

ARM 94 SUMMARY TABLE OF RESPONSES ON PROPOSED POM TO P RECLASSIFICATION FOR SILDENAFIL TABLETS

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential
1	Pharmacist, Wyvern Pharma Ltd		X		No
<p>Comments</p> <p>Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine? I believe that until SCR is more widely used and contains more information on conditions this is not a suitable medicine for sale. Sold in pharmacies, there is too much scope for patients to visit numerous pharmacies and not get the required health checks with their GP. OTC sales do not get inputted onto SCR, therefore no pharmacy will know if it has been sold before, or how recently. Risk of interactions with other medicines that cannot be checked (eg if patient has no SCR or if they do not consent for pharmacy to access) puts patients at risk of harm. Available over the counter, I believe will lead patients to consider the medicine overly safe and feel they can mislead to obtain it, at detriment to their future health. Pharmacies will be coerced into making supplies by demanding patients and the threat of complaints to head office, regulators and local news.</p> <p>Do you have any other comments on the reclassification? Given availability from registered prescribers and via PGD in pharmacies, I do not think a reclassification is in the patient's best interests. Some members of the public will still use online sales even if available in pharmacies, due to anonymity online. Please do not use reclassification in an attempt to stop these sales as I do not believe it will work.</p>					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
2	[redacted]				Yes
<p>Comments</p> <p>[redacted]</p>					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
3	Pharmacist	X			No
<p>Comments</p> <p>Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine? Makes sense and may allow for increased face to face consultations in regards to erectile dysfunction between pharmacist & patient highlighting any patients with other underlying causes, rather than people depending on the online based private prescription & pharmacy route.</p> <p>Do you have any specific comments on the checklist, leaflet or the label provided in the public reclassification report? In particular:</p> <ul style="list-style-type: none"> - 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? <p>Patient information leaflet & label look fine and understandable from patient perspective.</p> <p>The checklist looks usable and useful from the pharmacist perspective and is similar to questionnaires online private prescription pharmacies already use but a bit more in depth.</p> <p>Do you have any other comments on the reclassification? No concerns.</p>					

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
4	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
5	Chief Executive, Dispensing Doctors' Association	X			No
Comments We agree with the analysis set out in the consultation document.					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
6	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
7	[redacted]				Yes

Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
8	Patient	X			Partially (redact name)
Comments <p>Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine? Yes, this is a good patient-centred plan, which will improve safe accessibility to this medication.</p> <p>Do you have any specific comments on the checklist, leaflet or the label provided in the public reclassification report? In particular:</p> <ul style="list-style-type: none"> - 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? <p>Yes, the PIL is understandable. The Checklist appears to be suitable</p> <p>Do you have any other comments on the reclassification? I fully support this reclassification. Please note with recent plans proposed to make Tadalafil no longer prescribable on the NHS, consideration should also be given to reclassifying Tadalafil once</p>					

it becomes available as a generic product, as many men find its longer duration of action enables spontaneity in sexual activity, rather than the pre-planning required when using Sildenafil because of its much shorter duration of action.					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
9	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
10	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
11	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
12	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
13	Member of public	X			No
Comments Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine? it will reduce pressure on GPs and the NHS - streamline efficiency and promote fair access and public confidence. <p>Do you have any specific comments on the checklist, leaflet or the label provided in the public reclassification report? In particular:</p> <ul style="list-style-type: none"> - 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? 					

no comment. Except keep it simple and clear.

Do you have any other comments on the reclassification?

no except simple is best re public access info.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
14	Lead Pharmacist, Green Light Pharmacy	X			No

Comments

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

It is already available on PGD and has been shown to be safe.

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?**

Yes, I find the checklist ease to use and helpful.

Do you have any other comments on the reclassification?

Should be a positive for patients.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
15	Regional Superintendent Pharmacist, Weldricks Pharmacy	X			No

Comments

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

I feel that access to this medication via a regulated healthcare professional in community pharmacy has the following benefits;

Reducing the access through illicit means, unregulated websites, black market etc.

Earlier identification of other health issues during the consultation process of any OTC purchase, thus improving the health and prevention of subsequent sequelae from cardiovascular or mental health problems.

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?

The annex is a useful prompt to aid discussion with a patient, but I feel with the Health Living Pharmacy aspect of the new pharmacy contract, more emphasis could be placed on the follow up advice section of the annex. Any material to prompt or direct the discussion would be welcomed.

The annex also mentions providing a record of the advice for men deemed inappropriate for OTC purchase. I would suggest that a specific advice card, would be useful, rather than a copy of the pharmacy checklist (as that was I assumed was implied) – which could help emphasise the advice for referral given by the pharmacy team.

Do you have any other comments on the reclassification?

I personally feel that reclassifications of POM to P are to be welcomed, where the evidence for a product shows it to be safe to do so. In this reclassification, I think the increased opportunity of men accessing a healthcare professional are to be seized upon. It is known that men are poor in terms of accessing HCPs in a timely manner, and this product will be a starting point for a discussion covering cardiovascular and mental health, along with healthy living advice.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
16	Chair of Practice, Guild of Healthcare Pharmacists	X			No
<p>Comments</p> <p>Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine? We believe that introducing Sildenafil as a Pharmacy medicine is an appropriate reclassification. This will allow people to manage an aspect of their own health that has in the past required a prescription, and is in keeping with the wider move to encourage self-care.</p> <p>Do you have any specific comments on the checklist, leaflet or the label provided in the public reclassification report? In particular:</p> <p>We believe there are risks to taking this medication, but that they are adequately explained in the literature and covered in the screening checklist. The screening checklist is useful and easy to use.</p> <p>We feel it is unlikely that people will come to harm as a result of purchasing this medication unless they have misled the screening pharmacist in their responses. To counter this we would recommend that the screening tool also include a prompt for the pharmacist to check the pharmacies own records for evidence of recent supply of any of the counter-indicated substances. Of course, this may not always be accurate (e.g. if someone is attending a pharmacy for the first time), however it is a simple and proportionate step.</p> <p>One risk that we feel is perhaps not as clear as it should be is the concurrent use with amyl nitrate. It is referenced in a question but due to the illicit nature of this substances use it would be helpful to include a specific counselling point referencing why this is counter-indicated.</p>					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
17	[redacted]				Yes
<p>Comments</p> <p>[redacted]</p>					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
18	[redacted]				Yes
<p>Comments</p>					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
19	[redacted]				Yes
<p>Comments</p> <p>[redacted]</p> <p>.</p>					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
20	Liverpool John Moores University	X			No
<p>Comments</p>					

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

I believe that sildenafil tablets should be available for patients to buy in a pharmacy providing that these are supplied upon a consultation with a pharmacist and that there are some form of guidelines in place. Also, I believe that the pharmacist should have undergone additional training, e.g short training course, before supplying sildenafil to patients. Pharmacists have the appropriate skills required to recognise any contra-indications and medicines that may interact with sildenafil. In addition, pharmacists have the ability to discuss and explore the options with the patient which often the GP does not have time for. The patient should be reviewed by the pharmacist shortly after initiating treatment with viagra, similar to following up patients receiving NRT through the smoking cessation service. Patients with any signs or previous history of a renal or hepatic disorder should be referred to their GP so a blood test can be performed beforehand (hopefully this will be part of the pharmacists role in the future). There should be a restriction on the amount of sildenafil that a patient can obtain to reduce the risk of abuse and harm, supplies should be recorded on a shared system, e.g patients summary care record, and the patient should be asked to sign a consent form. Providing that there are procedures and standards in place I believe that pharmacists are a safe and reliable source for patients to obtain sildenafil.

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

Yes, a checklist is always useful.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
21	Chief Executive, Men's Health Forum	X			No

Comments

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

We welcome this proposed change.

If this proposal is implemented, it will mean that more men get help to tackle a common issue that causes many men and their partners distress. It also means that more men who are worried about erection problems but who are not currently getting help will be able to see a health professional on any high street. Pharmacies are much easier to access than GP services, especially for people in full-time work (work commitments are a particular barrier for men using GP services).

Erection problems are often a symptom of a serious underlying condition, such as cardiovascular disease or diabetes, so it is very important that more men with ED are seen as soon as possible by a health professional. In our view, it does not matter whether this is a pharmacist or a GP providing pharmacists and patient information materials encourage men to see a GP for a full assessment..

There is good evidence that many men are currently seeking Sildenafil and other ED drugs from illegal sources. This is a potentially dangerous activity which should be reduced in scale by easier legitimate access to drugs.

Overall, we are confident that the benefits of this proposal heavily outweigh any possible risks.

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?**

We recommend repositioning the PIL box beginning 'It is important to have a check-up' at or near the start of the leaflet. In fact, because of the importance of men seeing their GP for a full assessment, we would like to see this box reproduced on both sides of the leaflet and for its content to be also summarised on the outside of the box (eg.: 'It is important to have a check-up with your doctor as soon as possible - certainly within 6 months of using Sildenafil 50mg.')

It is also important for the box to make clear that even if Sildenafil successfully treats the ED that does not mean that the underlying condition has also been treated.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
22	[redacted]				Yes

Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
23	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
24	[redacted]				Yes
Comments [redacted].					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
25	General Practitioner Durham Road Medical Group	X			No
Comments Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine? Makes less embarrassing for some patients. Many patients but it on line with little or no control so safer to have pharmacist supervising who gets it. Might make less work for GPs doing private scripts etc [although may result in more people requesting it on prescription] - If you are a pharmacist or healthcare professional, do you find the checklist (Annex 5) useful? Yes					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
26	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
27	[redacted]				Yes
Comments [redacted]					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)

28	HEART UK- The Cholesterol Charity	X			No
<p>Comments</p> <p>Do you consider that Sildenafil 50mg Tablets should be available as a Pharmacy medicine? ED can be a problem men with CVD and high cholesterol. Men are reluctant to speak about it. Lipid Clinics also offer advice and it is reported that many patients find talking about ED difficult. Providing greater access to health care professionals in a pharmacy would increase awareness of the support available for men with ED and crucially help identify any underlying cause, such as CVD and high cholesterol. The availability in a pharmacy will also help reduce issues that arise when medicines are purchased online, without the support of a health care professional which may not be from a legitimate source and potentially counterfeited.</p> <p>- If you are a potential patient, do you find the patient information leaflet (Annex 2) and the label (Annex 3) understandable? CVD and cholesterol may be an underlying cause of ED and HEART UK are pleased that this is noted in Annex 2.</p> <p>Do you have any other comments on the reclassification?</p> <ol style="list-style-type: none"> 1. ED is association with CVD risk factors including dyslipidaemia and may the first sign of subclinical vascular disease 2. Patients with ED should have a CVD risk factor assesement – the pharmacist has an opportunity to enquire if a health check has been done 3. Reduction of CVD risk factors including lipid lowering therapy (LLT) may improve ED 4. Statins may be stopped when patients complain of ED, but statins are rarely to blame 5. Statins may actually improve ED, and sometimes patients who fail to respond to sildenafil respond when statin is added <p>References Modifying Risk Factors in the Management of Erectile Dysfunction: A Review.<http://www.ncbi.nlm.nih.gov/pubmed/27574592> DeLay KJ, Haney N, Hellstrom WJ. World J Mens Health. 2016 Aug;34(2):89-100. doi: 10.5534/wjmh.2016.34.2.89. Epub 2016 Aug 23. Review. PMID: 27574592 [PubMed] Free PMC Article Subclinical Vascular Disease and Subsequent Erectile Dysfunction: The Multiethnic Study of Atherosclerosis (MESA).<http://www.ncbi.nlm.nih.gov/pubmed/27145089> Feldman DI, Cainzos-Achirica M, Billups KL, DeFilippis AP, Chitale K, Greenland P, Stein JH, Budoff MJ, Dardari Z, Miner M, Blumenthal RS, Nasir K, Blaha MJ. Clin Cardiol. 2016 May;39(5):291-8. doi: 10.1002/clc.22530. Epub 2016 May 3. PMID: 27145089 [PubMed - indexed for MEDLINE] Free Article A review of the positive and negative effects of cardiovascular drugs on sexual function: a proposed table for use in clinical practice.<http://www.ncbi.nlm.nih.gov/pubmed/24155101> Nicolai MP, Liem SS, Both S, Pelger RC, Putter H, Schali MJ, Elzevier HW. Neth Heart J. 2014 Jan;22(1):11-9. doi: 10.1007/s12471-013-0482-z. Atorvastatin improves the response to sildenafil in hypercholesterolemic men with erectile dysfunction not initially responsive to sildenafil.<http://www.ncbi.nlm.nih.gov/pubmed/19865092> Dadkhah F, Safarinejad MR, Asgari MA, Hosseini SY, Lashay A, Amini E. Int J Impot Res. 2010 Jan-Feb;22(1):51-60. doi: 10.1038/ijir.2009.48. Epub 2009 Oct 29.</p>					
Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
29	GP, Newbattle Medical Practice	X			No
<p>Comments</p> <p>Do you have any specific comments on the checklist, leaflet or the label provided in the public reclassification report? In particular:</p> <ul style="list-style-type: none"> - 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? 					

YES AND YES

Do you have any other comments on the reclassification?

I would like to see the development of a shared prescription record to allow GPs and other doctors to know a patient is receiving this medication from the pharmacist to minimise adverse drug interactions. I also have some concern about this becoming overly used by a young population not necessarily in need of the medication but using it for perceived performance enhancement.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
30	Policy & Development Pharmacist Community Pharmacy Scotland	X			No

Comments

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

Please provide any comments or evidence to support your response:

Community Pharmacy Scotland believes that this POM-P switch presents a valuable opportunity for pharmacists to have meaningful conversations about healthcare issues with a notoriously hard-to-reach subset of the population. In addition, we expect to see a reduction in the purchase of unregulated products in favour of accessing Sildenafil from a trusted source.

We note that although there is an MDD, there appears to be no guidance as to what may constitute excessive use. It may be that that even daily use is of no safety risk to those who are deemed suitable, but it would be reassuring for this to be made explicit.

We recognise that the concerns with regards to existing medical conditions, other medications and the potential for missed diagnoses are greater than with perhaps any other P medicine, however the risk management plan would appear to be robust. This route of assessment and supply will be safer than some current alternatives, and as such we support its introduction.

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

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?

We welcome the checklist, but would have appreciated an opportunity to review the training materials as well to ensure they were fit for community pharmacy use. It would also be of use to have some form of verification process for when a patient qualifies for a supply, in order to make subsequent access as safe but also as patient-centred as possible. One suggestion would be a card which could be signed and dated/stamped by the pharmacist, much like has been used for supplies of Sumatriptan in the past.

With regards to the information leaflet, we are disappointed to see that the potential underlying mental health causes of ED are not included in the “Warnings and precautions” box. It is our opinion that undiagnosed mental health conditions should also be classed as serious, and deserve to be treated as such.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
31	Pharmacy Student		X		No

Comments

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

One of my concerns with the reclassification is the abuse potential that will follow. It is a drug already being abused at present and this will only further the abuse of the drug. Sildenafil as a PDE-5 inhibitor has several side effects and interactions with medication which are hazardous to health, nitrates such as nicorandil and glyceryl trinitrate are contraindicated with sildenafil and will potentate the hypotensive effect. People who are unaware of predisposed heart conditions or are unaware of the medication they take could fall through the net.

Priapism is more common than reported and drugs such as Trazodone can make these side effects worse and the worst-case scenario for priapism linked to Viagra untreated is Toxic Epidermal Necrolysis.

<http://www.drugwise.org.uk/viagra/> links the rising use of cocaine and other stimulants being used with sildenafil and the links between two cause unpredictable cardiac events.

An unhealth related concern to this is that this medication will be licensed for sale only by the applicant, as this medications patent for Erectile dysfunction as expired (Viagra). This will unfairly push up the price for people wanting to purchase it while generic versions are available and will be excluded from sale, this will unfairly gain huge profit for the applicant. As the patent for the applicants branded product has already expired not allowing other companies to manufacture sildenafil for pharmacy only, could potentially allow for a legal challenge to arise. The applicant seems to want to prolong their expired patent to an unfair advantage against competitors.

Do you have any specific comments on the checklist, leaflet or the label provided in the public reclassification report? In particular: Blood Pressure could be compulsory for sale

-If you are a potential patient, do you find the patient information leaflet (Annex 2) and the label (Annex understandable)? From working and advising the public in my experience the public will not understand and men in most instances will ignore the warnings.

-If you are a pharmacist or healthcare professional, do you find the checklist (Annex 5) useful?
It seems useful but may not be applicable in all circumstances, pharmacists may miss parts of the checklist such as sickle-cell (increased risk of priapism) and most patents under 30 may not know if they have vascular heart disease, cardiomyopathy or any other hypotensive heart condition.

Do you have any other comments on the reclassification?

Change the prescribing roles so nurse can prescribe it, at the GP nurse will have access to medical history and will be able to take relevant tests before prescribing. This will safe guard the patent from undue harm that a pharmacist may not be able to prevent due to less resources and more pressure.

Some PPI's (proton pump inhibitors) where reclassified and this saw a rise in undiagnosed oesophageal cancers as patents where taking these medications to medicate the symptoms thinking it was just acid reflux.

<https://www.ncbi.nlm.nih.gov> › NCBI › Literature › PubMed Central (PMC)

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
32	National Pharmacy Association	X			No

Comments

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

Community Pharmacists are the most accessible clinicians on the high street, and are increasingly, available over extended opening hours to provide advice on medications as well as the prevention of ill-health, without the need for an appointment.

Currently some pharmacists already provide Sildenafil under Patient Group Directions (PGDs).

The provision of Sildenafil through the pharmacy as a P medicine would aid in the accessibility of this medication. In addition, community pharmacists are well positioned to provide the advice and support to the customer, including side-effects, potential interactions, as well as lifestyle and usage advice. As mentioned in the consultation document the provision of this drug through the pharmacy, may also lead to an “increase and/ or earlier diagnosis of potential underlying conditions such as cardiovascular disease or diabetes”, which in turn would lead to early treatment for these individuals.

Supply through pharmacy may also encourage some people who seek a supply through unregistered online suppliers to choose a legitimate supply route.

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?**

Patient information leaflet (Annex 2)

The Patient information leaflet appears to be comprehensive as to the uses of sildenafil, contraindications and dosage. It also makes reference to seeking advice from the pharmacist and doctor.

Label (Annex 3)

The NPA has concerns with the packaging of the box and the explicit wording on the front “Helps you get and keep an erection” in regards to patient confidentiality and privacy.

The individual purchasing such an item would have already had a conversation with the pharmacist as to its usage and suitability. The usage of the medication is also written on the back of the box, and repeated on the patient information leaflet, hence, it is suggested that there is no further requirement for this to be written explicitly on the front of the packaging. Please note, that products of a similarly sensitive nature, do not have such explicit descriptions on the front of the packaging.

Checklist (Annex 5)

The checklist provided for use by the Pharmacist has all the necessary questions listed. The tick boxes also allow for ease of recording especially in the community pharmacy. The added points for counselling and other information would also be of use to the community pharmacists.

As highlighted in the consultation, this product requires a clinical assessment, and hence we suggest that the supply of Sildenafil will always require the intervention of a pharmacist and not delegated to members of the pharmacy team.

Do you have any other comments on the reclassification?

The NPA as a national body for independent community pharmacy will support its members with various education and training tools, should this change be approved.

As a representative body we have to consult with our members as part of the consultation process, and found the tight deadline rather a challenge, particularly over the holiday period. We would encourage MHRA to allow a longer period for these consultations.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
33	Community Pharmacy Advisor NHS Ayrshire and Arran		X		No

Comments

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?**

The checklist in itself is a useful tool, however without access to patient records/notes, then a community pharmacist is trusting that the patient answers the questions honestly and accurately to be able to make the professional judgement as to whether to make a supply or not.

Do you have any other comments on the reclassification?

Whilst applauding reclassification to be able to provide the community pharmacist with effective medicines to be able to “prescribe” for many illnesses and ailments, there is the balance that has to be made for those medicines that are subject to abuse, as community pharmacists are made the “gatekeepers” for the product without having access to medical notes to inform as to any diagnosis or previous or current medicines.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
34	Co-Chair - Self Care Forum	X			No

Comments

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

The Self Care Forum is supportive of moves to reclassify Sildenafil as a pharmacy or P medicine.

Reclassifying medicines to be available over-the-counter promotes and reinforces self care behaviour. Over-the-counter availability of medicines empowers people to self care, giving them faster, easier access to appropriate medicines; it makes more effective use of GPs’ time by reducing the number consultations for self-treatable conditions; and reduces NHS costs, in terms of consultation time, dispensing and prescribing fees.

Erectile dysfunction (ED) is a condition that is suitable for self care. It is easily diagnosed by the individual and

awareness of the availability of sildenafil as a treatment for ED is high. Making sildenafil available over-the-counter will prompt more conversations about ED and its treatment, which will reduce the stigma/taboo associated with the condition. It will also bring more men into the pharmacy, where pharmacists can discuss other health concerns at the same time, which could also increase detection rates of conditions associated with ED, including cardiovascular disease and diabetes.

Sildenafil has a history of appropriately safe use as a prescription only medicine and this knowledge of the drug can be applied to ensure it has a good safety profile as an over-the-counter medicine.

Sildenafil is a popular target for potentially dangerous medicine counterfeiters. Making Sildenafil available from Pharmacies will make it easier for men to access and reduce the likelihood of them buying a counterfeit product online.

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?**

We believe the patient information leaflet is straightforward and understandable.

The pharmacy checklist is long, but covers all the important information a pharmacist needs to determine the appropriateness of sildenafil for an individual. Pharmacists are highly trained healthcare professionals and have the ability to determine appropriate supply of sildenafil over-the-counter.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
35	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
36	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
37	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
38	Chief Executive PAGB	X			No

Comments

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

Sildenafil 50 mg is indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. PAGB believes that the switch proposal for sildenafil fulfils the criteria for a POM to P reclassification.

Pharmacy is the right classification for sildenafil

Reclassifying sildenafil to the P category would mean that the medicine could only be sold under the supervision of a pharmacist. We believe that this is the right classification for sildenafil as pharmacists are expert healthcare professionals with the skills and expertise to and assess whether it is an appropriate treatment for the particular individual and give appropriate advice in relation to the condition and any contra-indications.

PAGB considers that the proposed pharmacy protocol is thorough and comprehensive and will adequately support pharmacists to supply this medicine appropriately or signpost to another medical professional.

Increased awareness of erectile dysfunction

Making sildenafil available over-the-counter will enable it to be advertised to the public which may bring more men into the pharmacy to seek advice, where pharmacists can discuss other health concerns at the same time. It will also provide an opportunity to educate the public about erectile dysfunction. Each person who buys sildenafil from a pharmacist will be advised to see their GP within six months of purchase, so this will encourage men, who might not otherwise have sought the advice of a healthcare professional, to visit the GP where any other healthcare issues can be discussed.

We do not have any concerns about this product being advertised to the public. Advertising is governed by the Human Medicines Regulations 2012, MHRA guidance and the Advertising Codes enforced by the Advertising Standards Authority (ASA). As a member of PAGB, the applicant would have to comply with the additional requirements of PAGB's Codes and submit all advertising copy for pre-clearance before publication.

PAGB therefore considers that making sildenafil available over-the-counter through a pharmacist will prompt more conversations about erectile dysfunction and its treatment, which will improve understanding of the condition whilst helping men to self care.

Suitable for self care

Erectile dysfunction is a condition readily identified by those affected and awareness of medical treatment is high, therefore it is considered suitable for self care. Empowering people to self care appropriately brings many benefits, not only for the individual, but for clinicians, the NHS, government and society as a whole.

Expanding the range of medicines available to buy over-the-counter, where appropriate, helps to empower more people to self care, giving them faster, easier access to medicines. It also allows for more appropriate use of NHS resources by reducing the number GP consultations for self-treatable conditions, freeing up time and resources to be reinvested in other areas.

PAGB notes that NHS Choices describes erectile dysfunction as a very common condition with half of all men between the ages of 40 and 70 having it to some degree. Some men find it embarrassing to discuss the condition, and particularly so in a doctor's surgery. For these men, availability of sildenafil 50 mg in a pharmacy setting may be a more acceptable option.

Good safety profile

Sildenafil has had 18 years of appropriately safe use as a prescription only medicine, this data and experience can be applied to ensure it has a good safety profile as an over-the-counter medicine.

PAGB notes that sildenafil, particularly the brand Viagra, is a popular target for potentially dangerous medicine counterfeiters and people aren't always aware which websites they can trust. Making sildenafil available from Pharmacies will make it easier for men to access the genuine medicine where it is an appropriate treatment for them and reduce the likelihood of them buying a counterfeit product online.

Risk Management Plan

PAGB considers that the Risk Management Plan proposed is appropriate and that there are sufficient safeguards in

place to expect the medicine to be used appropriately, with little danger to the public. As with all reclassifications, until the product is actually available as a P medicine, it is difficult to predict what will occur in practice. Therefore, the applicant has been requested to undertake a survey based study to assess the proposed pharmacy checklist and training materials.

This will provide information on the utility and effectiveness of the material in conveying key messages to patients and pharmacists and their impact on patient behaviour and pharmacy practice. PAGB considers that this is a sensible approach to obtaining information which could inform future decisions.

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?

As above.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
39	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
40	Celesio UK	X			No

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

We consider that Sildenafil 50mg tablet should be made available as a pharmacy medicine providing that the appropriate safety measures and checks are in place and in the circumstances outlined in the consultation document i.e. for adult men with erectile dysfunction with a maximum dose of one tablet each day, and a maximum pack size of 8 tablets.

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?

- Yes, the patient information leaflet and label are understandable, but should always be coupled with counselling and checklist questions as outlined in Annex 5 (checklist).

If you are a pharmacist or healthcare professional, do you find the checklist (Annex 5) useful?

- The checklist has been reviewed by a pharmacist and there is concern that there are some specific medical and pharmaceutical terminology used which may not be easily understood by a patient, for example concomitant medication use and conditions and the information in the supplementary bullet points.
- The checklist should be completed with a pharmacist and not just handed to the patient to complete.
- It would be useful to view the content of the Pharmacy Training Guide to ensure that this is operationally sensible and meets other standards in the pharmacy setting.

Do you have any other comments on the reclassification?

Sildenafil can cause a potentially fatal reaction if taken with other medicines containing Nitroglycerin (GTN) and it is

vital that appropriate measures are put in place to ensure pharmacists are aware of the risks and that the consultation between patient and pharmacist explicitly addresses this risk during the consultation.

It is also crucially important to emphasise that erectile dysfunction can often be a symptom of overlying health conditions that affect the blood vessels and heart (such as high blood pressure, diabetes and high cholesterol). Therefore the consultation and counselling that sits alongside the supply of Sildenafil must be comprehensive and of the highest standards.

Advice for men seeking treatment for erectile dysfunction should always be to have a health check to rule out the possibility of their symptoms being related to something yet to be diagnosed.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
41	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
42	Royal Pharmaceutical Society	X			No

Comments

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

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.

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?

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.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
43	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
44	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
45	[redacted]				Yes

Comments

[redacted]

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
46	Prostate Cancer UK	X			No

Comments

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

At present men with prostate cancer, and men who have had a radical prostatectomy who are experiencing erectile dysfunction, can receive a prescription for Sildenafil (NHS Business Services Authority, NHS Electronic Drug Tariff, Part XVIIIB). Notwithstanding the ability for Sildenafil to continue to be prescribed through General Practice, we

consider it a positive decision to make the treatment available over the counter at pharmacies as well. This is primarily because making Sildenafil available in pharmacies may provide opportunity to reach more men experiencing erectile dysfunction who aren't engaging with their GP already.

An additional benefit may be that it is potentially (although not always) cheaper for men who pay for their prescriptions to buy Sildenafil over the counter, following a consultation with their GP. This is beneficial for both individuals and NHS England as Sildenafil is no longer on patent.

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?**

We consider it essential that pharmacists are sufficiently equipped to have informed discussions with men and to understand (insofar as possible) the nature of erectile dysfunction, as other treatments may be available in consultation with GPs which could be more effective for individuals. In the example of men who are living with or beyond prostate cancer, daily low dose tadalafil may be a better option depending on the situation of the individual patient.

There is a distinct clinical situation where men are seeking sildenafil over the counter for erectile dysfunction associated with treatment for prostate cancer, usually a penile rehabilitation programme following nerve-sparing radical prostatectomy. It would be useful to add to the pharmacy checklist the potential to refer the patient to the GP to consider other treatment options for erectile dysfunction before starting a course of sildenafil, or to discuss their other treatment options if sildenafil does not work for them. It could also be useful to make clear that sildenafil is only ever likely to return men to their baseline sexual function, as it could be important for pharmacists to manage men's expectation at the point of dispensing.

There are also two points from the patient information leaflet that we feel are important enough to merit inclusion in the pharmacy checklist:

The pharmacy checklist makes no mention of the fact that sildenafil is unlikely to work without sexual arousal. Men should be counselled that the tablets won't work on their own, there needs to be stimulation as well and libido. This is mentioned on the patient leaflet, but we think should be on the pharmacy checklist too, to make sure the pharmacist discusses this.

The pharmacy checklist doesn't mention that men shouldn't have grapefruit or grapefruit juice when using sildenafil, as it can affect how the drug works. It's in the patient leaflet but we think it's important enough to be

Do you have any other comments on the reclassification?

Erectile dysfunction is a clinically recognised side-effect of prostate cancer and its associated treatments, including radical prostatectomy. The consequences of erectile dysfunction can impact on multiple areas of an individual's life.

There are several treatment options available for men experiencing erectile dysfunction, which represents both individual preference and treatment efficacy. We therefore consider it essential that Sildenafil remains available for men on prescription, alongside over the counter availability, to ensure that men can have an informed conversation with their GP and pharmacist about the most appropriate course of treatment for them.

Response number	Organisation/individual	Agree	Disagree	No definitive view – issues raised	Confidential (Yes/No)
47	Maxwellia	Yes			No

Comments

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

We fully support the proposed reclassification, this is great news for men's health and for pharmacy.

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?**

Yes, it is simple and clear and will be able to be remembered intuitively over time, the rear of the pack also provides a useful aide memoire to help select the right cohort.

