Response document for MHRA public consultation on the proposal to make Sildenafil 50mg Tablets available in Pharmacies
Ref: ARM94

Your details

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a. Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine?

Yes √ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

The Royal Pharmaceutical Society fully supports the application for Sildenafil 50mg Tablets to be made available as a Pharmacy medicine so that it can be provided directly by pharmacists for erectile dysfunction.

Discussing health problems with patients and advising on the benefits and risks of treatment options is an integral part of the role of a pharmacist. Pharmacists are experts in medicines, and have the necessary skills and training to ensure the safe and appropriate supply of pharmacy medicines. We believe availability of this product as a P medicine will provide clear benefits for patients in terms of access and safety. Supply by community pharmacies will provide a genuine and safe source of supply (as opposed to counterfeit) and additionally will bring men into the healthcare system.

b. Do you have any specific comments on the checklist, leaflet or the label provided in the public reclassification report? In particular:

- **If you are a potential patient, do you find the patient information leaflet (Annex 2) and the label (Annex 3) understandable?**
- **If you are a pharmacist or healthcare professional, do you find the checklist (Annex 5) useful?**

Comments relating to Annex 5

A checklist is a useful tool for pharmacists (and their teams) to use and checklists can support pharmacists to ensure they are asking all the appropriate questions, particularly when dealing with a newly reclassified product for the first time. However checklists can also be seen as a barrier to supply by both patients and pharmacists. We would suggest that it is made clear that the checklist is an optional tool for pharmacists to use and that completion of the checklist is not mandatory. Pharmacists should be able to use their professional judgement to decide when and how to use the checklist and when supply is appropriate.

In addition we believe the format and language of the checklist needs to be revised. Currently the checklist is written in a yes/no format with questions phrased as though the checklist could be completed by the patient themselves. We would suggest that the yes/no boxes are removed and the checklist redesigned as a prompt of the useful questions to ask to support the pharmacist's consultation with the patient. Open questions should be used whenever possible to support the consultation process.

Specific feedback on the questions:

'1. Who is Sildenafil 50mg for?
It is important to confirm if the man is already receiving treatment for the condition. Men currently prescribed 50 mg of sildenafil can be supplied this product provided they do not take more than 50 mg daily.'
Should this also say 'different dose' (as in the following sentence) as some patients may take a lower dose?

‘3. Check concomitant medication use’
Would a statement such as 'Is the man taking any other medicines, including recreational drugs?' be better than individual questions about specific medicines? 'Are you taking any CYP3A4 inhibitors or alpha blockers' would not be a question that a pharmacist could ask a patient. The pharmacist could use the list of contraindicated medicines as a prompt.

‘Using Sildenafil 50mg
‘• Do NOT use nitrates to treat your chest pain.’
Should this point be a continuation of the point above it (rather than a separate one) as it still relates to chest pains?

c. Do you have any other comments on the reclassification?

As erectile dysfunction can be a warning sign of cardiovascular disease, increasing access to sildenafil via consultations at pharmacies means more men are likely to get the help they need. Pharmacists will provide referral to local GPs when necessary, which could help detect the underlying cause of erectile dysfunction and potentially reduce heart attacks and strokes.

d. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐ Partially* ☐ No √

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gsi.gov.uk) to arrive by **18 April 2017.** Contributions received after that date cannot be included in the exercise.