PSNC's response to Department of Health and Social Care's consultation on community pharmacy reimbursement reforms

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Introduction

The Pharmaceutical Services Negotiating Committee (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. We work closely with Local Pharmaceutical Committees (LPCs) to support their role as the local NHS representative organisations.

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.

We welcome the opportunity to be able to provide our response to the proposals set out in the Department of Health and Social Care's consultation on community pharmacy reimbursement reforms.

Principles for assessing community pharmacy reimbursement reforms

There are six key issues of concern to pharmacy contractors, which must be considered to ensure fair and equitable reimbursement for the dispensing of NHS prescriptions. In assessing the proposed reimbursement reforms, we will consider the following principles:

- Where reimbursement prices are set by reference to suppliers' prices, these should principally be the suppliers from which pharmacy contractors directly purchase medicines;
- Reimbursement mechanisms should as far as possible be designed to prevent contractors dispensing prescriptions at a financial loss;
- Reimbursement mechanisms should as far as possible seek to ensure a fair and equitable distribution of purchase margin;
- Reimbursement mechanisms should as far as possible provide certainty of reimbursement to contractors prior to the dispensing of the items concerned;
- There should be a smooth transition from current systems to any newly implemented system, with regular review points to assess the impact of the changes; and
- Reimbursement mechanisms should prevent any unintended patient safety risks and not conflict with any regulatory and/or professional guidance or standards expected of pharmacy professionals.

The United Kingdom already enjoys one of the lowest priced medicines markets in Europe. However, with a medicines supply chain showing signs of fragility and with Brexit looming, the risks of any changes to reimbursement must be carefully considered. PSNC looks forward to engaging with DHSC in discussions regarding the details of the proposed reimbursement reforms.

Furthermore, PSNC believes that now would be an appropriate time to revisit discussions regarding the introduction of generic substitution.

Consultation Questions

Section 4. Changes to the determination of reimbursement prices of generic medicines in Category A

Question 1. Do you agree with the proposed reform?

PSNC accepts that the current mechanism for setting Category A reimbursement prices is outdated and alternatives should be considered. PSNC would welcome the opportunity to discuss improvements to the mechanism for Category A price setting with DHSC.

Question 2. Do you have any comments on the proposed reform?

PSNC believes the following principles are of primary importance when considering any changes to the mechanisms for Category A price setting:

- **Price stability is important to ensure continuity in the supply chain**
- **Reimbursement prices should be based on wholesaler selling prices**
- **The 'reactivity' of the system to supplier price changes should not be reduced**
- **Changes to reimbursement prices should be implemented gradually, with regular review points**

Products listed in Category A of the Drug Tariff are readily available generic medicines which do not meet the qualifying volume or value criteria for inclusion to Category M. Any reimbursement mechanism must ensure that continuity and stability in the supply chain is maintained.

To avoid dispensing at a loss, PSNC believes that reimbursement prices for Category A medicines should principally be based on the suppliers from which pharmacy contractors directly purchase medicines.

Category A medicines prices are currently subject to monthly adjustment. Moving to less frequent price updates for Category A medicines would increase the risk of contractors dispensing at a loss, as price changes from suppliers would take longer to be reflected in reimbursement prices than in the current system. This would increase the need for price concessions, increase costs for the NHS and distort margin delivery for contractors.

A phased transition to any new system would mean that where prices change the impact will be smoothed. Any reimbursement mechanism that introduces price volatility amplifies the risk of shortages and reduces the market attractiveness to new entrants. Avoiding sudden shocks to the market will help ensure uninterrupted supplies, reducing the risk of increased costs for the NHS and helping to ensure access for patients. Review periods (e.g. quarterly) should be implemented to monitor the impact of the transition and identify any unintended or detrimental effects.

Section 5. Changes to the distribution of medicine margin added to generic medicines in Category M

Question 1. Do you agree with the proposed reform?

PSNC believes that the current mechanism for distributing margin within Category M has had unintended

consequences which have caused inequality of margin distribution amongst contractors. PSNC would welcome the opportunity to discuss improvements to Category M systems, subject to consideration of the concerns outlined in our comments below.

Question 2. Do you have any comments on the proposed reform?

PSNC welcomes the wider objectives this proposal seeks to achieve; however, the following key issues must be considered as part of any changes to price setting and margin distribution mechanisms:

- **Reduction of margin on certain Category M products should not increase risk of inequality in distribution of margin amongst contractors**
- **Reduction of margin on certain Category M products should not result in dispensing at a loss for those items**

Where margin is reduced on any affected Category M products it may be necessary to mitigate against any contractor losses by either adding these products to the list of drugs for which Discount Not Deducted (DND) or by applying a reduced level of discount deduction to these products.

If dm+d data were used as part of this process, e.g. in capturing branded prices, this would raise concerns as PSNC is aware that product availability information and published list prices on dm+d are not always reflective of the market. As such there would need to be improvements to procedures for updating dm+d to ensure only robust data is used to inform any new reimbursement mechanism and any appeals process referenced in the consultation will need to be agile.

There is a risk of exacerbating problems around drug availability and shortages by the reduction of medicine margin in individual Category M products. Changes to the system would need to be made gradually and would need to be carefully monitored to ensure any unintended or detrimental effects are identified.

As an alternative to DHSC's proposals, PSNC believes that now would be an appropriate time to revisit discussions regarding the introduction of generic substitution.

Section 6. Changes to the determination of reimbursement prices of medicines in Category C which are prescribed generically but have multiple suppliers

Question 1. Do you agree with the proposed reform?

PSNC believes there could be significant unintended consequences of the proposed reforms regarding changes to price setting for Category C medicines; as such before any changes could proceed there would need to be detailed discussions regarding caveats and safeguards in the system, to ensure the protection of patient safety and access, the prevention of dispensing at a loss for contractors, and to reduce the risk of supply issues.

Question 2. Do you have a preference for option 1 or option 2?

No comment

Question 3. Do you have any comments on the proposed reform?
PSNC has significant concerns about the proposed changes to Category C price setting. Any changes to Category C price setting mechanisms should only be considered if they can meet the following criteria:

- **Patient safety and access to medicines must not be put at risk**
- **Pricing mechanisms should not penalise pharmacy professionals who follow regulatory and/or professional guidance**
- **Changes to reimbursement must not result in increased risk of dispensing at a loss for contractors**
- **The 'reactivity' of the system to supplier price changes should not be reduced**
- **Changes to reimbursement prices should be implemented gradually, with regular review points**

PSNC has noted that there are many products listed in the Drug Tariff as Category C of which only a few are available from multiple suppliers that contribute to medicine margin.

Unless prescribers change their prescribing habits or prescribing systems are developed to default prescribing of certain products by brand name according to MHRA/BNF/SPS guidance, PSNC believes this proposal creates unintended risks to patient safety and is likely to increase workload for both pharmacy teams and prescribers. Patients are likely to experience delays in receiving their medicines if prescriptions need to be re-issued by prescribers so that patients continue to receive the brand of medicine they have been stabilised on. Any change to the reimbursement mechanism for Category C medicines should not penalise pharmacy contractors for following relevant guidance issued by any regulatory and professional bodies.

Contractors already dispense many medicines listed in Category C at a loss after discount deduction. Basing a reimbursement system for Category C medicines on averages would mean that pharmacy contractors who dispense a more expensive medicine against a generically written prescription due to patient need will further increase their risk of dispensing at a loss.

Currently, Category C reimbursement prices are updated monthly and moving to use of market data obtained under the 2018 regulations (option 2) could introduce lag for setting prices (using selling prices which may be up to six months' old) which is likely to be too slow to react to changes in market prices.

As PSNC is aware that product availability information and published list prices on dm+d are not always reflective of the market, there would need to be improvements to procedures for updating dm+d to ensure only robust data is used to inform any new reimbursement mechanism and any appeals process referenced in the consultation will need to be agile.

If any changes to Category C are to be implemented, it is essential to have appropriate transitional arrangements and notice periods in place with a mechanism to review processes regularly. The current notice period for any changes to Part VIII of the Drug Tariff is one month. For any changes to proceed, extended notice should be given of any changes to Category C reimbursement prices to allow contractors to run down stock of any products they are unlikely to dispense against generically written prescriptions. This notice period should also allow sufficient time for patients to be referred back to their prescribers for a branded prescription if a patient needs to remain on a particular brand. Regular review periods would allow for the impact of implementation to be examined and allow opportunities to refine systems, where necessary.

Section 7. Inclusion of drugs (other than licensed and unlicensed medicines) with a reimbursement price in Part VIII

Question 1. Do you agree with the proposed reform?

PSNC could only agree to proceed with this proposal subject to DHSC addressing the concerns outlined in the comments below.

Question 2. Do you have a preference for option 1 or option 2?

Option 1 but only applicable to drugs where a suitable medicinal (licensed or unlicensed) equivalent is not available, and these products are to be listed under a separate category in the Drug Tariff.

Question 3. Do you have any comments on the proposed reform?

Reimbursement for products not in Part VIII of the Drug Tariff is currently based on contractors' endorsements, this ensures contractors are reimbursed appropriately and do not dispense at a loss. Any changes to reimbursement for such products should only proceed if they can comply with the following principles:

- **Contractors must not be financially disadvantaged by moving from a reimbursement system based on endorsement to a system with prices listed in the Drug Tariff**
- **Prices in the Drug Tariff must be reactive to price changes in the market**
- **Changes to reimbursement prices should be implemented gradually, with regular review points**

PSNC could not support any proposals that directly or indirectly conflict with guidance issued by the UK regulators (MHRA / GPhC). In the absence of a licensed product, a pharmacist is required to act in the patient's best interests and make a professional judgement to determine whether it is clinically appropriate to supply an unlicensed medicinal or non-medicinal product. Any reimbursement rules should not conflict with a pharmacist's professional and clinical obligations to supply an appropriate product. As such, PSNC would only support the inclusion of non-medicinal products in the Drug Tariff where no medicinal equivalent (licensed or unlicensed) is available.

PSNC would support the creation of a new section in the Drug Tariff, e.g. Part VIIIC. This would include non-medicinal products (including any existing entries in the Drug Tariff) so it is apparent to prescribers and dispensers that the requested product is non-medicinal and may fall outside of the existing requirements under Clause 1 of the Drug Tariff (which indicates that drugs in the Drug Tariff should not be of a grade or quality lower than that ordinarily used for medicinal products). If a licensed or unlicensed medicinal product becomes available in the market, the equivalent non-medicinal product must be removed from Part VIIIC, and the newly available licensed or unlicensed medicine may be included in Part VIIIA or Part VIIIB if appropriate.

With current reimbursement based on endorsement for non-Part VIII products, there is no lag between a supplier's price changing and contractors being able to be paid the new price. Determination of reimbursement prices using market data or suppliers' list prices could therefore introduce significant lag. For this reason, PSNC prefers having monthly rather than quarterly adjustments to Drug Tariff reimbursement prices for products included in Part VIIIC. Furthermore, if any proposed changes to reimbursement were to go ahead, PSNC would expect these products to fall within scope of the price concession system.

To avoid pharmacy contractors dispensing at a loss, reimbursement for non-medicinal products must be based on wholesaler price data rather than manufacturer price data. Such items will generally be more niche products subject to significant price variation in the market. In addition to this, the addition of these products to the Drug Tariff must not impinge the current ability to make Broken Bulk claims in appropriate circumstances, or the ability to claim Out of Pocket Expenses where these have been incurred.

As PSNC is aware that product availability information and published list prices on dm+d are not always reflective of the market, there would need to be improvements to procedures for updating dm+d to ensure only robust data is used to inform any new reimbursement mechanism and any appeals process referenced in the consultation will need to be agile.

PSNC believes that if any proposed changes to add non-medicinal products to the Drug Tariff are implemented, it is essential to have appropriate transitional arrangements in place with a mechanism to review processes regularly. PSNC would expect to have suitable and regular review periods in place to examine the impact of implementation and allow opportunity to refine systems, where necessary.

Section 8. Changes to the determination of reimbursement prices for non-part VIIIA drugs

Question 1. Do you agree with the proposed reform?

PSNC has concerns about the proposed changes to reimbursement of non-Part VIIIA products, and any changes to reimbursement of non-part VIIIA products could only be agreed subject to addressing the concerns outlined in our comments below.

Question 2. Do you have any comments on the proposed reform?

Reimbursement for products not in Part VIII of the Drug Tariff is currently based on contractors' endorsements, this ensures contractors are reimbursed appropriately and do not dispense at a loss. Any changes to reimbursement for such products should only proceed if they can comply with the following principles:

- **Changes to reimbursement must not result in increased risk of dispensing at a loss for contractors**
- **Reimbursement prices should be based on wholesaler selling prices**
- **Reimbursement prices must be reactive to price changes in the market**
- **Reimbursement prices determined systematically (rather than dependent on endorsement) must be available to contractors before the act of dispensing takes place**
- **Changes to reimbursement prices should be implemented gradually, with regular review points**

Non-part VIIIA items will generally be niche products subject to significant price variation in the market. To avoid pharmacy contractors dispensing at a loss, reimbursement for non-part VIIIA products must be based on wholesaler price data, not manufacturer price data.

It is essential that reimbursement prices are reflective of the market in terms of selling prices and availability, and that contractors are provided maximum visibility of reimbursement before dispensing. DHSC propose to publish the weighted average of suppliers' list prices from the previous month to provide an indicative reimbursement price to pharmacy contractors. It is not acceptable for pharmacy contractors to rely on the previous months' reimbursement

prices as an indication of the expected reimbursement for the current dispensing month; any blended or weighted prices calculated from multiple suppliers' prices would need to be available in the month of dispensing.

Under these proposals, PSNC is unclear as to how a contractor who supplies a non-part VIIIA drugs that isn't listed on dm+d would be reimbursed. Currently, reimbursement is based on endorsement of product supplied, however, if there is no list price held on dm+d for a particular product this will not be captured for determining the reimbursement prices for single or multi-source non-Part VIIIA drugs.

As PSNC is aware that product availability information and published list prices on dm+d are not always reflective of the market, there would need to be improvements to procedures for updating dm+d to ensure only robust data is used to inform any new reimbursement mechanism and any appeals process referenced in the consultation will need to be agile.

If any changes to reimbursement of non-Part VIIIA drugs are implemented, PSNC would expect to have suitable and regular review periods in place to examine the impact of implementation and allow opportunity to refine systems, where necessary.

Section 9. Changes to the arrangements for reimbursing and procuring unlicensed medicines ('specials')

Question 1. Do you agree that DHSC should include tablets and capsules with a reimbursement price in Part VIII of the Drug Tariff?

PSNC would not object to the addition of unlicensed tablets and capsules to the Drug Tariff, subject to the consideration of the comments outlined below.

Question 2. Do you have any comments on the proposal to include tablets and capsules with a reimbursement price in Part VIII of the Drug Tariff?

Reimbursement for unlicensed specials and imports that are not in Part VIIIB of the Drug Tariff is currently based on contractors' endorsements, this is to ensure contractors are reimbursed appropriately and do not dispense at a loss. Any changes to reimbursement for unlicensed tablets or capsules should only proceed if they can comply with the following principles:

- **Contractors are not financially disadvantaged by moving from a reimbursement system based on endorsement to a system with prices listed in the Drug Tariff**
- **Prices in the Drug Tariff are reactive to price changes in the market**
- **Changes to reimbursement prices should be implemented gradually, with regular review points**

Pharmacy contractors should not be left out of pocket for procuring and dispensing oral solid-dose unlicensed drugs against NHS prescriptions. Under the current arrangements, Broken Bulk claims cannot be made on products listed in Part VIIIB of the Drug Tariff. This may be a less significant problem with liquid made-to-order specials; however, the majority of oral solid-dose unlicensed specials and imports will be bulk manufactured and only available to purchase in selected pack sizes. Pharmacy contractors will have no option but to order one or more of the available pack size(s) even though a prescription may specify a smaller quantity. As pharmacists are reimbursed for the exact quantity ordered on a prescription (with exception of any products classed as special containers), any residual stock

left over from the original pack size used for dispensing is unlikely to be used again and will need to be discarded. To avoid pharmacy contractors dispensing at a loss, PSNC would seek a change to the Drug Tariff so that all unlicensed part VIII and non-part VIII medicinal products are classed as special containers i.e. to facilitate original pack dispensing. At the very least, PSNC would only support the proposal to add unlicensed tablets and capsules to the Drug Tariff if Broken Bulk claims are permitted on all part VIII and non-part VIII products (unless special container criteria apply).

With current reimbursement based on endorsement for non-Part VIIIB unlicensed medicines, there is no lag between a supplier's price changing and contractors being able to be paid the new price. Determination of reimbursement prices using any market data could therefore introduce significant lag. For this reason, PSNC prefers having monthly rather than quarterly adjustments to Drug Tariff reimbursement prices for unlicensed medicinal products. Furthermore, if any proposed changes to reimbursement of unlicensed oral solid-dose drugs were to go ahead, PSNC would expect these products to fall within scope of the price concession system.

PSNC believes that if any proposed changes to reimbursement of unlicensed tablets and capsules are implemented, it is essential to have appropriate transitional arrangements in place with a mechanism to review processes regularly. PSNC would expect to have suitable and regular review periods in place to examine the impact of implementation and allow opportunity to refine systems, where necessary.

Question 3. Which is your preferred option for the procurement and reimbursement of specials that cannot be listed with a reimbursement price in Part VIII of the Drug Tariff?

PSNC is not in favour of any of the proposed options for procurement and reimbursement of non-Part VIII specials as they all have the potential to delay the supply of medicines to patients. With option 1 or 2, PSNC cannot advocate a position that may add additional burden on pharmacy teams when obtaining quotes and approvals. The new Community Pharmacy Contractual Framework (CPFC) arrangements seek to creates headroom for pharmacy teams to be more accessible to patients by moving pharmacy away from dispensing activity and into new services. However, PSNC is concerned that options proposed for procurement of specials may further increase the time spent by pharmacy staff sourcing stock by increasing the administrative burden. The least unattractive option is Option 3 i.e. 3a) central supply or 3b) central procurement service. An alternative proposal is outlined in PSNC's response to question 4.

Question 4. Do you have any comments on the options and/or do you think there are additional options that should be considered?

PSNC believes the proposed options will increase administrative requirements and divert pharmacy staff away from patient-facing care. They are likely to increase delays in getting the treatments to patients as they either require additional administration or intervention by a third party. The current system affords pharmacy contractors the flexibility to source unlicensed medicinal products to help meet the needs of their patients for e.g. next day delivery for urgent requests. PSNC is concerned that such flexibility and agility within the system may be lost with third-party approvals or distribution arrangements.

As an alternative to DHSC's proposed options, PSNC proposes that DHSC work with industry representatives to have a list of pre-approved specials manufacturers or suppliers that sign up to an agreed set of values or codes of practice to offer good value and quality for the NHS. The NHS could then be confident it is receiving value for money in specials

purchasing while maintaining the flexibility and agility of the current system, and without adding extra burden or delays at the procurement and dispensing stage.

Section 10. Changes to the reimbursement of generically prescribed appliances and drugs dispensed as 'specials''

Question 1. Do you agree with the proposed reform?

PSNC cannot support any proposals that directly or indirectly conflict with guidance issued by the UK's medicines regulator (MHRA) and the pharmacy regulator, GPhC.

Question 2. Do you have any comments on the proposed reform?

The proposed Drug Tariff reimbursement rules for non-medicinal products would penalise contractors for providing a medicinal product, which goes directly against MHRA guidance around supply of unlicensed medicines. The information outlined in MHRA Guidance Note 14 on "Supply of unlicensed medicines products ("specials") states the following in Appendix 2 on the hierarchy for the use of unlicensed medicines:

"This hierarchy is provided for guidance only and each case should be considered on its individual merit.

1. *An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need.*
2. *Although MHRA does not recommend "off label" (outside of the licensed indications) use of products, if the UK licensed product can meet the clinical need, even "off-label", it should be used instead of an unlicensed product. Licensed products available in the UK have been assessed for quality safety and efficacy. If used "off-label" some of this assessment may not apply, but much will still be valid. This is better than the use of an un-assessed, unlicensed product. The fact that the intended use is outside of the licensed indications is therefore not a reason to use an unlicensed product. It should be understood that the prescriber's responsibility and potential liability are increased when prescribing off-label.*
3. *If the UK product cannot meet the special need, then another (imported) medicinal product should be considered, which is licensed in the country of origin.*
4. *If none of these options will suffice, then a completely unlicensed product may have to be used, for example, UK manufactured "specials", which are made in GMP inspected facilities, but which are otherwise un-assessed (GMP inspection of "specials" manufacturers is not product specific). There may also be other products available which are unlicensed in the country of origin.*
5. *The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). For example, the use of products from countries where they are classed as supplements, not pharmaceuticals, and may not be made to expected standards of pharmaceutical GMP. These should be avoided whenever possible"*

Products manufactured as medicines in the UK (and in most other countries) are manufactured under pharmaceutical Good Manufacturing Practices, but non-medicinal products for example, food supplements, are not expected to meet the same manufacturing standards. Manufacturers of medicinal products which are manufactured to Good Manufacturing Practices are granted a licence where a product is shown to have met statutory standards of safety, quality and efficacy. According to the MHRA, it is therefore preferable to use products manufactured as medicines as these come with some assurance of manufacturing quality under good manufacturing practices.

The GPhC standards require a pharmacist to make the care of the patient their first concern and act in their best interests. A pharmacist is required to make a professional judgement to determine whether it is clinically appropriate to supply an unlicensed medicinal product or appliance against a generically written prescription. Any reimbursement proposals for appliances or non-medicinal drugs vs 'specials' should not conflict with a pharmacist's professional obligations and clinical responsibilities to supply an appropriate product to help meet the needs of a patient. Determination as to whether it is appropriate to dispense a medicinal product, or where applicable, an appliance or non-medicinal product, against a generically written prescription will depend upon availability of the product, the intended purpose and mode of action of the product and must be assessed on a case-by-case basis.

Section 11. Changes to the deduction scale to reflect different levels of discount for branded and generic medicines

Question 1. Do you agree with the proposed reform?

PSNC is supportive of this proposal. PSNC would welcome the opportunity to discuss improvements to discount deduction mechanisms with DHSC, subject to consideration of the comments below.

Question 2. Do you have any comments on the proposed reform?

PSNC welcomes the wider objectives this proposal seeks to achieve. The following key issue must be considered as part of any changes to discount deduction mechanisms:

- **Any changes to discount scale should not increase the level of discount deduction experienced by an "average" contractor**

It is expected that by splitting the discount scale, there will be contractors who experience higher or lower levels of discount deduction, dependent on whether their dispensing mix is above or below the national average in regard to brand/generic split. In other words, a pharmacy with a higher proportion of brand prescriptions should have a lower level of discount deduction than a pharmacy with a higher proportion of generic prescriptions.

PSNC looks forward to discussing details for implementation of this proposal with DHSC.