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EU Directive on Services in the Internal Market

Consultation Response Form

The closing date for this consultation is 30/6/2004

The Department may, in accordance with the Code of Practice on Access to Government Information, make available, on public request, individual consultation responses. This will extend to your comments unless you inform us that you wish them to remain confidential.

Please tick if you want us to keep your response confidential ☐

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Please tick one of the following boxes:

	Small to Medium Sized Enterprises
	Representative Organisation (please specify):
	Trade Union
	Interest Group (please specify):
	Big Business
	Local Government
	Central Government
√	Regulator – Royal Pharmaceutical Society of Great Britain
	Other (please describe):

The questions are divided into four sections (see page 9 of the consultation document):

I. General questions (page 4);
II. Questions for business (page 25);
III. Questions for regulators (page 38); and
IV. Questions for service recipients (page 46).

You are welcome to provide answers to questions in any of the sections.

In addition to feedback on the proposals we would welcome information about barriers that are not addressed in the proposals. When responding to the consultation please provide evidence to support your arguments wherever possible.

Return completed forms to:

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General Questions

Question 1.

To what extent do you think the objectives, as set out in Article 1, will be achieved?

Comments:

The RPSGB is the regulatory and professional body for pharmacists in England, Scotland and Wales. The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Royal Pharmaceutical Society welcomes the European Commission's intention to remove barriers to the freedom of establishment and to the free movement of services. However, the RPSGB considers that the proposed Directive on the recognition of professional qualifications (COM (2002)119) constitutes a sufficient regulatory framework to cover issues related to the free movement of service providers, where they are health professionals.

The RPSGB would like the EU institutions to ensure that health-related services, such as services provided by pharmacists, which are to be covered by the Directive on the recognition of professional qualifications, are given due consideration so that no contradictions arise between the two Directives. The RPSGB would encourage the UK authorities to pay particular attention not to compromise what will have been achieved so far through the proposed Directive on the recognition of professional qualifications in order to ensure a maximum level of public safety.

Question 2.

Do you think that the scope of the Directive, as given in Article 2 is sufficient?

☐ Yes	☐ No	☒ Not sure

If not, what changes would you like to see?

The achievement of the Internal Market objectives should not be realised at the expense of public health and safety.

The RPSGB considers that services provided by healthcare professionals, including pharmacists, should be granted special status throughout the text of the future Directive on Services.

The RPSGB calls for either assurance that there will be consistency between the Directive on the recognition of professional qualifications and this Directive or, alternatively, for health-related services to be removed from the scope of the Directive.

Question 3.

Do you think that the exclusions from this Directive given in Article 2(2) are sufficient?

☐ Yes	☒ No	☐ Not sure

If not, what changes or additions would you like to see?

See reply to Question 2.

Question 4.

Do you think the definitions given in Article 4, in particular those for "service", "requirement", "coordinated field" and "authorisation scheme", are adequate in the context of the sector in which you operate?

☐ Yes	☒ No	☐ Not sure

If not, what changes would you like to see?

The RPSGB has concerns with respect to the definition of "authorisation schemes". As explained in our answer to Question 10, the RPSGB disagrees with the principle of implicit consent as laid down in the authorisation procedure. We cannot, therefore, accept that a reference to "an implied decision" be included in the definition of the authorisation scheme.

Question 5.

Do you think that the Directive takes adequate account of other Community law, both in Article 3 and other articles, for example, Articles 17 and 19(3)?

☐ Yes	☐ No	☒ Not sure

Comments:

Article 3 - The actual implications of the Directive on Services on healthcare professionals remain unclear for the time being. Consistency between the Directive on the recognition of professional qualifications and the Directive on Services will be key.

Articles 17 and 19(3) are paramount to the RPSGB.

We understand that Article 17(8) grants a derogation to the country of origin principle for professions covered by the Directive on the recognition of professional qualifications, thus to healthcare professions. We assume that pharmacists will, therefore, not be subject to the country of origin principle.

However, Article 19 introduces some confusion as to whether all health-related professions would be exempted from the country of origin principle on a permanent basis. Article 19 foresees case-by-case derogations from the country of origin principle on aspects related to public health and the practice of a health profession.

We would welcome clarification on the scope of these two Articles.

Question 6.

Have you experienced any difficulties in completing administrative procedures and formalities in order to set up a subsidiary company in another Member State?

☐ Yes	☐ No	☐ Not sure

N/A

Question 7.

In relation to the rule prohibiting a host Member State from requiring further documentation in Article 5(2), do you think the exception '*where a requirement is objectively justified by an overriding reason relating to the public interest*' is too narrow or too wide?

☐ Too narrow	☐ Too wide	X	Not sure

As the registering body for Britain's pharmacists, the RPSGB may require documentation from an individual seeking to be registered with the RPSGB. If this rule were applied to the register of pharmacists maintained by the RPSGB, it would potentially hamper the RPSGB's ability to ensure that those on its register were appropriately qualified and therefore it would work to the detriment of the public interest.

However, our understanding of Article 5 is that restrictions on documentation to be provided will not apply to pharmacists since they derogate from the provision through Article 5(3).

Article 46 of the proposed Directive on the recognition of professional qualifications shall be the legal basis that applies to the documents requested. If confirmed, the RPSGB would not have any problem with this Article.

Question 9.

Do you think there is a need for single points of contact (Article 6)?

☐ Yes	☐ No	X	Not sure

How would you like to see the UK comply with this requirement?

Whilst welcoming the idea of the single point of contact aimed at providing information to service providers, the RPSGB has concerns how such a new system could apply to the establishment and regulation of pharmacies. The RPSGB maintains the register of pharmacy premises and of pharmacists; local health authorities (primary care organisations) award NHS contracts and are to maintain their own lists of practitioners; several UK agencies, including the RPSGB, are involved in ensuring standards in pharmacies are maintained.

The RPSGB considers that it would not be appropriate for the single point of contact to undertake all these functions. Our understanding is that Article 7 describes the single contact point as a mere source of information for providers. It would enable providers to identify the RPSGB as the competent authority for the registration of pharmacists and pharmacies.

However, Article 6 gives the impression that the single point of contact will do more than just being a mere intermediary body between the service provider and the RPSGB since it would deal with declarations, notifications and applications for authorisation from the competent authorities. With such a responsibility there is a risk that the single point of contact, instead of reducing bureaucracy, will become an additional tier of bureaucracy, delay administrative procedures and lead to lack of clarity for service providers.

The RPSGB would also like to draw the attention of the UK authorities to Article 53 of the proposed Directive on the recognition of professional qualifications. The article proposes a less ambitious role for contact points. There is a need for consistency between both Directives.

Question 16.

Do you think the conditions permitting Member States to retain the authorisation schemes, as set out in Article 9(1)(a) to (c) are sufficient?

☐ **Yes** ☐ **No** ☒ **Not sure**

Comments:

As a regulatory and professional body, part of the RPSGB's role is to protect the public and to ensure high standards of pharmacy practice. The registration of pharmacists and pharmacies is a condition for ensuring a high level of public safety.

In the case of healthcare professionals, authorisation schemes are equivalent to registration. It could be worth mentioning in the Directive that registration is the cornerstone of authorisation schemes for healthcare professionals, including pharmacists.

Question 17.

Do the conditions applied to authorisations of limited number or of limited duration in Articles 11 and 12 pose problems for regulators or indeed applicants?

☐ Yes	☐ No	☒ Not sure

If so, please provide suggestions on how such problems could be mitigated.

The register of pharmacists and the register of pharmacy premises run from January 1 to December 31 annually. Before a pharmacy can be registered, plans of its layout are submitted and it may be inspected by one of the Society's own inspectorate. However, the RPSGB has no power to refuse to register pharmacy premises. Premises are then re-registered by means of payment of a retention fee. Pharmacy premises may be re-inspected from time to time.

The RPSGB would want reassurance that the above system would not be jeopardized by Articles 11 and 12. It should be confirmed that the duration of the registration carried out by the RPSGB falls under the scope of Article 11(1)(c).

Question 18.

Do you think the provisions of Article 13 would pose problems for UK authorisation schemes, in particular concerning the costs of the authorisation process incurred by the parties referred to in paragraph 2?

☐ Yes	☐ No	☒ Not sure

If so, please suggest ways any such problems could be mitigated.

The RPSGB agrees with the principles laid down in Article 13(1) about the clarity, publicity, objectivity and impartiality of the decisions taken by the competent authorities for authorisation procedures.

With regard to Article 13(2), new members and premises pay a registration fee and thereafter an annual retention fee. Registration fees can therefore be considered proportionate to the RPSGB's work in carrying out this duty.

In fact, there are different categories of fees for pharmacists, depending on their circumstances, and it is likely that not all categories of fees cover the RPSGB's costs in levying them. A pharmacist over age 60 or who is not working only pays £22. Overseas pharmacists pay £100 (the standard annual retention fee for a pharmacist is £205). These fee scales are likely to be reviewed in due course.

Question 19.

Do you think the tacit consent provision in Article 13(4) would pose problems for any UK regulatory schemes?

[X]	**Yes**	[ ]	**No**	[ ]	**Not sure**

If so, please suggest ways any such problems could be mitigated.

The RPSGB registration standards are high, underpinned by rapid and straightforward processes. Any provision whereby registration of a health professional will be deemed to be granted should the competent authority fail to respond to an application within the time frame specified in its standards is clearly unacceptable as it would be detrimental to the public interest. This would apply to pharmacists, as much as for all other healthcare professionals.

To allow a health professional to be deemed to be included on the register without prior clear consent from the regulatory authority will undermine the general public's confidence in the UK's system for regulating healthcare professionals, which the UK Government is seeking to strengthen.

We ask for a derogation from this provision for healthcare professionals. Alternatively, this provision should be amended so that it follows the lines of Article 47 of the future Directive on the recognition of professional qualifications (see political agreement of the Council of 27 May).

Question 23.

Do you see any problems arising from the notification procedure set out in Article 15(6)?

[ ]	**Yes**	[X]	**No**	[ ]	**Not sure**

N/A

Question 24.

How well do you think the country of origin principle will work in practice (Articles 16 – 19)?

X	**Not well**	☐	**Well**	☐	**Very Well**	☐	**Not Sure**

Further comments:

The country of origin principle is inappropriate for healthcare services. As we understand it, Article 17(8) would grant pharmacists a derogation from the principle of the country of origin as they would be covered by Articles 5 to 9 dealing with the free provision of services under the Directive on the recognition of professional qualifications (see political agreement of the Council of 27 May).

If applied to healthcare professions, including pharmacists, the principle of the country of origin would pose a threat to the protection of the public.

Question 26.

Do you think the derogations given in Articles 17 – 19 are appropriate and sufficient?

☐	**Yes**	☐	**No**	X		**Not sure**	

What changes or additions would you like to see (for example, should there be a derogation for healthcare services or consumer protection where there is a serious problem)?

Should the RPSGB receive the confirmation that pharmacists be covered by the derogation in Article 17(8), we have no problem with Article 17.

Are the safeguards on the exercise of derogations set out in Articles 19 and 37 adequate and workable for businesses or regulators?

The RPSGB is more concerned with Article 19, which allows for derogations from the country of origin principle on a case-by-case basis. The first two possibilities, which could be invoked as a basis to derogate from the county of origin principle, have to do with public health (Article 19(1)(a)) and health professions (Article 19(1)(b)). It is not clear whether healthcare professions, which are covered by the derogation in Article 17(8), will also be covered by this Article.

The RSPGB asks for confirmation that all activities linked to the profession of pharmacist will be covered by the general derogation granted under Article 17(8). Clarifications on the concrete implications of this Article on healthcare regulators are crucial.

Is it clear to you when you would / would not be entitled to take regulatory action in derogation from the country of origin rule?

See answer above.

Question 28.

Are the provisions in Article 19 sufficient to ensure health and safety protection of service providers in other Member States?

☐ Yes	☐ No	☒	Not sure

Comments:

The RPSGB is of the opinion that all regulated healthcare professions should be covered by the derogation in Article 17(8).

Question 31.

Do you think the 'non-discrimination' requirement in Article 21 is sufficient and adequate?

☐ Yes	☐ No	☐	Not sure

N/A.

Question 32.

Do you think the provisions on the posting of workers, as set out in Articles 24 and 25, are sufficient and adequate?

☐ Yes	☐ No	X	Not sure

The RPSGB considers that a reference to the specific nature of healthcare professions, as well as the specific arrangements for these professions enshrined in the Directive on the recognition of professional qualifications, shall be included so that there is no possibility to apply this Article to healthcare professionals, including pharmacists.

Question 35.

How easily do you think the provisions under Articles 24 and 25 can be implemented? For the service provider, the posted worker and public bodies charged with policing the regime?

☐ Not easily	☐ Easily	☐ Very easily	☐ Not Sure

NA

Question 36.

Do you agree that the use of certification and voluntary marks improves the quality of services and should be encouraged?

☐ Yes	☐ No	X	Not sure

Comments:

The RPSGB already applies high standards for performing its role. However, should the European certification and voluntary marks do not undermine UK standards or become burdensome, we would support their development. European certification and voluntary marks should aim at ensuring the highest level of quality to competent authorities' work in dealing with pharmacists and pharmacies across the EU.

Question 38.

What are your views on the information provision requirements in Articles 26 – 30?

Comments:

The RPSGB is concerned that Article 26(3)(d) does not take account of the fact that healthcare professionals who move to another Member State to provide a temporary service will be registered with the competent authority of the host Member State under the proposed Directive on the recognition of professional qualifications. They will, therefore, apply the professional rules of the country in which they temporarily provide the services, not the country in which they are established. Some adjustments to the proposed Directive on Services may be necessary in order to make both Directives work coherently with one another.

The RPSGB welcomes the provision in Article 27(1) that services that present a particular risk to the health or safety of the recipient shall be covered by professional indemnity insurance appropriate to the nature and extent of the risk.

We would ask for the wording of this provision to be consistent with the wording of the future Article 7 of the Directive on the recognition of professional qualifications, which requires service providers in the healthcare sector to provide the competent authorities with the details of their insurance cover with regard to professional liability (see wording of Article 7 of the Council's political agreement of 27 May 2004).

Question 43.

How easily will it be to draw up European level codes of conduct (Article 39) in the sector in which you operate?

X	**Not easy**	☐	**Easy**	☐	**Very Eas**	☐	**Not Sure**

Who should be involved in the drawing up of the codes?

We recognise that there could be high level European codes of conduct for pharmacists and pharmacies, although this would need to allow detailed provision to reflect practice and standards in each Member State.

With respect to Article 39(1)(b), the RPSGB considers that a move to a European code of ethics for pharmacists could presumably only be successful if it remains generic and takes account of cultural differences between Member States.

We would recommend competent authorities, such as the RPSGB, to be involved in the drafting of these codes.

The RPSGB already requires the promotion of pharmacy services to conform to standards of professionalism and objectivity.

On commercial communications (Article 39(1)(a)), the advertising and promotion of medicines are strictly regulated in the UK, where all existing EU Directives apply. No advertising of prescription only medicines direct to the public is permitted; non-prescription medicines advertising is also regulated and the otc industry enforces a code of practice.

Question 44.

Do you think the areas considered for additional harmonisation in Article 40 are sufficient and adequate?

☐ **Yes** ☐ **No** ☐ **Not sure**

N/A

Question 45.

Assuming the Directive is adopted as per the planned schedule, is the timetable for implementation achievable?

☐ **Yes** ☐ **No** ☐ **Not sure**

N/A

Question 49.

Are there any other risks associated with not taking action?

☐ Yes	☐ No	☒ Not sure

Comments:

The Directive on the recognition of professional qualifications will constitute the main EU legislative framework regulating the practice of the profession of pharmacist and will deal with most aspects of the profession. In that sense, the Directive on Services is redundant for the pharmacy sector and the healthcare sector in general.

Question 50.

Are there any other options which would achieve the objective?

☐ Yes	☐ No	☐ Not sure

Comments:

See answer to previous question.

Question 56.

Which proposals in the Directive will you derive most benefit from?

What is the likely scale of the associated benefits?

There are no clear benefits stemming from this proposal for the RPSGB. On the contrary, it may create confusion with the proposal on the recognition of professional qualifications, which will regulate most aspects of regulated healthcare professions, including pharmacists.

We believe the Directive on Services should reflect the changes that are being introduced to the Directive on the recognition of professional qualifications in order to protect public health and patient safety. These achievements should not be unravelled by the Directive on Services whose scope should, possibly, exclude health-related services. If not, consistency with the two proposals should be ensured.

Question 57.

Are there any potentially useful measures which are missing from the Directive?

☐ Yes	☐ No	☐ Not sure

Comments:

N/A

Question 60.

Are there any sectors, groups or types of firm, for example Small and Medium Enterprises that will gain more or less in terms of the potential benefits that could result from the Directive?

☐ Yes	☐ No	☐ Not sure

N/A

Question 61.

Will any particular country or region in the UK gain more or less in terms of the potential benefits that could result from the Directive?

☐ Yes	☐ No	☐ Not sure

N/A

Question 62.

How significant are the risks that the anticipated benefits will not be realised?

☐ Not Significant	☐ Significant	☐ Very Significant	☐ No Change

N/A

Question 63.

How significant are the risks of taking action under Option 2?

Not Significant	Significant	Very Significant	No Change
☐	☐	X	☐

Comments:

As explained previously, the risks are substantial for the healthcare sector.

Question 64.

Are there any other risks associated with option 2?

Yes	No	Not sure
☐	☐	☐

N/A

Question 65.

Which parts of the Directive should be:

Retained?

- Article 5(3): derogation concerning the documents requested under the Directive on the recognition of professional qualifications

- Article 17(8): derogation for service providers covered by the Directive on the recognition of professional qualifications

- Article 27(1) on professional insurance

Deleted?

- Article 14(5) on the economic test - on the ground of public interest.

- Article 15(2)(c) on requirement relating to the professional qualifications in order to hold capital

Improved?

- Article 4 on the definition of "authorisation schemes"

- Articles 6 and 7 on the single points of contact

- Articles 9 and 10 on authorisation schemes

- Article 13 on authorisation schemes (costs of the authorisation process and tacit consent)

- Article 19: case-by-case derogation

- Articles 24/25 on the posting of workers

- Article 31 on the policy on quality of services

- Article 39 on codes of conduct at Community level

- Article 15(2)(g) on fixed minimum/maximum tariffs

Added?

Question 71.

Are there any sectors, groups or types of firm that will lose more or less in terms of the potential costs that could result from the Directive?

☐ **Yes** ☐ **No** ☐ **Not sure**

N/A

Question 72.

Will any particular country or region in the UK lose more or less in terms of the potential costs that could result from the Directive?

☐ **Yes** ☐ **No** ☐ **Not sure**

N/A

Question 75.

What will be the likely impact of the Directive on competition?

New NHS pharmacy openings in the UK are subject to a mechanism known as "control of entry". Local Primary Care Trusts (health authorities) award contracts to dispense NHS prescriptions on the basis of whether a new pharmacy would be "necessary or desirable" and on the basis of other assessments, including an impact assessment on other pharmacies in a locality. Over the years, a considerable body of case law has defined these criteria.

An enquiry by the UK Office of Fair Trading recommended to the UK government that this mechanism should be removed to allow a more open market. Pharmacy organisations, including the RPSGB, conducted a high-profile campaign, supported very widely by the public, to highlight the risks of destabilising the provision of pharmacy services in areas where opening a pharmacy might be less economically attractive.

The UK government has yet to announce its final plans but has said that it has moved from total abolition of the mechanism to a "Balanced package of measures" to foster competition.

Having achieved this potential concession in the public interest, we would be concerned if the UK government's "balanced package of measures" to replace "control of entry" were to be swept away under Article 14 (5).

Question 76.

Are there likely to be any impacts on competition other than those described?

☐ **Yes** ☐ **No** ☐ **Not sure**

N/A

Question 77.

Do you foresee any likely problems with enforcement and sanctions other than those discussed?

N/A

Questions for Regulators

Question 10.

If you are a regulator, do you think the simplification process and the provisions concerning authorisations (Articles 5 - 13) would have serious consequences for the regulation of the sector for which you are responsible?

☐ Yes	☒ No	☐ Not sure

If so, please provide details of such consequences and how they may be mitigated.

Single points of contact (Articles 6 and 7)

Whilst welcoming the idea of the single point of contact in order to provide information to service providers, the RPSGB has concerns how such a new system could apply to the establishment and regulation of pharmacies. The RPSGB maintains the register of pharmacy premises and of pharmacists; local health authorities (primary care organisations) award NHS contracts and are to maintain their own lists of practitioners; several UK agencies, including the RPSGB, are involved in ensuring standards in pharmacies are maintained.

The RPSGB considers that it would not be appropriate for a single point of contact to undertake all these functions. Our understanding is that Article 7 describes the single contact point as a mere source of information for providers. It would enable providers to identify the RPSGB as the competent authority for the registration of pharmacists and pharmacies.

However, Article 6 gives the impression that the single point of contact will do more than just being a mere intermediary body between the service provider and the RPSGB since it would deal with declarations, notifications and applications for authorisation from the competent authorities. With such a responsibility there is a risk that the single point of contact, instead of reducing bureaucracy, will become an additional tier of bureaucracy, delay administrative procedures and lead to lack of clarity for service providers.

The RPSGB would also like to draw the attention of the UK authorities to Article 53 of the proposed Directive on the recognition of professional qualifications. The article proposes a less ambitious role for contact points. There is a need that both Directives are consistent.

Authorisation schemes (Articles 9 and 10)

As stated in our answer to question 16, the RPSGB wonders whether this Article should not make a more precise reference to the fact that registration is the cornerstone of the authorisation schemes for healthcare professionals.

Authorisation procedures (Article 13)

With regard to Article 13(2), new members and premises pay a registration fee and thereafter an annual retention fee. Registration fees can therefore be considered to be proportionate to the RPSGB's work in carrying out this duty.

In fact, there are different categories of fees for pharmacists, depending on their circumstances, and it is likely that not all categories of fees cover the RPSGB's costs in levying them. A pharmacist over age 60 or who is not working only pays £22. Overseas pharmacists pay £100 (the standard annual retention fee for a pharmacist is £205). These fee scales are likely to be reviewed in due course.

The RPSGB has concerns in relation to Article 13(4), which introduces the concept that registration will be deemed to be granted if the competent authority failed to respond to an application within the time frame specified in its standards. From a health professional regulatory body's point of view, this concept is clearly unacceptable.

This provision goes against high level of public safety and health. Allowing pharmacists to consider themselves as being registered without prior clear consent from the RPSGB will undermine the general public's confidence in our registration system, as well as put people at risk.

We ask for healthcare professionals to derogate from this provision or for this provision to be amended so that it follows the lines of Article 47 of the future Directive on the recognition of professional qualifications.

Question 12.

If you are a regulator, do you think that the simplification process (Articles 5 - 8) can be satisfied in the existing legislative framework?

[X] **Yes**	[ ] **No**	[ ] **Not sure**

Do you think that it can be achieved within existing infrastructure and resources?

Yes. Estimated costs deriving from a simplification of the process will be closely linked to the role granted to the single points of contact.

Question 15.

If you are a regulator, do you think that the provisions governing authorisation schemes (Articles 9 - 13) can be implemented under the existing legislative framework?

X	**Yes**	☐	**No**	☐	**Not sure**

Do you think that it can be achieved with existing infrastructure and resources?

Yes. The Directive on Services does not seem to be necessary to the practice of the pharmacy profession.

Question 21.

If you are a regulator, will Articles 14 and 15 significantly impact on the regulation of the area for which you are responsible?

X	**Yes**	☐	**No**	☐	**Not sure**

If so, how?

The RSPGB welcomes the reference to professional qualifications in Article 15(2)(d). However, the RSPGB has concerns with the following paragraphs of Articles 14 and 15. These are Article 14(5) and Article 15(2)(c).

Article 14(5)

In the UK, an application for a contract to dispense NHS prescriptions is subject to a mechanism known as "control of entry". Local primary care organisations (health authorities) award contracts to dispense NHS prescriptions on the basis of whether a new pharmacy would be "necessary or desirable" and on the basis of other assessments, including an impact assessment on other pharmacies in a locality. Over the years, a considerable body of case law has defined these criteria.

An enquiry by the UK Office of Fair Trading recommended to the UK government that this mechanism should be removed to allow a more open market. Pharmacy organisations, including the RPSGB, conducted a high-profile campaign, supported very widely by the public, to highlight the risks of destabilising the provision of pharmacy services in areas where opening a pharmacy might be less economically attractive. The public interest is served by the ready accessibility of a network of pharmacies where people live, shop and work.

The UK government has yet to announce its final plans but has said that it has moved from total abolition of the mechanism to a "Balanced package of measures" to foster competition.

Having achieved this potential concession in the public interest, we would be concerned if the UK government's "balanced package of measures" to replace "control of entry" were to be swept away under Article 14 (5).

Article 15(2)(c)

The RPSGB has concerns with the last part of the paragraph, relating to the removal of the requirement for someone "to have a specific professional qualification in order to hold capital in or to manage certain companies".

The Medicines Act 1968 (Section 71) requires the following:

- If a pharmacy business is to be run as a partnership, then, in England and Wales, all the partners must be pharmacists;
- If a pharmacy business is to be run as a partnership in Scotland, then at least one of the partners must be a pharmacist;
- If the pharmacy is to be run as a body corporate (e.g. a limited company) then a pharmacist superintendent must be appointed who is responsible for the pharmacy activities of the business.

It should be pointed out that the numbers of pharmacies run as sole trader and as a partnership is reducing and the most common mechanism for provision is now the body corporate model. In other words, the Medicines Act has not acted as a barrier to competition.

Moreover, the requirement for a pharmacist superintendent provides a mechanism for quality assurance by making a pharmacist directly responsible for the pharmacy elements of a pharmacy business, ensuring adherence to the Society's code of ethics and practice standards, which promotes public safety. We believe that it would not be in the public interest to remove this requirement.

Article 15(2)(g)

Finally, on Article 15(2)(g), the RPSGB would like the UK authorities to clarify whether this provision would not affect current rules applying for the sale of medicines. Currently, the situation is as follows:

Resale Price Maintenance on non-prescription medicines was abolished some years ago, so pharmacies now have the freedom to set whatever price they choose.

The NHS applies an agreed price formula for patent protected prescription medicines that are sourced by pharmacists. The price for generic medicines is set by means of a competitive market.

What are the estimated costs?

What changes or additions would you like to see?

How could any problems be mitigated?

Are the restrictions identified in Articles 14 and 15 on the right list?

Question 22.

If you are a regulator or responsible for policy in such an area, will the restriction on Article 15(5) on the introduction of new regulatory schemes be a problem for you?

☐ Yes	☒ No	☐ Not sure

Question 27.

If you are a regulator, to what extent will the requirement in Article 16(3) on Member States to supervise UK service providers who provide their services in other Member States have an impact in your area?

☐ Yes	☒ No	☐ Not sure

Pharmacists' services will derogate from this principle through Article 17(8).

Question 41.

If you are a regulator, how easy will you find it to provide assistance and to co-operate with a regulator in another Member State (Articles 34 - 38)?

☐ Very Easy	☐ Easy	☒ Not Easy	☐ Not sure

Comments:

Articles 34 to 38 are to be seen in relation to Article 16 on the country of origin principle. The RPSGB's understanding is that pharmacists will derogate from the country of origin principle through the derogation laid down in Article 17(8). We, therefore, consider that the provisions contained in Articles 34-38 will not affect the RPSGB's activities.

Furthermore, there is no existing system for sharing information between EU competent authorities on the fitness to practice. We would like to see this made compulsory within both the Directive on the recognition of professional qualifications and the Directive on Services.

Question 67.

Are these assessments of costs for Government and regulators reasonable (C.78 p.83)?

[X] **Yes**	[ ] **No**	[ ] **Not sure**

Question 68.

What will be the likely cost of setting up a "single point of contact" (Article 6)?

The cost of simplifying the process will depend on the scope of the role of the single point of contact.

Question 69.

What other likely costs can you foresee?

N/A

Question: 78

Are the proposed arrangements for monitoring adequate (c.102 – C.108 p.92-3)?

[ ] **Yes**	[ ] **No**	[ ] **Not sure**

N/A

Question 79.

What will be the likely costs of monitoring for your sector?

N/A

Do you have any other comments that might aid the consultation process as a whole?

Please use this space for any general comments that you may have, comments on the layout of this consultation would also be welcomed.

Comments:

The Royal Pharmaceutical Society of Great Britain is the regulatory and professional body for pharmacists in England, Scotland and Wales. The primary objective of the Society is to lead, regulate and develop the pharmacy profession.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Society is also a Chartered body with objects to promote the interests of members in the exercise of the profession of pharmacy; the advancement of science and the application of pharmaceutical knowledge.

Further Comments:

Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below.

Please acknowledge this reply [X]

Here at the Department for Trade and Industry we carry out our research on many different topics and consultations. As your views are valuable to us, would it be alright if we were to contact you again from time to time either for research or to send through consultation documents?

[X] **Yes** [ ] **No**