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Dr Sarah Wollaston MP Chair, Health and Social Care Select Committee House of Commons London SW1A OAA

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Dear Dr Wollaston,

Further to our helpful meeting earlier this week, I thought it would be useful to follow-up on the main issues in writing. As you know, I am CEO of the PSNC, which is the only representative body for all 11,600 community pharmacies in England on NHS matters.

PSNC has a wide working remit covering all NHS services that community pharmacies offer. A significant part of our role is to ensure that community pharmacies can access and dispense prescription medicines to patients as they are needed. Crucially, and linked to this, community pharmacies must also be appropriately reimbursed for doing so. Unsurprisingly, we are taking a keen interest in the UK's exit from the EU and the impact that it may have on the supply of medicines to pharmacies and the communities they serve.

Like many other sectors, community pharmacy is concerned about the impact Brexit will have on its ability to perform this vital service to patients and the wider NHS — and indeed the impact on pharmacy itself. Ensuring the continuity of medicines supply to pharmacies and patients is our main area of focus, and our objective is to ensure that all possible steps are taken to reduce the impact of the UK's exit from the EU on this. I have set out below the work we are currently doing in this area and some of our key areas of concern.

Community Pharmacy Brexit Work

PSNC is working closely with officials at the Department of Health and Social Care (DHSC) to help minimise any possible disruption from the UK's exit from the EU, particularly in the event of a no-deal scenario. The community pharmacy sector has also come together, along with representatives from industry across the medicines supply chain, in a PSNC-led Brexit Forum to ensure that we have ongoing dialogue between ourselves and with the DHSC as we approach 29 March 2019. The Forum is supportive of the work that DHSC is doing on this, but we are also keen to ensure that all appropriate steps to maintain the supply of medicines to UK pharmacies and patients are taken, and that contingency plans for any medicines shortages that might occur, particularly in a no-deal scenario, are in place.



Medicines Shortages: present situation

Medicines shortages are not a new phenomenon, and community pharmacies already spend a lot of time trying to source medicines for their patients and managing any shortages when they do occur. As with any commodity, shortages lead to price increases. This in turn leads to community pharmacies purchasing, and thus dispensing, medicines at a price higher (in some cases, much higher) than the NHS will reimburse at according to their monthly Drug Tariff. There is a mechanism in place to help to deal with this – PSNC will collate data and ask DHSC to set a 'price concession' for a particular medicine to try to ensure that pharmacies are not unfairly impacted by supply chain problems that are outside of their control. These concessions may be agreed by DHSC but sometimes are not. Concessionary lines are also considered in the annual Margin Survey which assesses the margin available to independent contractors, but this of course does not help with short-term cashflow issues or ensure equity of margin delivery.

The number of products on concession has grown in recent years and pharmacies are spending longer trying to source medicines at or below Drug Tariff price. Following major shortages in the generics market in 2017, the number of concessions being granted each month has slowly decreased (53 in April 2018 as compared to 109 in November 2017). However, we are now seeing another surge in the number of generics unavailable to purchase at Drug Tariff price. There are particular issues with Buprenorphine and Risperidone given the nature of the drugs (it is not easy to switch patients to alternatives). Others drugs for which we have had pricing concerns during the year are Allopurinol, Bicalutamide, Latanoprost and more recently Naproxen.

Last month, the number of price concessions jumped up to 72 and the number in December 2018 is likely to be higher. The surge may be due to a combination of factors including Brexit planning and contingency; stockpiling; the reduction in Category M prices to recover overpaid margin from previous years; and DHSC using its new data gathering powers to identify stock levels and manufacturer selling out prices to determine concessionary prices.

For some medicines, pharmacies have to contact up to seven or eight wholesalers and they are increasingly reporting that none have stock available of products at the Drug Tariff price or even at the concessionary prices. Under their Terms of Service, pharmacies are obliged to supply drugs with reasonable promptness, so many pharmacies are therefore dispensing drugs at a significant loss. This is having a huge impact on cashflow at a time when many pharmacies are already being hit by funding cuts and recovery of excessive margin made in previous years by DHSC.

Medicines Shortages: Brexit

The medicines supply chain is complex and as I have mentioned community pharmacies are struggling both to obtain some medicines and to pay for them. There must be recognition that the competitive market in generic medicines, which over the years has driven down costs for the NHS, will behave differently in a time of crisis, leading to supply issues and an increase in the cost of medicines.



Any further disruption to the supply of medicines to the UK following Brexit, for example if delays at border crossings disrupt the flow of medicines from Europe, could create a real risk of further medicines shortages, or perceived shortages (which can be just as problematic, in pricing terms).

As well as potentially impacting on patient safety and care, further medicines shortages could destabilise the already fragile medicines pricing and reimbursement systems operated by DHSC. If a large number of drugs remain unavailable at Drug Tariff prices, the current system for setting price concessions could be at risk in the immediate post-Brexit era. The generics market is particularly vulnerable to actual or perceived drug shortages which would trigger price increases. If medicine prices increase significantly post Brexit, there could be a huge impact on individual pharmacies which dispense large volumes of any affected lines, particularly where the difference between purchase price and concessionary price is significant.

PSNC is concerned about the impact that shortages on a significant scale could have on pharmacies' cashflow and workload at a time when many pharmacies are already under significant pressure following funding cuts to the sector. If pharmacies are unable to purchase medicines or are stretched financially to the extent that they start to go out of business, then this could harm patients and add further pressure to already struggling GP practices and hospitals.

To help to mitigate against some of these risks, we would like to continue to work with DHSC to put in place:

- measures to ensure that community pharmacies have quicker and clearer reimbursement and stock availability information;
- greater responsiveness of the concession pricing system so that pharmacies can ensure the supply of prescription drugs to patients; and
- reimbursement for pharmacies of any additional costs incurred to help them to cover their costs and continue to offer the full range of patient services.

We have also explored below a number of other measures which we believe would help to safeguard the supply of medicines to UK patients following Brexit.

Brexit: further contingency measures

You will know that the Government has asked the manufacturers of prescription medicines to hold an additional six-week stockholding of medicines in the UK, but there are question marks as to whether this will be enough to provide continuity of supply to patients. In addition to this stockpile, there will need to be processes in place to help community pharmacies and other healthcare providers to work together to manage any shortages that do occur. Community pharmacists and GPs in particular will need to work together with clear guidance on the steps to follow in the event of a drug shortage. There will also need to be flexibility in the regulatory, contractual and reimbursement structures.



Where actual shortages of branded medicines occur, our preferred option would be to allow pharmacies to generically substitute certain medicines. Generic substitution would see pharmacies dispensing cheaper generic equivalents in place of certain prescribed branded products that have been agreed at a national level. This would mitigate issues caused by shortages for selected products which can be easily substituted with an equivalent generic product. However, the feasibility of enabling generic substitution within a short space of time may make this option difficult to implement.

In the short term, as well as working towards giving pharmacists appropriate professional discretion to dispense an alternative equivalent medicine to patients, it makes sense to relax the NHS Terms of Service obligation on pharmacists to allow pharmacists to refuse supply if necessary. This would allow pharmacies to avoid dispensing drugs at a significant loss and incurring costs that their business could not survive, but it would also allow pharmacies to refuse to dispense complete prescriptions where, for example, patients were seeking several months' worth of a medicine at once, or where they already had sufficient stock from a previous prescription. Again, this would allow pharmacists to use their professional discretion to manage the demand for medicines better and to prioritise stock for patients who need it most in a shortage situation.

To help manage speculative shortages, we would like DHSC to use the new Information Disclosure Regulations to monitor and communicate stock availability issues to pharmacies so that timely interventions can be made to minimise delays in procurement. Drug Tariff pricing needs to be more responsive to market prices to avoid a lag in price setting so that pharmacies' reimbursement is reflective of actual purchase prices. We also suggest that the Department could relax the restrictions on pharmacy-to-pharmacy wholesale dealing without wholesaler dealers licenses. This would allow pharmacies to trade stock between them at a local level, helping to allow medicines to reach those patients who most need them without regulatory barriers. We would also like to explore with DHSC how pharmacies could be reimbursed for what they have dispensed to avoid dispensing at a significant loss.

Conclusion

As outlined above, PSNC is working closely with others in community pharmacy to help support the DHSC's contingency planning for Brexit. Our objective is to minimise the impact of Brexit on the medicines supply chain, so that healthcare professionals can spend more time focusing on patient care, rather than sourcing medicines. We are also very concerned to ensure that Brexit does not have an impact on pharmacies' ability to continue serving NHS patients and their local communities.

We are pleased that DHSC is now consulting on legislative changes which, in the event of a no-deal Brexit, would assist with implementing many of the measures that we have suggested. We will continue to work closely with them on the detail of that and we have committed to assisting their work in the event of there being a significant impact on the medicines supply chain after Brexit.

However, while community pharmacies will continue to do all that they can to manage the supply of medicines to patients, there must be recognition of the impact that this will have on their businesses, particularly in a



crisis scenario. We would like the Government to commit to protecting pharmacies where they are required to invest significant amounts of extra time sourcing and managing stocks, or where they incur significant financial costs as a result of medicines price increases. Safeguarding pharmacies in this way will be an important step to ensure that in a time of crisis, patient safety and medicines supply can be maintained, and pressure on other healthcare providers is not unduly increased.

If I can provide any further information on this, or assist your work in any other way, please don't hesitate to be in touch.

Yours sincerely,

Simon Dukes

PSNC Chief Executive