



## **Department of Health & Social Care - Rebalancing Medicines Legislation and Pharmacy Regulation**

Consultation on draft orders under section 60 of the Health Act 1999: Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

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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, LloydsPharmacy, 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.

## Our response

We welcome the opportunity to respond to this consultation and would be happy to provide you with more information and discuss our response with you in more detail.

We have concentrated our response on Part 2 of the consultation, in relation to the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018, because this has a direct impact on our members as community pharmacies. In relation to Part 1, we would like it to be noted that the CCA supports the attainment of parity between the hospital and community pharmacy sectors with regard to a criminal defence for inadvertent errors. Although we have not responded to the questions in Part 1.

Overall, we welcome the direction of travel presented by Part 2 of the consultation.

We particularly agree with the move from Ministerial legislation to professional regulation, where this does not introduce regulatory burdens or regulatory creep that would unnecessarily constrain the pharmacy sector. We reflect that, for example, the significant length of time it has taken to amend the Medicines Act 1968, in order to introduce a defence for offences under sec. 63 and 64 of the Act in registered pharmacies, indicates that legislation can sometimes be too inflexible to adequately support the development of pharmacy, in a way that supports individual pharmacy professionals and service providers to meet the future needs of patients.

Our response to the consultation also includes the following key points:

- We agree that the Superintendent Pharmacist must have a level of decision-making and influence within a community pharmacy company commensurate with their statutory duties.
- We believe it should be for the pharmacy company to determine whether the Superintendent Pharmacist is a Board-level role, in the context of their business structure.
- We have concerns about a lack of clarity around the duties, roles and responsibilities of the Superintendent Pharmacist and Responsible Pharmacist in relation to other company decision-makers, who may also be Board members within large community pharmacy companies.
- We would welcome more engagement on the general duties definition of the Superintendent Pharmacist as the current definition could, unhelpfully, be widely interpreted.

- We agree that the statutory duties of the Responsible Pharmacist can only be discharged when they are designated as being in charge of a pharmacy.
- While we continue to support the principle of 'one pharmacy, one pharmacist', we agree in principle that pharmacy regulators should have the power to make exceptions to Responsible Pharmacists only being in charge of one pharmacy at a time.
- We think the Responsible Pharmacist role could be enhanced and allow for delegated responsibility by other named competent pharmacy professionals during periods of Responsible Pharmacist temporary absence.
- We strongly agree that the responsibility for establishing, maintaining and reviewing policies should be subsumed within the general duties of the Superintendent Pharmacist.
- We agree that setting out the statutory responsibilities of the Responsible Pharmacist role within professional regulation would be clearer, more agile and responsive as pharmacy services continue to develop, but it must not create a burdensome regulatory framework.

## Part 2 - Consultation questions

**Question 1: Do you agree that the Superintendent Pharmacist should be a senior manager of the retail pharmacy business (which may be just one part of the company for which they work) with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products and the supply of such products?**

We agree that the Superintendent Pharmacist (SP) must have a level of decision-making and influence within a community pharmacy company, or a company that has a community pharmacy arm, commensurate with the roles and responsibilities of the SP. However, we note the proposed 'senior manager' definition of 'Chief Pharmacist' within hospital or other pharmacy services (as set out in Part 1 of this consultation) is defined in specific relation to the pharmacy service, rather than necessarily the wider organisation/institution (re: para 32, consultation document). We think the role of the Superintendent Pharmacist in community pharmacy should also be delimited in this way and that should be reflected in any definition set out in law.

Indeed, at this stage, we would like more information about the intended definition of a 'senior manager', to ensure proportionate, equivalent and consistent interpretation and application across the whole pharmacy sector. We would like to know where such a definition would be derived from, for example, if it would be from an established definition in law and if it were to indirectly introduce or imply additional duties and obligations upon the SP role. We believe the proposed intention may be to apply or derive the 'senior manager' definition from Article 1(4(c)) of the Corporate Manslaughter and Corporate Homicide Act 2007, but we would like confirmation of this.

Given the size of CCA member companies, and particularly where pharmacy is not the only business area, there are a number of roles within the company structure that are individually or collectively responsible for running the business. At present we do not think the definition of 'senior manager' sufficiently takes into account the variety of business structures that exist. If the definition is based on the legislation cited above, this would impose significant responsibility and accountability upon an individual pharmacist. It must be recognised that there are differences in the model, scale and size of community pharmacy companies across the country, and the SP role must be defined so as to be workable alongside other company decision-makers where they exist. This includes the expectations of the pharmacy business owner and their role in relation to the Superintendent Pharmacist and Responsible Pharmacist, where different individuals occupy these roles in accordance with the varied business models and company structures.

Overall, we view the Superintendent Pharmacist role as predominantly one of upholding patient safety company-wide and the role should be focused on this. We believe the definition should reflect this emphasis more clearly.

We also welcome more engagement in this area to ensure there is adequate understanding of community pharmacy business models and that the Superintendent Pharmacist role is defined in a way that is workable across the sector, before any definitions are enshrined in law.

**Question 2: Do you agree with the removal of the restriction for companies with “chemist” in their title such that the Superintendent Pharmacist no longer has to be a member of the board of the body corporate?**

Yes, and we also note that the term ‘chemist’ is somewhat more reflective of the common nomenclature when the legislation was originally introduced rather than today.

For us, it is most important that the Superintendent Pharmacist (SP) has decision-making authority and the ability to have a direct and material impact on safety in community pharmacy, which may not warrant a Board-level position. In this light, we believe it should be for the pharmacy company to determine whether the SP is a Board-level role in the context of their business structure, rather than it being necessitated in certain cases by the business name.

We would like to ensure that across all community pharmacy companies - regardless of size and scale, the SP is enabled to fulfil their duties and exercise their responsibilities. Where they are not a Board member, those responsibilities must also be mutually compatible with those of Company Directors, such as under the Companies Act 2006.

We would like assurance that the proposals would actually create proportionate, clear and effective governance arrangements in community pharmacy. In the context of a potential ‘senior manager’ definition in law (see Question 1) for the SP, the statutory duties of the Superintendent Pharmacist; any additional legal duties and obligations by virtue of them being a ‘senior manager’ - who may or may not operate at Board-level; and any potential future regulatory standards and requirements (see Question 8) must be effectively reconciled.

**Question 3: Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?**

The Superintendent Pharmacist plays a fundamental role in every community pharmacy business, as the guardian of ethics and patient safety, advising key decision makers in the organisation, setting policy and managing risks for both the public and for staff.

With the exception of the General Sale List items outside of a registered pharmacy area, which we believe would be disproportionate (see Question 4), the CCA agrees in principle with the general duty as set out at 72AA in the draft Order: *“It is the duty of the superintendent in relation to a retail pharmacy business to secure that the business is carried on in ways that ensure its safe and effective running so far as concerns— (a) the retail sale of medicinal products (whether they are on a general sale list or not), and (b) the supply of such products in circumstances corresponding to retail sale”*.

We also believe that at present the definition could be open to wide interpretation, particularly on what may be encompassed in the ‘safe and effective running’ of the business, and how the role of the Superintendent Pharmacist works together with others in large companies, including the Pharmacy Owner, and those who have similar or complementary responsibilities outside the legislative and regulatory framework for pharmacy (such as Company Directors). At present the definition may not achieve the clarity and certainty intended without more engagement and

guidance. We would welcome more engagement with the sector on the proposed duty, particularly how it would work in the context of large community pharmacy companies.

**Question 4: Do you agree that the Superintendent Pharmacist general duty should extend to all medicines – general sale list (GSL) medicines, as well as prescription only medicines (POM) and pharmacy (P) medicines?**

We agree that the Superintendent Pharmacist (SP) general duty should extend to general sale list (GSL) medicines but only within the registered pharmacy area. We also agree that the general duty should encompass prescription only medicines (POM) and pharmacy medicines (P).

We believe it would be disproportionate for the duty to extend to GSL items under the Medicines Act where the products are outside of the registered pharmacy area. This, for example, would occur in cases of supermarket pharmacy services where some GSL products may be in the registered pharmacy area and some located in other parts of the store. We do recognise that where this occurs the SP, for business-wide continuity, may wish to have responsibility for GSL items company-wide, but it would be disproportionate to set this out in legislation and we believe it would be better addressed by professional regulation or indeed company policy.

**Question 5: Do you agree that the role of the Superintendent Pharmacist should extend to other services, such as clinical and public health services?**

We agree with this proposal in principle.

The CCA believes that community pharmacy plays a fundamental role in providing the public and their patients a safe and effective supply of medications and services, using their multifaceted skillset to deliver better patient outcomes. We outline in response to Question 12 (see below) how change in the community pharmacy sector – and indeed in wider healthcare – is in some cases moving at pace and we envisage is likely to further extend into clinical and public health services where the funding framework supports it.

In the context of the proposed statutory duty on Superintendent Pharmacists to *'secure the safe and effective running of the pharmacy business'*, we can see how that could encompass the full range of services being delivered by a pharmacy business. Nevertheless, a decision whether or not it pursues certain NHS contracts, such as those commissioned locally by Clinical Commissioning Groups or local authorities, may not rest with the SP alone – such as in large company structures. Although they should have influence in and be a contributor to decision-making, there should be no presumption within the SP role that the term *'secure...the effective running'* extends to making contractual decisions.

If the legal and regulatory framework came to embed an expectation of extended responsibility to deliver clinical and public health services, we would anticipate that the NHS fees and funding mechanism for community pharmacy would provide an enabling environment to support the delivery of these services.

**Question 6: Do you agree that the restriction whereby a Superintendent Pharmacist can only be a Superintendent Pharmacist for one business at any given time should be removed from primary legislation and the issue be left to the pharmacy regulators?**

Yes.

We support the flexibility this would create and that could enable community pharmacies to make their own decisions about what is safe and proportionate, which could for example change from time-to-time such as in cases of mergers and acquisitions. We reflect that, for example, the

significant length of time it has taken to amend the Medicines Act 1968, in order to introduce a defence for offences under sec. 63 and 64 of the Act in registered pharmacies, indicates that legislation is simply too inflexible to adequately support the development of pharmacy that supports individual pharmacy professionals and service providers to meet the future needs to patients.

We would not wish to see a Superintendent Pharmacist being burdened with responsibilities and accountabilities which are unreasonable for a single individual to hold and execute, and we would not wish to see a maximum number of businesses to be imposed.

In all cases, we think it should be for the community pharmacy company to demonstrate its approach is safe and proportionate, within the context of enabling pharmacy regulation.

**Question 7: Do you agree with the proposal to retain the requirement for Superintendent Pharmacists to notify the General Pharmaceutical Council when they stop being Superintendent Pharmacist for a particular pharmacy and to extend the requirement to Northern Ireland and the Pharmaceutical Society of Northern Ireland?**

Yes.

We agree with the proposal to retain the requirement to notify the General Pharmaceutical Council (GPhC), in order to maintain the transparency and accountability associated with the role of the Superintendent Pharmacist.

**Question 8: Do you agree with the proposal to provide the pharmacy regulators with power to set professional standards for Superintendent Pharmacists and describe their role?**

Yes.

We support the proposal that pharmacy regulators have the power to set professional standards for Superintendent Pharmacists (SP) and to describe their role. We think this would ensure clarity and consistency in interpretation and application of requirements across the sector. However, there must be early and active engagement by regulators with the sector to, ensure any new regulations are fit for purpose, maintain patient safety while enabling the sector to develop, and guard against unfair and non-transparent regulatory creep.

We do not think this would necessarily require the creation of separate and additional professional standards for SPs. We think it would be more proportionate to integrate any new standards into existing regulation, such as the General Pharmaceutical Council's *Standards for Pharmacy Professionals* and *Standards for Registered Pharmacies*.

Related to the points we make under Questions 1 and 2 above, the roles and responsibilities of the SP in the context of the proposed statutory duty, must be proportionate and workable in the context of the range of business models that exist in community pharmacy. This includes where pharmacy and pharmacy-related are the only business areas, where pharmacy is part of wider company, and where the SP may or may not have a Board-level position. It must also be recognised that the fiduciary responsibility such as for property and finance, where community pharmacy is just one part of a company, would not rest with, or solely with, the SP. In this light, the SP role must be defined in such a way as to respect the range of collaborative relationships and company-wide governance that exists particularly within larger companies.

Importantly - together with all relevant parts of the pharmacy sector, we must be engaged and consulted with by regulators on any emerging proposals at the earliest stages and any draft standards to ensure they are fair, proportionate and workable. We would be concerned if any new regulatory powers gave rise to the development of a burdensome and disproportionate regulatory

framework, and unnecessarily constrained the ability of community pharmacy to innovate, develop new forms of service provision and further develop pharmacy roles.

**Question 9: Do you agree that the statutory duty of the Responsible Pharmacist should be engaged only for the time when the Responsible Pharmacist is actually designated the RP role for that pharmacy, and is therefore in charge?**

Yes.

We agree that the statutory duties of the Responsible Pharmacist (RP) can only be discharged when they are in active (i.e. designated) charge of a pharmacy, which may be providing on- and off- site services within or out-of-hours. We do not believe the duties should extend to periods when they are not and cannot fulfil those duties in practice.

Under Questions 12 and 13 below, we consider the concept of delegated responsibility of the RP duties for temporary periods of absence. In such cases, the RP could share responsibility with another designated competent professional, e.g. another Pharmacist on the premises or Pharmacy Technician, during periods of temporary absence.

**Question 10: Do you agree that the trigger for when there needs to be an RP in charge of the premises is when medicines are being sold or supplied, or handled, assembled prepared or dispensed at or from the premises with a view to sale or supply?**

We do not agree with the inclusion of *handling* medicines in this proposal, where that means any form of medicines handling on the pharmacy premises. This is because we believe it renders the legislation too blunt and disproportionate, and does not sensitively reflect the range of interactions relating to the sale or supply of medicines. We believe the term 'handling' should be more accurately defined or removed.

We do agree that the Responsible Pharmacist (RP) must be in charge of the pharmacy premises in order to maintain patient and public safety, where medicines are being 'assembled and prepared' as part of the dispensing process "*with a view to ...sale or supply*" (draft Order 2018, 5(2)(b)).

In terms of the '*handling*' of medicines, this occurs at a number of stages in the preparation and dispensing process. Where that 'handling' is integral to assembly and preparation in relation to a prescription, we agree that the RP must be in charge of the premises. However, where 'handling' amounts to the handing out of pre-assembled, clinically and accuracy checked and bagged medicines, that the RP has already deemed suitable and not requiring specific interaction or advice from a pharmacist, we believe it is disproportionate. This is because it creates a situation where patients cannot be served in the pharmacy unless the RP is present and available.

We believe this can greatly inconvenience the patient or give rise to an unnecessary log-jam of activity within the pharmacy which the RP must be directly engaged in, despite other competent members of staff being available to handover medicines to patients. It also arguably creates an illogical situation where for example, if the RP is satisfied, the medicines can be transferred from the pharmacy to a patient off-site by a delivery driver without the RP being present at the point of handover. However, they cannot be handed to a patient by, such as, the counter assistant on the premises unless the RP is present. There are also consequences for the future development of pharmacist-led clinical and public health services etc, where the pharmacist's role and available time is unnecessarily constrained.

We would be happy to provide more information to you about our perspective on this.

**Question 11: Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?**

Yes.

We welcome the recognition that the nature of pharmacy services is changing to further encompass a range of on- and off-pharmacy premises service provision, but that those services continue to be provided at or from particular premises which must be identifiable.

**Question 12: Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist's statutory responsibilities?**

Yes.

We agree that setting out the statutory responsibilities of the Responsible Pharmacist (RP) role within professional regulation, rather than within primary or secondary legislation, would provide a clear, more agile and responsive supporting framework as pharmacy services continue to develop beyond traditional dispensing. However, as we describe above, regulators must practise early engagement with community pharmacy and actively consult, in accordance with their statutory duty. This is to ensure the regulatory approach is fit for purpose, avoids unnecessary burdens and constraints on the future development of pharmacy, and guards against regulatory creep.

The world of pharmacy is moving at pace and we are seeing changes in technology, significant advances in medicines development, and shifts in consumer demand and patient behaviour across the UK. In particular, the CCA foresees the pace and volume of change only accelerating as we move further into the modern digital and genomic era of medicines and healthcare. We are acutely aware that the NHS has ambition for pharmacists and the pharmacy sector to step up into more clinical roles in a variety of settings and integrated models.

It is vital that any approach to setting out the detail of the statutory responsibilities of the RP is flexible enough to accommodate developments such as these, and those which may not presently be foreseen. They must also sit coherently alongside the duties and responsibilities of the Superintendent Pharmacist, and the Pharmacy Owner.

We advocate an 'enabling' approach that makes clear the required or expected regulatory outcomes, without introducing unnecessary constraints on how these may be achieved where that would only serve to impede the appropriate and necessary development of pharmacy services. We think this would also present an opportunity to re-consider the responsibilities and supporting activities of other pharmacy roles to support the development of a clear end-to-end governance structure, as new roles emerge and new approaches to service delivery develop. We would like to see more clarity and clear guidelines to enable delegated responsibility to become second nature to suitably competent pharmacy professionals.

The CCA particularly believes the Responsible Pharmacist (RP) being responsible for the pharmacy is critical to the safety of all the clinical processes operating in the pharmacy, with the RP retaining overall responsibility. However, through regulatory change we believe flexibility of the Responsible Pharmacist role could be enhanced, especially where more than one Pharmacist and/or Pharmacy Technician may be present.

This could for example, take the form of delegated responsibility by other named competent pharmacy professionals carrying out the function of the RP during periods of their temporary absence. Where absence from the pharmacy premises by the RP occurred, the responsibility for the safe and effective running of the dispensary could potentially fall to a Lead Technician, as is often

the case in hospital pharmacies, in the temporary absence of a Pharmacist. This would also serve to encourage and develop leadership amongst the community pharmacy workforce.

The CCA is agreed that consideration should be given to defining the scope of practice of both the Pharmacist and the Pharmacy Technician in community pharmacy, and creating a series of activities which a Pharmacy Technician can be responsible for both in general and in the temporary absence of a pharmacist, where they have the skills to do so.

More widely, the CCA is wholly supportive of a review of pharmacy supervision and its implications, but any changes would need to be introduced with a measured and moderate approach, to avoid unintended consequences and to ensure the profession and pharmacy companies could be fully supported to implement change.

**Question 13: Do you agree that the pharmacy regulators should have the power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time?**

Overall, we continue to support the principle of 'one pharmacy, one pharmacist' because to remove this would be to materially change the role and nature of the Responsible Pharmacist (RP). We believe that to move away from this could have an unintended potential negative impact on the maintenance of clinical governance, patient safety and professional accountability in community pharmacy.

However, we agree in principle that pharmacy regulators should have the power to make exceptions to the rule that RPs can only be in charge of one pharmacy at a time. We believe exceptions should only apply where there are 'good reasons' (see below), and appropriate safeguards in place - including that the Superintendent Pharmacist must provide express permission.

We could particularly envisage that there may be some rare force majeure exceptions where the responsibilities of the actual or intended RP could be temporarily taken on by a Pharmacist already fulfilling RP duties at another pharmacy. This should only be where a pharmacy would not otherwise be able to provide services that would have an immediate detrimental patient impact. These should only be in cases of serious unexpected absence of an RP due to, for example, widespread crisis situations like pandemic flu or civil unrest, or more localised and temporary situations, such as serious adverse weather conditions etc.

Exceptions should only ever apply where it is reasonable and feasible for the duties of a RP to be fulfilled at a second pharmacy such as geographic proximity, remote communication channels etc. We believe any exceptions should always be time-limited until a dedicated RP arrives, although the actual duration would be determined on a case-by-case basis. It should not be arbitrarily curtailed, and exceptional circumstance may continue until a 'business-as-usual state' recommences.

We do not believe exceptional circumstances should ever extend to a Responsible Pharmacist being in charge of more than two pharmacies at one time, as this would fundamentally change the nature of the role. We do not wish to see a situation where an exception-based approach morphed into normal practice over time.

**Question 14: Do you agree that the duty on the Responsible Pharmacist to establish, maintain and keep procedures under review is removed and instead is subsumed into the general duties of Superintendent Pharmacists?**

Yes.

We strongly agree that the responsibility for establishing, maintaining and reviewing policies should be subsumed within the general duties of the Superintendent Pharmacist. We also recognise that there may be a role for Responsible Pharmacists in contributing to the establishment, maintenance and review of procedures and, where that is appropriate and in accordance with the business model, it should not be unnecessarily impeded.

**Question 15: Do you agree that the duties relating to record keeping should be set out by the pharmacy regulators, rather than in Ministerial legislation, and be enforced where appropriate via fitness to practise procedures?**

Yes.

We agree that record keeping duties should be set out by the pharmacy regulators and where standards and requirements are not maintained this would be a fitness to practise matter.

As we reflect throughout this response, regulators must practise early engagement with community pharmacy and actively consult, in accordance with their statutory duty, to ensure the regulatory approach is fit for purpose, avoids unnecessary burdens and constraints on the future development of pharmacy, and guards against regulatory creep.

**Question 16: Do you agree that the pharmacy regulators should be provided with a new general rule/regulation making power in respect to the Responsible Pharmacist and remove the specific Ministerial regulation making powers in respect of: (a) the qualification and experience of Responsible Pharmacists; (b) the Responsible Pharmacist and supervision; (c) procedures; and (d) the record-keeping of the Responsible Pharmacist**

Yes.

We agree that regulation would provide a more agile and responsive framework in support of the Responsible Pharmacist role compared to Ministerial regulation and we recognise this may encompass various dimensions of the roles including those set out. We are also supportive of this approach where it provides clearer and more consistent application of the Responsible Pharmacist role across the sector.

However, we reiterate our point above, that we would be concerned if new regulatory powers gave rise to the development of a burdensome and disproportionate regulatory framework, and unnecessarily constrained the ability of community pharmacy to innovate and further develop. We would like reassurance that any new regulatory powers would be consulted upon and, based on active engagement with the pharmacy sector, be defined in a way that proportionately serves these current purposes while guarding against non-transparent regulatory creep.

**Question 17: Do you agree that the pharmacy regulators should be given new powers to set professional standards for Responsible Pharmacists and describe their role?**

Yes.

We agree that the pharmacy regulators should be given new powers to set standards for Responsible Pharmacists and describe their role. In doing this the regulators must engage and consult proactively with the sector to ensure any future standards are fair, proportionate and workable in the context of all business models within community pharmacy.

As we highlight above in response to Question 12, we believe a new regulatory framework in pharmacy presents the opportunity to re-consider the roles, responsibilities and supporting activities

of all pharmacy roles to support the development of a clear end-to-end governance structure, as new roles emerge and new approaches to service delivery develop.

The regulation that may be developed around the Superintendent Pharmacist and Responsible Pharmacist, as well as the Pharmacy Owner, must remain coherent and not result in unnecessary regulatory burdens. Again, we would be concerned if new regulatory powers gave rise to the development of a burdensome and disproportionate regulatory framework, and unnecessarily constrained the ability of community pharmacy to innovate and further develop.

**Question 18: Do you agree that the Pharmacy (Northern Ireland) Order 1976 should be amended to provide for the appointment of a Deputy Registrar and to provide that the Deputy Registrar may be authorised by the Registrar to act on their behalf in any matter?**

Yes.

We agree the proposal to amend the Pharmacy (Northern Ireland) Order 1976.

**Question 19: Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.**

We cannot comment as we believe the impact will depend on a number of factors we do not yet know about such as timescale for implementation, lead in time for community pharmacy, how any new developments or requirements are introduced alongside existing obligations, and peak periods in the sector.

We also believe there should be fuller consultation with the pharmacy sector reflective of the range of large, medium and small community pharmacy companies to ensure all the relevant impacts are identified and understood. We do not currently believe this has been sufficient to date, as reflected through our responses above.

**Question 20: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?**

We cannot comment as we believe the impact will depend on a number of factors we do not yet know about such as timescale for implementation, lead in time for community pharmacy, how any new developments or requirements are introduced alongside existing obligations, and peak periods in the sector.

We also believe there should be fuller consultation with the pharmacy sector, such as through focus groups, reflective of the range of large, medium and small community pharmacies to ensure all the relevant impacts are identified and understood. We do not currently believe this has been sufficient to date as reflected through our responses above.

*For more information about our response, please contact:*

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