to the NHS.

But schemes which could reduce the cost of prescribing in primary care are much less common – and more contentious. Pharmaceutical companies are often reluctant to reduce the price of medicines nationwide because the UK is used as a reference point by other countries: reducing the price in the UK can have far wider repercussions.

But they are aware that some medicines can appear expensive – for example, when compared with others in the same field – and may therefore not be being used very much.

So it is not surprising that, given the pressure on prices in primary care and the difficulties some companies have in reducing UK prices, pharmaceutical companies have developed primary care rebate schemes. These don't affect the headline price for medicines but do allow CCGs to benefit from rebates which effectively reduce the price they pay.

Lukewarm reception

HSJ reported earlier this year that around 30 per cent of CCGs have taken advantage of these schemes, with savings ranging from a few hundred pounds to over £100,000. Typically, a CCG will be charged the normal list price for the medicine but will have an agreement with the manufacturer which reduces the cost through a rebate. These agreements are negotiated locally, although some areas have a region-wide assessment process in place.

'If this is the only way that the effective price of medicines can be reduced, people in the NHS feel they should be willing to accept it'

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Nearly two thirds of the schemes offered a straight rebate not related to the volume of the medicine prescribed, although a few are related to target volumes prescribed or are on a sliding scale with the rebate increasing as more is prescribed.

Not surprisingly, some CCGs find this attractive. Kevan Wind, medicines procurement specialist pharmacist for London and the East of England, says: "The best way would be to reduce the cost price of the drug but there are difficulties with reference pricing and that means that it is not always commercially attractive to the industry. So they offer other schemes.

"If this is the only way that the effective price of medicines can be reduced then people in the NHS feel they should be willing to accept it."

CCGs can reduce spending on medicines – or they can buy more medicines for the same money. This can be important if the use of a medicine is restricted or limited to a small group of patients, and some who could benefit from it are not receiving it because of the cost rather than any clinical indications.

But why don't all CCGs enter into such schemes? The answer is a lack of support from "official" bodies, concern about

how such schemes operate and whether they are legal and ethical, and practical considerations such as the amount of administration involved in running them.

One of the biggest barriers has been opposition from the Department of Health, which has been reluctant to say anything which could be seen as support for such schemes and has, on occasions, been reluctant to clarify its position. The Association of the British Pharmaceutical Industry has also been lukewarm, if not totally opposed, to such schemes. The reason is that the schemes need to run alongside the pharmaceutical price regulation scheme (PPRS). Pharmaceutical companies want to see the PPRS – which regulates prices and profits – maintained because they feel it offers stability. However, the UK prices often act as a reference price for medicines sold in other countries. This means companies are reluctant to drop prices for the UK market but are willing to talk about local agreements which will lead to rebates and, effectively, lower prices. This lack of support – and even opposition – from the Department of Health and the ABPI can be enough to stymie such schemes at birth with CCGs uncertain whether they are able to enter into them.

But there can be other concerns especially around the ethics of such schemes. There is sometimes a misconception that the schemes can benefit individual GPs or practices although the schemes operate on a CCG-wide basis and all money goes back to the CCG, an NHS statutory body – so GP and practice income is unaffected.

However, there is a range of views on whether GPs should be informed of the schemes and whether this should affect their prescribing.

If rebate schemes mean the effective price of the drug is reduced then it will affect its cost effectiveness – potentially making it more attractive than other drugs with similar clinical outcomes but a higher cost. In theory, this can influence formulary decisions and potentially decisions by individual prescribers, if they are aware of the "real" cost. This can obviously increase use of a particular medicine.

But in some areas GPs will see a medicine on the formulary but won't be aware of any change to the actual cost – and their prescribing may not change. Pharmacists involved in such schemes say there is a mix of views among GPs on whether they want to know the details of any schemes.

The administrative burden of such schemes can also be considerable although CCGs tend to process them more quickly as they become more experienced. Schemes which only require existing data to be examined to establish what rebate a CCG is entitled to will be much less onerous to operate than those which require new data collection.

Mr Wind says it is important that schemes which are suggested to CCGs are assessed to make certain there are no hidden issues and that the CCG understands what it is doing.

But assessing such schemes can be a challenge for CCGs. Individually, they may not have the expertise to do this and it can be time-consuming if multiple schemes have to be assessed. And there is duplication of effort if CCGS are each assessing schemes individually.

There have been moves in some parts of the country to make this easier by developing a framework or principles which can be adopted by multiple CCGs. These can reduce the burden of assessment, provide assurance of good governance, and can encourage companies to develop schemes which comply with the framework.

"There is always safety in numbers," says Mr Wind. "If 20 people are doing something then we feel more secure in doing it."

He suggests frameworks will encourage a consistency of approach and can also be more transparent – which can help to deal with some of the ethical concerns. "We need to demonstrate that there is nothing nefarious going on. It is going to increase transparency and consistency and perhaps lead to better decision making."

These frameworks can also make it easier for companies to produce schemes which are likely to comply with their underlying principles.

And once a scheme has been assessed under the framework, CCGs will be able to make their own decisions on whether to take it up, informed by the process it has already gone through and any issues arising from the assessment. ●

A CLOSE LOOK UNDER THE MICROSCOPE

Some areas are further advanced in exploring the feasibility of rebate schemes, such as London and the East of England, which are using an assessment process after frequent demands for consistency from PCTs

LONDON AND THE EAST OF ENGLAND SCHEMES

The rise of primary care rebates has encouraged some areas to set up assessment processes to look at the schemes.

The most advanced of these have been set up in London and the East of England. The East of England process was set up a couple of years ago because of a perceived need for some form of advice to guide primary care organisations which were offered rebates. "We were being asked for that by all the PCTs at the time," says Mr Wind. "They felt they needed a consistent approach.

"In some ways we were more concerned about the clinical issues and not using medicines that we did not want to use," says Mr Wind. "That was the concern of the PCTs – that they were being induced to use medicines that they really did not want to use."

An assessment system was set up to look at such schemes across the region, with clinical input coming from a medicines information pharmacist.

London was able to draw on some of the learning from this and eventually to develop a structured set of principles of its own which could guide assessments.

Under both the East of England and the London schemes, assessments concentrate on the potential benefits and pitfalls of a scheme, culminating in a report outlining any issues for CCGs to consider. The assessment panel does not make the final decision but restricts itself to pointing out aspects for CCGs to bear in mind when making a decision whether or not to go ahead.

"We can't pass or fail a scheme," says Mr Wind. "Administrative effort is one of the things that we measure. If the scheme is very onerous and complicated... then the burden of this can be an issue."

Sometimes there will be an opportunity to automate some of the data collection involved in such schemes which can, in theory, tip the balance and make it more attractive.

"The schemes are becoming easier to assess because companies have learnt from their experience and the really complicated schemes are fewer. Most of the schemes we see now are straightforward discounts. We used to see ones based on targets."

The London Procurement Partnership became involved 18 months or so ago. "There were a number of rebates being presented by the industry," says Jasbinder Khambh, primary care lead in the pharmacy team. "Very few PCTs in London were (signing up); some were not and some were not sure."

But it was obvious there were substantial savings available for PCTs that did get involved and, with the financial climate, it was

hard to ignore them. But there was a need for some direction, she adds.

Although the Department of Health was contacted, it did not give a clear answer on what should be done if such schemes were offered.

At that point the LPP decided to get legal advice on whether the schemes could be accepted. The resulting advice was around 20 pages long but argued that the schemes could be operated in a way which was not illegal. CCGs could, in principle, enter into such schemes if they were approached by pharmaceutical companies.

"It was something that PCTs – and now CCGs – could take part in as long as it was done appropriately and certain criteria were met," she says.

The LPP team decided to distil the advice into a set of good practice principles which could be used to look at schemes and decide if they were appropriate.

These were then published on the organisation's website in the form of a checklist. A pan-London subgroup was established which would assess proposed schemes against these criteria and highlight whether they complied with the required criteria.

This would save the 32 CCGs from having to assess each application – which would take time and money – but would still allow them to make their own decisions about whether or not to accept a scheme.

'That was the concern of PCTs: that they were being induced to use medicines that they really did not want to use'

If they do go ahead, they know that the scheme has been tested against a set of consistent criteria.

Ms Khambh points out the principles are also available to pharmaceutical companies through the LPP website so they can see in advance whether their schemes are likely to tick the right boxes.

"That does not always happen," she says. The subgroup met recently to assess four proposed schemes, all of which had many issues with them (although this assessment is non-binding on CCGs).

"We don't make any decisions for anyone – it is down to local decision-making groups whether they sign up or not," she says. "But because we have a good reputation within London most of the advice we give is taken up."

The sorts of medicines involved in these schemes are varied. Some may be medicines which have been restricted to a small group of patients in the past (often because of cost) but a reduced price means they can be made more widely available without increasing overall spend, she says. They have also assessed some drugs put forward which they felt were not clinically appropriate, even at a lower price.

But it has not been an easy ride, with some influential voices arguing that NHS organisations should not enter into such schemes. There have been concerns about transparency – although the principles by which such schemes are assessed are in the public domain, the details of each scheme remain commercially confidential.

Some people within the NHS don't like working with industry in this way and simply don't want to enter into such arrangements, she says.

The London-wide assessment process only started earlier this year so the data is not available yet to show the outcomes. "We will only be able to see the whole impact a year down the line," she says. "At the moment we don't know the local level of sign-up."

The success of the London and East of England schemes has meant that their influence extends across the country – with CCGs in other areas often asking what has happened when a particular scheme has been put forward for assessment. Ms Khambh says she gets regular requests for a copy of the principles and legal advice. And she adds: "Where the savings are huge we can use that money to improve patient care elsewhere. It is difficult to justify not using schemes like these."

"To have a positive assessment from one of these two patches is very important to them if they want to sell it anywhere in England," says Mr Wind.

The LPP assessment process: some of the key principles

- clinical decision making should inform the financial/procurement decision rather than the other way around;
- health professionals should base prescribing decisions on the patient's clinical circumstances;
- rebate schemes should be approved through robust local governance and should be agreed at a statutory organisational level, not a practice level;
- assessment of potential financial benefits should include any administrative burden in running the scheme;
- the existence of rebate schemes should be made public through the primary care organisation's website, although commercially sensitive information can be withheld. Contracts should allow the discounts and details of schemes to be shared within the NHS. ●

Read full details at: http://tinyurl.com/njagus6

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IS IT NOW TIME TO REASSESS REBATES?

Primary care rebate schemes are a good financial deal for patients to some people, and to others an ethical minefield they are unconfident about crossing

Primary care rebate schemes have the potential to offer benefits to the NHS but the confusion and concern around their operation means that many clinical commissioning groups are not taking advantage of this opportunity.

Could this be improved by some form of agreement on how such schemes could work ethically? This has already been tried on a regional basis – the model developed by the London Purchasing Partnership, for example – and the response from the rest of the NHS suggests there is enthusiasm for such an approach.

With this in mind, pharmaceutical company Takeda has decided to try to encourage the process by finding out what a scheme acceptable to healthcare professionals and managers would look like.

A spokesperson said: "At Takeda we are constantly striving to deliver better value to the NHS and better health for patients. Our aim to provide best in class medicines at a cost-competitive price can often be challenging as we can be bound by the constraints of global price referencing. Therefore, a simple reduction of our NHS list price is often not an option in such circumstances.

"Primary care rebate schemes allow pharmaceutical companies to pass on local savings in the absence of being able to reduce NHS list prices whilst delivering a much needed income stream to the NHS. However, we understand that for some, rebate schemes are still a contentious topic.

"We know from experience that there is a real appetite for rebates within the NHS as financial constraints become more acute. However, awareness of local rebate guidance and an understanding of how to engage with these schemes is variable. What is clear is the desire for a consensus view on how the NHS should be utilising primary care rebate schemes as a mechanism for reducing costs. In the absence of clear guidance from the Department of Health we have embarked on a project that aims to ultimately provide an NHS consensus view."

So what is the company doing? The first step has been to set up a multidisciplinary steering group, which met in August. This group was able to crystallise some of the key issues around rebate schemes and come up with some statements. These cover a wide range of the facets of such schemes – from the ethical elements of what the benefits are and how they should be distributed, to more practical considerations such as the amount of administration involved.

These are now being further tested, with larger audiences using a questionnaire looking at the level of agreement with the statement. This is known as the DelphiTM consensus method: a systematic, interactive method which relies on a panel of experts.

"The results of this questionnaire will inform us which statements have achieved consensus and which have not. From here we are able to reconvene the steering group and revise the statements as appropriate and if necessary conduct the exercise again, before ultimately arriving at a robust peer-reviewed consensus. From this a manuscript will be generated for publication," says the Takeda spokesperson.

No panacea

As part of this process, Takeda invited those attending the *HSJ* Commissioning Summit to hear from those involved in such schemes and to discuss some of the key benefits and problem areas.

Ben Woodhouse, medicines optimisation and prescribing lead for Bolton CCG, outlined some of the barriers to rebate schemes. These included the need to be compliant with a number of laws and regulations – which he argued schemes could be – but also uncertainty

QUESTIONNAIRE INDICATES SURPRISING LEVEL OF AGREEMENT ON KEY TOPICS

There may be controversy over the use of rebate schemes but the early indications are that there is an emerging consensus on some questions.

A questionnaire was distributed at the Commissioning Summit and at the Commissioning in Healthcare event at Olympia. Those responding were asked to say whether they agreed or not with some key statements drawn up by the working group. A total of 47 responses were received from a range of people including CCG chief officers, GPs and pharmacists.

A number of these statements were met with support from over 90 per cent of those who responded. They included:

- The need for clear direction on implementation of primary care rebate schemes
- The need for such schemes to be signed off at organisational level
- Guidance on schemes is helpful in ensuring robust governance
- Best practice should be disseminated to stakeholders involved in rebate schemes
- The NHS should partner appropriately with industry

These statements and others are now going to be further refined and may eventually form part of a consensus statement on rebate schemes.

So what is the end point?

"Our objective is for this project to deliver much-needed consensus on this important topic that will define the most appropriate way forward and will encourage the DH and APBI to develop a framework for the NHS and the industry," says Takeda.

‘We would like a definitive yes or no from the DH. A lot of the guidance is rather woolly’

about how the DH viewed such schemes.

“We would like a definitive yes or no from the department,” he said. “A lot of the guidance is rather woolly.”

He stressed rebate schemes were not a panacea for the challenge of prescribing costs but did help. In his area such schemes went through an ethical approval process with the Greater Manchester Commissioning Support Unit.

The Isle of Wight has been one of the most enthusiastic CCGs in adopting such schemes. Head of medicines management Paul Jerram said: “Morally and ethically I have to support rebates and get the pennies I can back for the NHS.”

Setting the need for such agreements in the context of the financial position many NHS organisations find themselves in, he said CCGs needed to go for rebates quickly and in depth to get the maximum benefit they could.

The whole issue of pharmaceutical pricing came under attack from some members of the audience, who questioned whether it was appropriate to try to mend a broken system.

Many pharmaceutical companies use rebates to reduce the price of their products while maintaining the all-important list price which is then used by other countries.

Dr Shane Gordon, a GP and chief officer for North East Essex CCG, said his difficulty was that it occurred within a pricing system which he believed artificially inflated prices.

“What we are doing with the rebates is putting a sticking plaster on a broken system,” he said.

Former deputy chair of the BMA’s GPs committee Simon Fradd was unhappy with the idea of rebate schemes. “It seems to me this does not feel ethical and does not feel transparent... I would not want to be part of it,” he said.

He said there were already repercussions for primary care when hospitals cut deals on pharmaceutical pricing and patients then continued with the same drugs in the community but had to meet the full cost.

Mr Jerram pointed out the need for NHS bodies to save as much money as possible. “I think it is unethical not to do this because it means our patients get a worse deal. The important thing is that there is transparency and governance.”

And Mr Woodhouse said: ‘I agree the system is broken. We can’t fix that. We have to work within the constraints we have and make the savings we are asked for.’

But other audience members wanted more details about how such schemes would work – with one commenting that her CCG had such schemes and she had not realised they were so controversial.

One issue for some audience members was around what level of detail would or could be made transparent in the operation of such schemes.

Mr Jerram said that details of schemes would be commercial agreements. And there was a question of what GPs should know about such schemes when prescribing. A reduced cost could alter how cost and effectiveness were viewed.

Mr Jerram said he did make GPs aware of the real cost of a medicine to the CCG. And he said in one case he got a 50 per cent rebate on the list price of what was a superior product to available alternatives.

“We are treating twice the number of patients with a superior drug. I am getting maximum bangs for my bucks,” he said. ●

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