Response to the Department of Health and Social Care consultation on:

Community pharmacy drug reimbursement reforms

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About the Company Chemists' Association (CCA)

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. Our membership includes ASDA, Boots, Lloyds Pharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate over 6,000 pharmacies, which represents nearly half the market. Our members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing almost 500 million NHS prescription items every year.

The CCA represents the interests of its members and brings together their unique skills, knowledge and scale for the benefit of community pharmacy, the NHS, patients and the public. Our vision is that everyone, everywhere, can benefit from world class healthcare and wellbeing services provided by their community pharmacy.

Introduction

The CCA welcomes the opportunity to respond to the consultation: 'Community pharmacy drug reimbursement reforms.'

We understand the background to the Department of Health and Social Care's (DHSC) proposals on community pharmacy drug reimbursement reform and we agree with DHSC that the reimbursement arrangements have generally worked well and to the benefit of both businesses at each point in the supply chain and the NHS. We acknowledge that improvements can be made to the mechanisms which reimburse community pharmacies, however, given the complexity of the medicines supply chain, we want to highlight that there are several factors that need to be considered to avoid unintended consequences.

It is widely recognised that the UK medicines supply chain is already highly effective in keeping the cost of medicines low and that the NHS benefits from one of the lowest costs of medicines in comparison to other parts of the global market. The recent Oxera report on the supply of generic medicines in the UK[1] states that '*the current UK system provides strong incentives for competition and delivers significant benefits relative to other systems.'*

Whilst we fully acknowledge the need to ensure value for money for taxpayers, we are concerned that the full implications of driving prices even lower, in an already fragile market, have not been fully considered.

From a manufacturer's perspective this may lead to generic manufacturers seeing the UK market as unattractive and will view other markets more favourably. They could decide to withdraw from the UK, which in turn could reduce the availability of medicines to the NHS and patients and subsequently lead to an increase in prices which is not the intention of the proposals.

The consultation's impact assessment states that the policy '*is not intended to push market prices below the level at which companies can viably sell and that any risk to medicine supply or the viability of firms producing medicines in the UK should be minimal*.' We believe that this statement underestimates the current situation with generics supply and the difficulties that are faced by community pharmacy contractors in accessing certain medicines for patients on an ongoing basis.

[1] Oxera, 2019. *The supply of generic medicines in the UK*, Oxera on behalf of the British Generic Manufacturers Association (BGMA) [online]. Available here: https://www.oxera.com/wp-content/uploads/2019/06/Oxera-study-on-the-supply-of-generic-medicines-in-the-UK-26-June-2019.pdf [Accessed on 17 September 2019].

From a community pharmacy perspective, the reimbursement mechanisms should as far as possible seek to ensure a fair and equitable distribution of medicines margin and should be designed to prevent contractors dispensing prescriptions at a financial loss as well as providing certainty of reimbursement to contractors prior to purchasing.

Whilst community pharmacy has always delivered value for taxpayers through competition and effectively driving down the price of medicines, we are concerned that some of the proposals will further increase the administrative burden on contractors. The advent of the new Community Pharmacy Contractual Framework (CPCF) will result, over time, in the sector becoming even more patient facing and the implementation of these reimbursement reforms should not detract from that direction of travel.

We would encourage DHSC to ensure there is a smooth transition from the current system to any newly implemented system, staging the implementation with regular review points to assess the impact of any change on the sustainability of the supply chain.

At the time of writing our response we are uncertain of the impact of the UK leaving the European Union and consequential impact on borders, exchange rates and medicines availability. Any changes to reimbursement would need to reflect on these wider issues which could seriously affect the UK medicines supply chain and the timing of the implementation of any reforms will be critical to ensure sustainability and stability.

We have made suggestions within our response which we believe would be better mechanisms to deal with branded generics.

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?

We accept that the current mechanism for setting Category A reimbursement prices is outdated and alternatives should be considered.

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

We believe the following principles are of primary importance when considering changes to the mechanisms for Category A price setting:

- Reimbursement prices should be based on wholesaler selling prices
- The system should be highly responsive to supplier price changes to ensure contractors are not disadvantaged
- Changes to reimbursement prices should be implemented gradually, with regular review points

Category A medicines prices are currently subject to monthly adjustment. We believe that 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.

We believe that there should be a phased transition of any new system, taking a staged approach to enable any disruption to be assessed and action taken to mitigate any negative impacts. This would mean that where prices change, the impact could potentially be smoothed. Avoiding sudden shocks to the market will help to ensure uninterrupted supplies, reducing the risk of increased costs for the NHS and help safeguard access to medicines for patients. Review periods (e.g. at least 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?

We believe that the current mechanism for distributing margin within Category M has had unintended consequences which have caused inequality of margin distribution amongst contractors. The CCA would welcome DHSC having discussions with representatives of the community pharmacy sector around improvements to Category M systems, including the ability to introduce generic substitution by community pharmacists.

Question 2. Do you have any comments on the proposed reform?
We welcome the wider objectives that 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 result in dispensing at a loss for those items
- Reduction of margin on certain Category M products should not increase risk of inequality in distribution of margin amongst contractors

The CCA is concerned about the principal of winners and losers at individual pharmacy level, which may be exacerbated by the reduction of margin on a section of Category M products.

We suggest that an alternative solution would be the introduction of generic substitution by community pharmacy, where pharmacists could switch a non-originator branded medicine for a generic version of the same medicine. DHSC should also consider the significant role prescribers and medicines management teams could play in achieving best value for the NHS.

We believe that there is a risk of exacerbating problems around drug availability and shortages by the reduction of medicine margin in 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.

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?

The CCA believes there could be significant unintended consequences of the proposed reforms regarding changes to price setting for Category C medicines and consequently there would need to be detailed discussions regarding caveats and safeguards in the system before any changes could

proceed, to ensure the protection of patient safety and access, to prevent dispensing at a loss for contractors, and reduce the risk of supply issues.

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

We believe both options have flaws however, to reduce the administrative burden on contractors dm+d would be the preferred option.

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

The CCA 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
- Changes to reimbursement must not result in increased risk of dispensing at a loss for contractors
- The system should be reactive to supplier price changes to ensure contractors are not disadvantaged
- Changes to reimbursement prices should be implemented gradually, with regular review points

We believe this proposal creates unintended risks to patient safety, as changes in Category C reimbursement prices would inevitably lead to changes to patient's therapy. If a prescription does not specify a brand, pharmacy staff may be compelled to dispense 'cheaper' products to avoid dispensing at a loss. Unless prescribers change their prescribing habits or prescribing systems are developed to default prescribing of certain products by brand name based on MHRA/BNF/SPS guidance, this proposal is likely to bear significant consequences for patient safety arising from unwanted changes to patient treatment.

The proposed changes are likely to increase workload for both pharmacy teams and prescribers and introduce delays in patients receiving medicines where prescriptions need to be rewritten to allow dispensing of products which are above the new price.

Contractors already dispense many branded items at a loss. Basing a reimbursement system for Category C products on averages would mean that pharmacy contractors who dispense a more expensive product against a generically written prescription, due to patient need, will further increase their risk of dispensing at a loss.

We are 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.

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 enough time for patients to be referred 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?

We agree with the proposed reform, 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 medicines where a suitable (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 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

We would only accept inclusion of non-medicinal products in the Drug Tariff where no medicinal equivalent (licensed or unlicensed) is available. We 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).

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. The CCA recommends 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, we would expect these products to fall within scope of the price concession system.

If a licensed or unlicensed medicinal product becomes available in the market, the equivalent non-medicinal product must be removed from Part VIIC, and the newly available licensed or unlicensed medicine may be included in Part VIIIA or Part VIIIB if appropriate.

We are 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.

We believe 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. We 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?

We have 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 financial 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 highly responsive 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

To avoid pharmacy contractors dispensing at a loss, reimbursement for non-part VIIIA products must be based on distributor/wholesalers list prices rather than manufacturers list prices. Such items will generally be more niche products subject to price variation and fluctuation in the market.

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, we are unclear as to how a contractor who supplies a non-part VIIIA medicine 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.

We are aware that product availability information and published list prices on dm+d are not always reflective of the market, therefore we would expect improvements to procedures for updating dm+d to ensure only robust data is used to inform any new reimbursement mechanism.

If any changes to reimbursement of non-Part VIIIA drugs are implemented, we 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 the Part VIII of the Drug Tariff?

The CCA would agree to the additional 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 the 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 ensures 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 (BB) 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, we would expect that all unlicensed part VIII and non-part VIII medicinal products are classed as special containers i.e. to facilitate original pack dispensing. We could only support the proposal to add unlicensed tablets and capsules to the Drug Tariff on the condition that BB 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, we recommend 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, we would expect these products to fall within scope of the price concession system.

We believe 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. We 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?

We have concerns about all the options proposed, any proposed system must be operationally simple, with minimum bureaucracy and we suggest more discussion is required before taking this forward.

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

The CCA believes all of the proposed options 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 needs of their patients for e.g. next day delivery for urgent requests. We are concerned that such flexibility and agility with the system may be lost with third-party approvals or distribution arrangements.

Whatever system is put in place needs to be operationally straightforward and not increase the administrative burden on pharmacy contractors.

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

Question 1. Do you agree with the proposed reform?
The CCA cannot support any proposals that directly or indirectly conflict with guidance issued by the UK's medicines regulator (MHRA).

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

The proposed Drug Tariff reimbursement rules for non-medicinal products inadvertently encourages the supply of a non-medicinal product over medicinal products which directly contravenes MHRA guidance around supply of unlicensed medicines. Guidance 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.

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?

The CCA understands the rationale behind the proposal however we believe some caution is required due to the potential impact on the market.

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

We welcome 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 regarding 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.

We believe that any new discount deduction mechanisms should be designed so the contractors with an "average" level of brand/generic split in their item mix, i.e. their individual split is in line with the overall national average, their level of discount deduction should be commensurate with what they would have experienced under the current system.

We also see some risks with regards to the market:

Branded medicines
It is unlikely that such a change could occur without there also being a movement in the prices to the NHS overall. The discount pharmacies achieve on different branded products will vary between manufacturers, with some manufacturers offering more 'lean' discounts than others.

Any reduction in branded discount rate could 'signal' to branded manufacturers that this is the new expectation of discount levels, resulting in a convergence at this lower rate. Equally, where manufacturers already only offered discounts below the existing clawback rates, making these lines profitable for pharmacy again may be seen by those manufacturers as a reason to reduce discounts

further to (or even below) this new level. The negative 'noise' on dispensing at a loss would subside, along with any indirect effect this has on discount levels.

Although branded manufacturers have reduced discount levels below average clawback rates for a reasonably sized pharmacy, it is likely that the sliding scale also acts as a counter to further reductions. Rebasing this at a lower level (whether it remains a sliding scale, or a flat fixed rate) would open up continued downward pressure. It has been noted that it is thought (at least theoretically) that DHSC can recoup any cost movement as a result of discounts changing, but in practice have not used these powers so far.

Were branded manufacturers (or wholesalers) to do this, the net cost would increase to the NHS. The amount of margin in this medicine category would consequentially decline again, meaning that once more increased margin would be required to be delivered through generic medicines to achieve the overall £800m. If this occurred, the downward pressure exerted by Category M would be reduced (or increased money put into the Tariff to allow this).

Generic medicines
A second risk is also apparent. The initial increase in generic discount rate would see further downward pressure on generic medicines – pharmacies would continue to source generics drugs and attempt to procure at a lower price (to still make a similar margin on these medicines, as already with the existing Category M mechanism). Although beneficial to the NHS in the short term, it is possible that this will increase supply chain fragility further.

In their representations to the National Audit Office, DHSC stated that one of the three major underlying causes of an increase in concessionary pricing (2017-2018) was '*governments and insurers in other countries putting downward pressure on the price of generic medicines, resulting in lower returns and manufacturers withdrawing from some markets or medicines: the reduced capacity and competition then increased prices within the UK market.*'[2]

A rebasing of the generic clawback rate would apply a similar downward pressure, on top of that already exerted through Category M and Scheme M, risking further supply chain shortages and disruption. As has been noted, there are already considerable volumes of generic medicines not obtainable at Tariff prices and increasing clawback rates (in the absence of increasing the headline tariff rate as well) would logically see the number of these increase, and shift the narrative on dispensing at a loss from branded medicines to generic ones.

There is the risk that a major price reduction in prices paid to pharmacies by the NHS would result in lower returns and manufacturers withdrawing from the UK itself (or some of the specifically affected medicines, thus further reducing competition).

[2] National Audit Office, 2018. Department of Health and Social Care: Investigation into NHS spending on generic medicines in primary care. [online]. National Audit Office, page 10. Available at https://www.nao.org.uk/wp-content/uploads/2018/06/Investigation-into-NHS-spending-on-generic-medicines-in-primary-care.pdf [Accessed on 17 September 2019].