Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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Dear Mr Evans,

Re: Chemical substances that can be used in the manufacture of illegal drugs: consultation on proposal for legislation

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation.

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

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 wishes to highlight that pharmacy premises and the supply of products from them are already highly regulated. If the additional proposed regulations set out in the regulatory impact consultation assessment are put into place we request that the following points be taken into consideration:

- The Society generally supports the measures being introduced to monitor the trade in licit substances that can be used in the manufacture of illegal drugs.

- The Society notes that in relation to the intra community regulations, it is clear that pharmacists and persons lawfully conducting a retail pharmacy business fall within the 'special licence' provisions (reg 5). The Society believes in the concept of proportionate regulation in relation to the risk posed and there appears to be no evidence of a major risk posed by the pharmacy profession in relation to the supply of precursor chemicals.

- Clarification is sought on the following questions: Do all pharmacists need a licence or just those working with precursors etc.? / How do pharmacists get hold of a licence? / Is the responsibility on the pharmacist to ensure they have such a licence? Guidance may need to be provided to pharmacists in this respect.

- The legislation referred to in the Controlled Drugs (Drug Precursors) (Intra-Community Trade) Regulations 2007, from which they take the definition for a pharmacist, is out of date as it refers to the Pharmacy Act 1954 which has been repealed by the Pharmacist and Pharmacy Technicians Order.

- Pharmacy is already a highly regulated profession and the Society has recently worked with the Medicines Healthcare products Regulatory Agency to introduce professional controls on the sales of medicinal over the counter products containing ephedrine and pseudoephedrine in a multi agency approach to tackling concerns about the use of these products in the manufacture of the Class A drug, methylamphetamine, without the requirement for statutory controls. The Society believes it could have worked with the relevant agencies to operate professional, rather than statutory controls over the sales of precursor chemicals.

- Notwithstanding this, the Society welcomes the 'special licensing' provisions, as an alternative to the usual licensing provisions, as this acknowledges the fact that there does not appear to be evidence that pharmacists and persons lawfully conducting a retail pharmacy business are the main source of supply in substances used for manufacture of illegal drugs and that pharmacists are generally involved in the legitimate supply of products such as potassium permanganate to patients.

- These intra community regulations make it a legal requirement that operators who possess or place on the market a scheduled substance (substances useful for the manufacture of controlled drugs, known as drug precursors) have a licence where that substance is in Category 1 of Annex I to the Community Regulation and to register where that substance is in Category 2 of Annex I to that Regulation.

- The Society notes that in the Directive 111/2005, Category 2 products include potassium permanganate. As a number of community pharmacies stock this product it seems to be the case that pharmacists will be affected by licensing requirements imposed by the Regulations if they possess this product.

- It is not clear whether there will be a charge for the 'special licence' provisions, which are available for pharmacists and persons lawfully conducting retail pharmacy businesses. As this is proposed to be a one off licence, the Society would not support costs of this new scheme being transferred to pharmacists and persons lawfully conducting retail pharmacy businesses. All pharmacists and persons lawfully conducting a retail pharmacy business are required to be registered with the Society and proposed retention fee increases to pharmacy premises and individual registration fees for 2008 are partly as a result of the impact of an increasing regulatory burden. Further costs of increasing regulation imposed by the Government would be unacceptable.

- The Society notes also that Category 3 products contain HCl, acetone, which are not uncommon in community pharmacies.

The Society has a Memorandum of Understanding with the National Treatment Agency for Substance Misuse. The following comments [verbatim] have been provided by representatives from the RPSGB/NTA working party:

- It is our understanding that the European Regulations 1277/2005, 273/2004, and 111/2005 are directly applicable. They formed part of national legislation across the EU as soon as they came into force and are binding. They do not need to be implemented nationally to be effective unlike an EU directive.

- These regulations leave the individual states to determine penalties for breaching the European Regulations and for choosing who the competent authorities are. In effect if this is not done, then the European Regulations cannot be enforced or complied with.

- The consultation discusses two UK regulations which would flesh out the Regulations and make them operational.

- As soon as the UK regulations come into force, it will be an offence to be an operator[1] without a licence or special licence.

- The EU regulations do not apply to medicinal products[2].

- It is our understanding that all operators[1] will need a licence which is valid for a maximum of 3 years. Some categories of people, including pharmacists, or persons lawfully conducing a retail pharmacy can apply for a special licence which has no expiry date. It is our belief that if a pharmacy did not want to be an operator, they would not need a licence or special licence as long as they did not sell/supply/handle/store the listed scheduled items.

- It is our understanding that pharmacies will be operators[1] **if** they 'place onto the market[3] listed scheduled products **unless** these listed scheduled products are all medicinal products[2] under the EU definition. It would be helpful if this could be confirmed.

- We believe that the record keeping requirements which apply to licence holders do not apply to pharmacies if they hold special licences (please double check this). A5 273/2004

- An obligation is imposed to report suspicious transactions or orders (including unusual quantities or orders). This is imposed by the European Regulation 273/2004 Article 8.

- There are penalities for non-compliance (not directly related to point above). The two UK regulations which are being implemented will make it a criminal offence not to comply with certain parts of the European Regulations. Not being licensed or not registering will be offences for which there may be fines or imprisonment.

- We would be concerned that enough time and notice is given to operators to comply with the proposed legislation to obtain licenses once the legislation is implemented. There would need to be sufficient of time during which the competent authority starts to issue license before the penalties come into force or all current operators would be breaking the law.

- We would want assurances that special licences will be granted as quickly as possible to pharmacies conducting retail businesses.

- The draft explanatory notes for the intra-community precursor UK regulations mentions 6 months reporting to the competent authority – we cannot see a reference to this in the legislation itself or in the European Regulations (which seem to indicate yearly reporting). We are also unsure if the exemption from documentation will exempt special licence holders from the reporting requirement too.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sadia Khan
Lead Pharmacist for Self-care

1. Defined in A2 273/2004 Regulations
2. Defined in 2001/83/EC Directive
3. Defined in A2 273/2004 - defined widely, supply, store, process, distribute etc