Written evidence from Dr Natasha Campling and Professor Sue Latter (MED0004)

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Professor Sue Latter is Professor of Health Services Research and leads the Medicines Management Research Group in Health Sciences, University of Southampton. For the last 20 years, Professor Latter has led a research programme of over 30 studies that focuses on large-scale, nationally funded studies investigating prescribing and medicines optimisation. This includes working with policy makers and health care professionals on the local, national, and international level in order to disseminate findings and generate impact. Her research has shaped health care professional policy, education and practice. She has led interdisciplinary teams of world-leading academics; delivering complex, large-scale studies which have resulted in a sustained record of international quality publications and generation of knowledge exchange and global impact. She was the Chief Investigator of the ActMed Study (1).

The response authors are responding on behalf of the ActMed Study team. In collaboration with colleagues at the Universities of Bradford and Leeds, they were awarded funds to evaluate patient and carer access to medicines at end-of-life. The NIHR funded ActMed Study (Accessing medicines at end-of-life: a multi-stakeholder, mixed method evaluation of service provision) examined supply into community pharmacy. **Text and quotes below have been taken from our NIHR Journals Library report [1], key publication summarising the supply chain findings [2] and policy brief [3].**

Executive Summary

Medicine supply is vital for individuals living at home in the last year of life (end-of-life). Without this, symptoms cannot be effectively managed, causing high levels of distress. For community pharmacists (CPs), medicine supply to those at end-of-life was central to their role, significantly impacting individuals and their families:

> *These are the most vulnerable people at the most vulnerable time looking to spend time [together] at the end of their life and a prescription [without the medicine] is no use to them nor their family . . .* *CP16, independent*

Our submission focuses on the issues related to palliative and end of life Medicine Supply including stock levels, the impact of shortages, communication breakdowns, and inadequate stock level monitoring. The ActMed study highlighted significant issues affecting supply of medicines into community pharmacy in the context of end-of-life care.

Abbreviations

CP = Community Pharmacist
FL = Full line wholesaler / distributor (definition p5)
SL = Short line wholesaler / distributor (definition p5)
WD = Pharmaceutical wholesaler / distributor

Implications and Policy Recommendations

- Medicine shortages cause considerable unnecessary extra work for community pharmacy, as well as potential financial loss.
- There is a need to formalise collaboration and relationship building between CPs, WDs and manufacturers, leading to more efficient and responsive communication about medicine shortages.
- Agile two-way information-sharing mechanisms are required by all players in the supply chain:

  Community pharmacists need better live online details about medicine stock, particularly medicines in short supply

  Manufacturers need accurate demand profiles and activity from wholesales and distributors to inform manufacturing capacity management

  Wholesalers/distributors need timely release of information from manufacturers and the DHSC medicines supply team where shortages occur to enable alternative arrangements

As a result, patients will be less likely to endure the impact of medicines shortages and disrupted access at end-of-life, and CPs will have more time needed to undertake the extended roles in this area advocated by professional bodies [3]. **This covers inquiry questions 1a), 3a), 4a) and 4b).**

Question Responses

1. a) What are the impacts of medicine shortages on patients and frontline services when they occur? And what is the significance of the impact when they do occur?

Medicine shortages were a universal challenge experienced by CPs. A lack of information surrounding medicines shortages was problematic, with CPs having to seek information via various sources, such as professional organisations, rather than from WDs and manufacturers. This contributed to pharmacists' workload and further delays in accessing medicines:

> *If I give them, the wholesalers, a call . . . they just say, 'we're not getting it back until this date' and that's it. They don't really tell you what's going on. Really what I have to do is search online through the PSNC [Pharmaceutical Services Negotiating Committee] and obviously various pharmacy channels to see what's happening, if it's a manufacturing problem, if it's a licensing problem or there's another issue . . . CP05, small multiple*

In relation to palliative medicines specifically, CPs reported varying difficulties related to shortages, '*which is more distressing . . .*' (CP07, independent). It appeared that some CPs had successfully weathered palliative medicines shortages because of the efforts they and their pharmacies put into sourcing medicines, sometimes from all over the world.

Medicine shortages led to quotas being imposed by the WDs and/or manufacturers. These quotas were perceived as a hurdle that the CPs had to navigate to gain supplies, and were often harshly viewed as creating additional work and causing a delay in supplying to patients:

> *Often we're having to fax anonymised prescriptions to a quota team which has been set up by the mainline wholesalers who then ration out stocks . . . We've had a patient on phenytoin suspension, in the last year of her life . . . It's been a challenge to get hold of that for her family. So, we've had to contact [named manufacturer] directly to get supplies issued . . . CP07, independent*

CPs highlighted that any shortage in the market would drive up the price of the respective medicine. This was a key issue because of professional obligations to supply the medicines, but prices frequently exceeded the monthly stated Drug Tariff price (i.e. purchase cost to the pharmacy exceeds reimbursement price). In addition, at the time of purchase, CPs did not know whether or not a price concession would be granted retrospectively and at what price. This led to profound consequences, with pharmacies dispensing such medicines at a loss, contributing to some pharmacies operating at a

loss overall. Alternatively, medicines were returned to the WD because the purchase price was deemed too far in excess of the Drug Tariff price, leading to delays in patient access:

> *As soon as something becomes short in the market the prices go sky-high . . . Sometimes we're getting reimbursed £1 for it and we paid £20 . . . you've got patients who need their medication, so you take a gamble and order it in and hand it out and just hope for the best . . . CP19, independent*

Needing to use multiple WDs was part of the context of medicine shortages, but it precluded straightforward supply, adding complexity to supply chain routes into pharmacies and contributed to the onerous workload of CPs:

> *So, over the last year we've increased it by three wholesalers . . . short-liners, just to give us extra options if we can't get hold of things . . . CP19, independent*

CPs also perceived that Solus agreements (i.e. when the manufacturer uses a sole/single WD to distribute their products) contributed to their need to use numerous WDs. They were often critical of such practices, describing them as monopolies or restrictive practices:

> *It annoys me intensely that something like midazolam we seem to only be able to get through one particular wholesaler . . . The fact that we have restrictive practices in what wholesalers can supply seems to fly in the face of all logic to me . . . CP15, independent*

For some CPs, mainly those in independents, it was only their pharmacies' use of numerous WDs that enabled them to accommodate such Solus agreements and access the full range of medicines prescribed for patients during the last year of life.

Supply chain monitoring

3. a) Are stock levels communicated effectively and in a timely manner between different parts of the supply chain?

Data from community pharmacy illustrated that this was not occurring. This was due to i) a lack of communication and relationships with WDs and manufacturers, and ii) shortcomings of IT ordering systems.

A significant barrier to supply was the lack of meaningful communication (two-way information transfer underpinned by trust) that community pharmacy had with WDs and manufacturers, and the consequent lack of relationships. CPs highlighted that when they needed to speak to WDs, particularly regarding medicine shortages, they did so by telephoning the respective company's customer services team. It was relatively rare (according to CPs) for WDs to contact CPs and so communication was generally pharmacist-initiated. Telephoning service centres was time-consuming and like telephoning a 'call centre', not knowing who they were talking to:

> *It's always the telesales consultants . . . There's no clinical knowledge there at all . . . that's just how it works, you just phone up, have you got so and so, and they'll say yes or no . . . CP17, large multiple*

The lack of clinical insight held by those answering the telephones at WDs was an issue for some CPs because they did not appear to understand the urgency of palliative medicine supply:

> *It used to be quite some time ago that when you'd speak to someone, they'd have more of an awareness about the medication . . . Now there's less . . . so, they may not understand how urgent it is . . . CP23, large multiple*

Furthermore, a lack of understanding could preclude the WDs' sales staff searching for alternative options and a total reliance on their IT systems:

> *We look at the product and go right eight different manufacturers they all come with their own seven-digit PIP [Pharmacy Interface Product] code and we've been in situations where we've read each code out on the phone and they've gone 'no, no, no, no, oh the fifth one is in', brilliant. 'Is your software not searching for it' . . .? CP06, independent*

This lack of meaningful communication and information exchange precluded relationship development between CPs and WDs, and this was a fundamental barrier to supply:

> *I don't think you do have a relationship with them, not like you used to. There are no reps that come round. I wouldn't even know who my account managers were anymore with these big companies [FLs]. Never see them. Never ring up or anything . . . CP14, independent*

This appeared to be underpinned by mistrust on the part of the CPs towards WDs and manufacturers, triggered by conflicting cultures and priorities. The CPs argued that they were primarily focused on patient care and needs (and accountability to the patient), whereas CPs perceived the WDs and manufacturers to be focused entirely on commercial priorities:

> *[To get access to medicines] . . . I have to jump through hoops, spend time which equals money, takes me away from looking after patients and all of my staff away from looking after patients to try and source medication or products . . . they're commercial operations looking to make the most that they can out of what they're doing . . . CP16, independent*

Despite IT ordering systems often being a facilitator of supply, many CPs identified shortcomings:

> *A lot of times I've given [named full-line wholesaler] a call and I've said 'oh yes I placed the order online' and it said it went through and they were like 'oh well yes we only had this reserve amount and you are number 40 something and you will be waiting for it'... CP02, small multiple*

CPs stated that the majority of orders could be dealt with solely online, but as soon as there was an issue (e.g. the product being identified as out of stock), then they would need to ring the WD (e.g. to find out if there was a date the product would be back in stock). Other reasons for needing to telephone the WDs were to find out about specific brand availability, expiration dates of the product, the price of the product (as prices altered daily), where a product was low in stock if they actually had it, if the product was a switch line (i.e. switched to supply from a different warehouse/distribution centre and, therefore, how long it would take to be delivered), and where a third-party order platform was used to ascertain availability (as in such cases availability of products was not stated on the platform system). The telephoning round WDs, although it did not occur for most ordering, was perceived as hugely time-consuming to gain 'definitive answers' and source product for the patient.

4. To what extent is the Government able to predict supply chain issues before they occur?

a) What barriers are there to predicting supply chain issues?

b) What strategies are in place to mitigate the impact of a possible shortage when it has been predicted/detected?

When interviewing WDs, most discussed i) commercial and quality drivers, ii) the need for upstream relationships with manufacturers and suppliers, iii) collaborative relationships in the context of severe shortages, and iv) stock management practices.

Three large national wholesalers provided a full-line (FL) service of all pharmaceuticals, including palliative medicines, in contrast to short-liners (SLs) that provided a limited range and usually at a

competitive price. Competition in the branded medicines market was more limited, with three FLs mainly competing for manufacturers' business. Competition was based on winning business from their competitors, as they all serviced the same customer group. Some participants discussed Solus or dual arrangements, which, according to interviewees, assured continuity of supply from the WD. Solus or dual arrangements were, therefore, perceived to generate more secure business:

> *Commercially it's better for us to get all of the volume where you get 100% market share [Solus contract]. We're in a volume-based business so this brings us volume… WD03, FL*

Despite this perception, the Solus contract could increase the risk of supply failure, as the product could not be accessed by pharmacies via other WDs.

Contracts or agreements with manufacturers/suppliers could provide assurance of inbound stock to WDs; however, formal contracts were not universally used because of manufacturers/suppliers not being able to guarantee to supply against an order (e.g. owing to adverse weather, shortage of raw materials or quality audit failure). When supply disruptions were envisaged, manufacturers were responsible for informing and communicating this information to the Department of Health and Social Care (DHSC):

> *What does work very well is when the manufacturers help us and let us know when they've got a [shortage] problem because that allows us to make alternative arrangements . . . from time to time it could be better and that's always something we'd work together with… WD03, FL*

A few WDs discussed good practice in supply chain management when severe medicines shortages, such as with diamorphine injection, had been co-ordinated nationally via the DHSC Medicines Supply Team. There was a willingness to work collaboratively to get medicines to patients, setting aside competitive relations in response to the shortage:

> *I think that . . . where there has been a problem where we've seen collaboration across the commercial medicines unit the DHSC and the manufacturer and ourselves as wholesalers in the middle I think it's probably when we see best practice… WD03, FL*

Relationships between WDs, manufacturers and community pharmacies were viewed as extremely important in supplying palliative medicines, and WDs reported acting as a point of mediation in the supply chain.

WDs sought to ensure supply continuity into community pharmacies, with a key element being access to stock within the UK market and, if there was a shortage, their ability to source an alternative product outside the UK. If the product was generic, then there tended to be a greater source of alternative suppliers. If a product could not be sourced, then it was because it could not be found (as opposed to no attempt made):

> *The majority of time that shortages occur are about not having the product available for supply and that's down to maybe raw material, maybe choice and allocations to different countries, maybe production issues . . . WD05, FL*

> *If we can't get hold of one drug, we'd probably work with another company that had got a competitor drug . . . WD02, FL*

WDs advised that they shared their demand profile and activity with manufacturers to inform manufacturing capacity management. This information transfer aimed to ensure that stock levels were as needed and that medicines shortages did not develop. The majority of WDs described complex systems for managing stock in response to forecasted demand.

However, the inability of manufacturers to adequately predict operational issues or forecast demand led to production issues and shortages of manufactured stock. WDs considered the notice period and delay in release of information from manufacturers/DHSC problematic, reportedly due to commercial sensitivity of information. WDs considered that there was not always enough time to make alternative arrangements (e.g. ordering in alternative products) to maintain supplies into pharmacies.

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