CCA
COMPANY CHEMISTS' ASSOCIATION LIMITED

4th Floor
Euston House
24 Eversholt Street
London
NW1 1AD

Mobile: 07554 669 002
Office: 020 3874 3210
www.thecca.org.uk
office@thecca.org.uk

Dr Sarah Wollaston MP
Chair of the Health and Social Care Committee
House of Commons
London
SW1A 0AA

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Dear Dr Wollaston MP,

Impact of a no deal Brexit on health and social care inquiry

Thank you for the opportunity to submit written evidence to the Health and Social Care Committee's *Inquiry into the impact of a no-deal Brexit* from the Company Chemists' Association (CCA).

The CCA was established in 1898 and is the trade association for large pharmacy operators in England, Scotland and Wales. Our vision is that everyone, everywhere, can benefit from world class healthcare and wellbeing services provided by their community pharmacy. Between them, our members own and operate over 6,000 pharmacies, which represents nearly half the market and they are ASDA, Boots, LloydsPharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well. 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.

The CCA's written submission is below. In relation to aspects of the Inquiry's terms of reference relevant to us, we specifically address the issues of:

- Medicines supply into community pharmacy in the short and longer-term following Brexit;
- Readiness and implementation of the patient safety features regulation under the Falsified Medicines Directive shortly before the UK leaves the EU;
- Community pharmacy workforce challenges exacerbated by Brexit uncertainty.

We would be happy to provide more information as we are able.

Impact of a no-deal Brexit on the health and social care system.

Medicines Supply

1. We are concerned that a 'no deal' scenario could result in longer and more uncertain flow of medicines and medical devices through the EEA supply chain and across the UK border. This could result in the inability of pharmacists to dispense prescription medicines on a regular and continuous basis in community pharmacies if the large quantities of medicines normally imported into the UK from the EU are delayed at the UK border (37 million packs of medicine every month, according to the ABPI). Delays of prescription only medicines and pharmacy medicines into community pharmacies ultimately means delays to patients receiving their medication. This could have an adverse impact on condition management for patients and in

some cases a very serious impact where it involves vital products such as insulin. It could also place additional pressure on other parts of the health and care system, such as where health conditions become exacerbated and require additional or alternative management, or as patients choose to seek alternative advice and care to that normally easily provided within community pharmacies. If there is panic, which could be exacerbated by alarmist media coverage or insufficient official public information, and prescribers start to increase the prescribed period of treatment/issue double scripts it could exacerbate stock shortages and the 6 weeks manufacturer stock holding may not be enough.

2. We are also concerned about the risk of price increases within the medicines and devices supply chain. The medicines supply chain is part of a global market and subject to market forces. Fluctuations in currency, border tariffs, and speculative trading around the world could also lead to product shortages, which could have a financial consequence for community pharmacy in the UK and for the NHS. Manufacturers and other parts of the medicines supply chain may come to see the UK as a less favourable market for their products if it becomes increasingly difficult to export here, with the consequential effect on UK supply. The nature of any cost pressures may also depend on how they occur in relation to branded products, which are normally more expensive to purchase, or generic products. This could have a negative impact on community pharmacy cash flow that could be alleviated, for example with more responsive NHS concessionary pricing. Similarly, price increases could be caused by the introduction of import costs if any import tariffs were to become applicable or the increased costs of administration associated with cross border trade.

3. The risk of supply shortages could also arise from a range of other interdependent factors, such as fuel availability and continuity of air, sea, road and rail transport links. Disruption caused by these factors would also impact on the cross-border and domestic supply chain. For example, we recall during the fuel crisis in 2000, pharmacists and wholesalers were given exemptions from fuel restrictions which could be a consideration if a similar situation were to arise here.

4. In the long term there may be an impact on the 'batch release' of medicines from the EU into the UK and to the granting of Marketing Authorisations. At present there is a system of mutual recognition of approved batches of medicines, within the EEA, which we recognise the Government has committed to maintaining in the event of a no deal Brexit. Close regulatory alignment with the EU must be maintained to avoid additional regulatory burdens associated with batch release into the UK medicines supply chain. Nevertheless, future applications for Marketing Authorisation of new medicines may be delayed, or not even sought, in the UK if manufacturers turn to larger markets such as the US and EU, and then Russia, China and India.

Falsified Medicines Directive – Safety Features

5. On the 9 February 2019 the Delegated Regulation (EU) 2016/61 safety features, supplementary to the EU Falsified Medicines Directive (2011/62/EU) (FMD), enters into direct effect in the UK. This takes place only seven weeks before the UK leaves the European Union on 29 March 2019. The Delegated Regulation requires the development and implementation of an 'end-to-end verification system' to identify and verify Prescription only Medicine products from manufacture to dispensing within the EEA. The pharmacy sector (manufacturers, distributors, wholesalers and pharmacies) has established and funded the not-for-profit SecurMed as the UK Medicines Verification System. This will be connected to a European Medicines Verification System (the European hub) to meet the requirements of the Regulation (including IT scanning of products throughout the supply chain and decommissioning on the system at the dispensing stage). The community pharmacy sector, including CCA member companies, are also investing significantly in IT, training and changes to operating procedures in readiness for the regulation entering into force.

6. While the sector places patient safety at the forefront of service provision at all times, community pharmacy businesses and wider pharmacy do not know how long the FMD system will be in place following Brexit. One indication we have at present is Article 7 of the draft EU withdrawal agreement that sets out

the UK will 'cease to be entitled to access any (EU) network' on leaving the EU. Despite this situation of significant uncertainty, pharmacy businesses are having to enter into legal agreements and make financial investments to comply with the Regulation without knowing if it will be required from 29 March 2019 onwards. For example, it is unknown at present if the UK will be 'switched off' from the European verification hub and if it is what the consequences will be for the national hub managed by SecurMed, whether the UK system will continue for domestic purposes only, whether it will form part of transitional arrangements with the EU, or play any part in longer-term international trade agreements the UK may enter into.

Pharmacy Workforce

7. While we welcome the Statement of Intent issued by the Home Office regarding the EU Settled Status scheme to allow EEA nationals currently residing in the UK to apply to stay, we are concerned about longer term human resource planning in the health and care system, including community pharmacy. It is challenging for organisations to make accurate forecasts about their resource needs when no clear framework has been published about a future immigration system.

8. According to the General Pharmaceutical Council's (GPhC's) latest registration data, for example, provided to us at the time of writing, there are 3,533 pharmacists and pharmacy technicians trained in other parts of the EEA currently registered to practise in England, Scotland and Wales. Continued uncertainty around rights to remain could adversely impact those regulated pharmacy professionals who already hold the right to practise, as well as impacting on those who may or may not seek registration in the UK in the future, due to actual or perceived uncertainty or unpredictability. This is alongside what the Cavendish Coalition estimates to be over 165,000 EEA nationals in total working in health and social care in England alone.

9. Several programmes co-ordinated by Health Education England and NHS England using the Pharmacy Integration Fund have been set up in recent years designed to increase the number of pharmacy professionals working in new settings such as GP practices, care homes and emergency departments. We support these initiatives to increase access to the clinical skills and expertise of pharmacists to meet the needs of patients. However, this increase in the number of employment opportunities available for the current pool of practitioners (at the time of writing, there are 80,587 pharmacists and pharmacy technicians overall registered to practise in England, Scotland and Wales, according to the GPhC), compounded by a decrease in students entering pharmacy schools and a significant decrease in applications to join the register from EEA trained pharmacy professionals, could make it increasingly difficult for community pharmacies to recruit to certain posts in the short to medium term. Furthermore, any shortages of health professionals in other parts of the health system could have a consequential impact on increasing demand from frontline services, such as community pharmacy.

10. We must ensure that the health and care workforce strategy for England to 2027, currently in development by Health Education England, takes into account these challenges to ensure we have a sustainable supply of pharmacists, pharmacy technicians and other health and care professionals. This should also form part of a coherent approach to workforce supply in the longer-term, together with any future immigration policy as it would apply to qualified pharmacists and pharmacy technicians.

Risks to patients and to the health and social care system of leaving the European Union without a withdrawal agreement.

Stockpiling medicines

11. We are as yet unsure whether the additional six-week stockpiling proposals for pharmaceutical manufacturers will be sufficient to ensure safe and effective supply of medicines to pharmacies and to patients. We believe there is particular risk to those with long-term conditions including diabetes, asthma, and heart problems, and those who rely on timely and urgent treatment, such as for cancer. However, we

know the Department of Health and Social Care (DHSC) is liaising with community pharmacy sector representative bodies about the implications of Brexit and we anticipate this will result in timely and workable official plans to protect patients and the public.

12. According to the DHSC, clinicians should advise patients that the Government has plans in place to ensure a continued supply of medicines to patients from the moment we leave the EU. While we support this intention, it is possible that patient behaviours may change with regard to taking their medicines in fear of potential future shortages. Any non-compliance or intentional non-adherence to medicines would place significant pressure on the health system due to the potential adverse health effects on patients. We are also concerned that there could be a risk of patient stockpile/panic purchasing from community pharmacies at key times, such as in the run up to the 29 March leave date, that could lead to sudden medicines shortages within the system from rapid run down in stocks. All communications must be clear to patients and must come from trusted sources. We believe all providers of health services should be supported and equipped to give patients and the public consistent, comprehensive and clear information system-wide. It should not fall solely to community pharmacy teams to be the creator of the message, or sole communicator.

Stakeholder planning for the possibility of a no-deal Brexit.

Falsified Medicines Directive – Safety Features
13. The community pharmacy sector, including CCA, has established FMD Source a website from the *UK FMD Working Group for Community Pharmacy* as a source of up to date information. The FMD Working Group comprises the main membership bodies representing community pharmacy to inform the implementation of FMD in the UK and raise awareness throughout the sector. The Group meets regularly with IT system suppliers, NHS Digital, the Department of Health and Social Care, the Medicines and Healthcare products Regulatory Agency and the General Pharmaceutical Council to discuss how the FMD safety features will operate in UK community pharmacies and prepare effectively for the implementation of the Delegated Regulation (EU) 2016/61 on 9 February 2019.

Further planning, or reassurances, required to ensure the impact of a no-deal Brexit on health and social care would be minimised.

Medicines Supply
14. We are concerned that uncertainty or late decisions will lead to inconsistent levels of medicines and devices supply into wholesale, which in turn will create shortages of available medicines for patients. We believe the six weeks extra stock could mitigate some but possibly not all categories/products depending on any 'surges' in demand/shortages. If border delays become an on-going issue, then contingency planning must consider replenishment/prioritisation strategies beyond six weeks to avoid shortages of medicines supply. We believe that shortages of certain products (e.g. Specials, unlicensed, surgical, General Sale List items/Pharmacy medicines) that are out of scope of the Medicines Supply Contingency Programme (MSCP) could arise unless clear plans for cross border trade are in place or arrangements for parallel trade.

15. The Government should consider whether parallel importing schemes from outside the EU could be established, to alleviate supply issues. In the event of an expected or actual supply shortage, prescribers could reduce the prescribing period, such as from 28 to 7 or 14 days, or the use of short-dated, returned or expired medicines could be considered where the benefits outweigh the risks, and generic substitution (of branded medicines prescriptions) by pharmacists could be permitted. Clear guidance also needs to be given to prescribers not to prescribe outside of normal parameters. Overall, we believe that any deviation from official guidance on medicines supply and prescribing should be actively enforced in order to preserve and manage supply system-wide and avoid local imbalances.

Falsified Medicines Directive – Safety Features

16. It is vital the Government is open and transparent with the pharmacy sector about the consequences of a no-deal Brexit for the implementation of FMD safety features. This is in order to minimise uncertainty and financial risk for community pharmacies many of which are already experiencing financial constraint and challenge. This is to ensure that community pharmacy overall is not required to invest in FMD systems if they will not be needed into the future. In the event of the UK medicines verification system being disconnected from the European hub, we think there should be a means of financial compensation for the sector for the cost and impact of having had to invest in new systems that become redundant.

Medicines regulation

17. We believe there is still no clarity on centrally authorised products (CAP) lines and whether the deadline of 29th March will be met for licensing products in the system. However, we welcome the no-deal contingency planning currently being carried out by relevant Government Departments and being consulted upon by the Medicines and Healthcare products Regulatory Agency (MHRA). We believe that regulatory continuity is essential and that the process to achieve this must be determined promptly. We would like to see all relevant Government Departments, Arms' Length Bodies and agencies consulting with stakeholders about their contingency plans. Health and care providers, contractors and businesses need as much certainty as soon as possible to ensure any plans to ensure they are workable and that they can in turn achieve a state of readiness.

Once again, thank you for the opportunity to submit written evidence and we would be happy to provide more information.

Yours sincerely,

Malcolm Harrison
Chief Executive, Company Chemists' Association