

Dear Anne Ryan,

RE: INFORMAL CONSULTATION ON THE PROVISIONS FOR PATIENT GROUP DIRECTIONS AND OTHER MATTERS

Thank you for asking the Royal Pharmaceutical Society (RPS) to comment on proposals to changes for PGDs and other matters.

The RPS is the new professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain and we lead and support the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

Consultation Response

Positive and negative aspects of PGDs (paragraph 5)

We consider that PGDs are a valuable mechanism for the provision of healthcare to the public and support their use in their current form.

The pharmacy profession has engaged in the use of both NHS and private PGDs, from emergency hormonal contraception schemes to seasonal influenza and initiatives to provide healthcare to patients with ailments ranging from obesity, alopecia and impotence.

We acknowledge that the quality of individual PGDs may vary and agree that it is important that these are therefore crafted by doctors and pharmacists who are specialists in the clinical area of the individual PGD.

We would however like to highlight the importance of the work of the Harmonisation of Accreditation Group and would hope the aims of reducing obstacles to continuity and timely provision of pharmacy services to patients can be transferred where applicable to NHS PGDs.

Further information on the work of the Harmonisation of Accreditation group can be found here <http://www.pcc.nhs.uk/200>

Should there be a review of Department of Health guidance on PGDs? (Paragraph 6)

We agree that it would be beneficial for the revision and update of Department of Health Guidance on PGDs.

Should there be clarification of patient specific directions and directions for administration? (Paragraph 9 or Article 12 of the POM order)

We agree that it would be useful to clarify any confusion related to patient specific directions (PSDs) and directions for administration.

Who should commission, develop and authorise NHS PGDs in the future? (Paragraph 10)

Regarding the organisational changes and ensuring that the use of NHS PGDs continues to be enabled by legislation, we agree that amending the POM order is necessary. Although the commissioning body (GP Consortia) will be monitoring for services provided, there could be a potential conflict of interest resulting in a scaling back of NHS PGDs and this could be detrimental to patient access to medicines and safeguards must be put into place to ensure that NHS PGDs continue to be commissioned where appropriate and the decision making process, in addition to the commissioning process, is fair and transparent.

Any organisational change should also guard against a postcode lottery for PGD services in the future. It may be beneficial for providers of services, rather than commissioners to be responsible for developing and authorising PGDs.

Should non-medical prescribers be able to authorise written directions in hospitals? (Paragraph 11)

We support the proposal to amend the exemption to allow the supply for the purposes of administration in accordance with the written directions of non-medical prescribers.

Should only registered health care professionals be able to supply or administer medicines under PGD? (Paragraphs 13 to 14 or Article 12B of the POM order)

We strongly agree with the proposal to retain the requirement that only registered health professionals can supply or administer medicines under PGD.

Should independent providers entering into arrangements with a pharmacy be required to register in the country where the pharmacy is registered?

Clarification is necessary regarding whether this review will be for all devolved countries as there have been anecdotal reports of different interpretation of PGD legislation between countries.

Should GP and dental surgeries and other registrants with CQC be able to offer private PGDS? (Paragraph 16)

This could lead to increased confusion for patients who need to know clearly whether an NHS service or private service is being provided. There could also be an unnecessary risk of disrupting the existing arrangements for the provision of private PGD where there is no evidence of a problem. There may be additional conflict of interest, particularly if GP consortia become responsible for commissioning NHS PGDs.

Within the prison environment, should a PGD which has been authorised by an NHS body continue to require the prison governor to also sign the PGD. (Paragraph 19)

We agree that within the prison environment, where a PGD has been authorised by an NHS body, then it would be unnecessary for the prison governor to also sign the PGD.

Should a review date be added to the requirement for PGDs? (Paragraph 20)

We agree that there should be a review date for any PGDs which is in force for more than 2 years. We understand that there is currently a requirement for a start date and an expiry date however it is only a recommendation which restricts the expiry to 2 years. We acknowledge where the recommendation for a 2 year expiry is followed, then this is in reality the review date, however there may be circumstances when this guideline is not adhered to, in which case a review date would be beneficial. An earlier review date is also necessary in other circumstances, such as in response to an incident or new information.

Should unlicensed medicines be allowed to be supplied under PGD? (Paragraph 21)

We agree with the principle of allowing unlicensed medicines to be supplied under PGD where there is a nationally identified need to use a specific unlicensed product.

Should prescription medicines supplied under PGD be subject to labelling requirements? (Paragraph 22)

We agree in principle with the proposal to amend the Marketing Authorisation Regulations so that prescription only medicines supplied under PGD require labelling in the same way in which dispensed medicines are required to be labelled. This is particularly important if the patient is taking the medicine away for self-administration. If however the medicine is being administered directly such as in the case of a vaccine, then it would be unnecessarily burdensome for this to be labelled.

We hope these comments are useful.

Thank you for contacting the Society.

Yours sincerely,



Wing Tang MRPharmS GDL
Senior Legal and Ethical Pharmacist