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The Pharmaceutical Services Negotiating Committee

Response to:

Department of Health Consultation on

Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines

PHARMACY
the Heart of our Community

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PSNC promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health as the body that represents NHS pharmacy contractors. Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.

PSNC's response is confined to questions where we believe our knowledge is valuable to the consultation. We have focused on four issues: the exploitation of the current pricing systems to increase costs to the NHS, and how this could be addressed; the implications of proposed arrangements for hospital pricing; the adverse impact on security of supply and patient access of introducing price changes on 1st January; and the need to incorporate obligations on manufacturers to ensure speedy supply to patients through their chosen dispenser.

Scope of the scheme

The proposed scope of the scheme is 'branded medicines'. It is intended to make provisions for the pricing of medicines eligible for control under the voluntary PPRS, where the manufacturer does not consent to be bound by the PPRS. Although primarily seeking to control the prices of medicines with patent protection, the definition in both the draft regulations and in the PPRS allows the inclusion of medicines that are out of patent protection, where a manufacturer chooses to apply a brand name. It excludes medicines marketed under a generic name, even where patent protection applies.

This, as a consequence of features of pharmacy funding mechanisms, enables manufacturers to sell branded generic medicines on terms that result in higher cost to the NHS than the net cost of the true generic, with transfer of costs away from the prescribing budget. We comment on this under question 16, below and would be happy to explain the operation of the arrangements.

As presently proposed, the scheme does not apply to 'divestments' that are marketed under a generic name, even where they remain covered by patent protection. In practical terms, the specialist nature or limited demand for these products means that there is no stimulus to other entrants into the market, and even on patent expiry, excessive prices can continue to be charged.

Recent activity has highlighted the failure of current pricing schemes for medicines prescribed in primary care to prevent exploitation of loopholes. We believe there is an urgent need to re-examine the scope of the scheme to ensure that mechanisms are in place to limit opportunities for businesses to make excessive profits from NHS and taxpayer funds.

We suggest that the scheme should apply to all medicines where there is only one person placing product on the market, and should not seek to regulate by reference to the application of a brand name, which is an inappropriate definition. We recognise that this requires significant amendment to the draft regulations to re-define "branded health service medicine", add definitions to cover branded generics and 'divested' medicines, and make provision for their pricing. New paragraphs would be required for the two new categories that require control, but within the current draft regulations, relevant criteria to be applied in determining prices can be found, and we are happy to explain our proposals separately.

5) Is the proposed £5 million small firms exemption needed?

As noted, there has been significant activity recently in 'divestments': the sale of the IP or marketing rights in low volume medicines to businesses that are not covered by the PPRS. The medicine is commonly marketed under its generic name (thus bypassing the statutory scheme) and the price for the medicine is greatly inflated, with a price rise of 2,400% being recorded recently. The current arrangements for setting reimbursement prices are ineffective to deal with this practice. Given the current prevalence of this practice, and the very large numbers of low volume medicines, we believe the statutory scheme should address the practice. In view of the market size of some of these medicines, we believe the potential for misuse of the £5m firms' exemption for these products should be explored.

7) Do you agree with the proposal to apply the price adjustment to ASPs in hospital, aligning this more closely with the PPRS?

The consultation records that average prices charged for branded medicines to hospitals have typically been substantially lower than the drug list price to which the statutory scheme applies. It proposes new arrangements that would apply price

adjustments to historic Average Selling Prices (ASPs) in hospitals. In many cases manufacturers have charged lower prices to incentivise prescribing of a medicine in secondary care, in the expectation that when the patient's treatment is transferred to primary care, the medication will continue to be prescribed and the manufacturers will benefit from the higher prices. The effect of the proposal will be to create two statutory scheme prices for a medicine, with the hospital scheme price in most cases being lower than the primary care price.

We are concerned about the implications of this for decisions on patient care. Where the hospital price of a high price medicine is well below the primary care price, there will be a clear incentive for CCGs to access secondary care prices by retaining hospital prescribing of the medicine, and this will have a substantial negative impact on health policy in England, including integration of care and expanding the community pharmacy role in optimising use of medicines. Of course we support the ambition to secure the best possible prices for medicines, but we do not believe the implications of the proposal to establish two separate statutory price schemes have been fully explored.

16) Is it likely that the proposed changes will create any risks around continuity of supply of branded medicines?

Timing of changes

The proposed timing of the changes to the statutory scheme and to the PPRS, 1 January 2014, is extremely difficult for pharmacy suppliers and pharmacies, and PSNC requests that the adoption of the new scheme prices be deferred to 1st February 2014.

The levels of price cuts proposed will mean both pharmacies and wholesalers will significantly reduce their stock holding in the period running up the price cut, to minimise loss of stock value. Around the Christmas period pharmacies face many pressures, with prescribers changing their prescribing practices and many patients using pharmacies other than their normal pharmacies, when they are away from home. This always places significant pressures on the distribution network, and the need to de-stock to avoid financial loss will add significantly to the problems and to the risk that patients will be unable to obtain their medicines over the period.

Our request is made against the background of the increase in shortages of branded medicines which, although they were beginning to become a feature of the market when the PPRS was last negotiated, were a far smaller problem at the time.

In addition, we believe that manufacturers should be required to give a minimum notice period of changes to prices. This will support wholesale suppliers in managing their stocks and help pharmacies to offer a reliable and speedy service to their patients,

Ensuring access to medicines

PSNC, together with the BAPW wrote to Katy Peters on 24th June 2013, proposing provisions to include in the PPRS. This is the most recent of many attempts to ensure that manufacturers of medicines covered by the scheme have responsibility for ensuring that they can be quickly and simply obtained by the dispenser chosen by the patient, normally a local community pharmacy. The same obligation should apply to medicines covered by the statutory scheme.

In our letter we proposed inclusion of a provision that obliges a manufacturer covered by the scheme to ensure that it has effective arrangements to ensure the supply of medicines required by a dispenser to meet an NHS prescription, within 24 hours of the request being made. The obligation should specify the exceptions, which would include some provision for requests made over weekends, and when manufacturing problems make compliance impossible. We would like to see the provisions include an obligation to submit to adjudication of complaints of a breach of this requirement. In practice we would expect to have few, if any, adjudications because such a requirement would change the behaviours of those manufacturers that at present rely on the total absence of any standards regulating their supply arrangements.

This provision is necessary to support the legal duty of the pharmacy to supply any medicine prescribed for a patient 'with reasonable promptness'.

Branded generics

PSNC proposes new provisions to ensure the inclusion in the statutory scheme of medicines for which the patent has expired to which a brand name is applied, marketed by a body other than the brand originator where there are several manufacturers of the generic medicine.

This requires changes to the PPRS as well as to the statutory scheme. The PPRS is an umbrella scheme to control the prices of branded medicines sold to the NHS, and its aim is to provide a framework for pricing of patent medicines. Branded generic manufacturers, where the manufacturer is not and does not claim to be the brand originator, use the scheme to list a price, which allows them to market and encourage prescribing of their products to the NHS. In doing this they bypass the Category M pricing mechanism systems, and this results in increased costs to the NHS. The increased cost is not evident, and indeed the direct cost to the prescriber's budget will be lower. Given the financial constraints faced by the NHS, this is not an acceptable use of taxpayer funds.

PSNC believes that the PPRS should apply only to manufacturers who certify that they qualify as the brand originator, either as holder of the patent or because they have procured the certified brand from the brand originator. The statutory scheme should be extended to apply to all medicines not covered by the PPRS for which there is only one manufacturer.