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Professional Compounding Chemists of Australia Submission to House Standing Committee Roundtable Forum into Impotence Medications

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Introduction

Professional Compounding Chemists of Australia Pty Ltd (PCCA) is a TGA licensed supplier of compounding ingredients and Pharmaceutical Society of Australia accredited continuing education programs to pharmacists in community, tertiary and hospital settings. PCCA is endorsed by The Pharmacy Guild of Australia as a supplier of ingredients, equipment and training to pharmacists and is a member of the Pharmacy Manufacturing Technical Working Group established by the Therapeutic Goods Administration to develop standards for pharmacy compounding. PCCA has more than 170 member pharmacies in Australia and New Zealand who offer specialised compounding services and supplies ingredients for compounding to over 1000 other pharmacies.

The extemporaneous preparation of medicines is a traditional component of the practice of pharmacy. The increasing need for extemporaneous products is noted in the British Pharmacopoeia 2007 and is attributed to patients requiring unavailable dosage forms and access to products that have been discontinued or are unavailable for economic reasons. PCCA support any improvements in compounding standards that are necessary to ensure the public are able to continue to access quality medicines in a timely and cost effective manner.

Why pharmacy compounding is necessary

The extemporaneous preparation of medications is a traditional part of the practice of pharmacy. There are a number of reasons to compound medications, including but not limited to: medications that are not commercially available, patient allergies to ingredients in commercial products, and customising the dosage form of a medication for increased patient compliance. The Pharmaceutical Society of Australia (PSA) defines compounding as:

> *"The preparation and supply of a single unit of a product intended for immediate use by a specific patient. It is also referred to as 'extemporaneous dispensing'. When the prescribed product is not commercially available, a pharmacist may need to compound it in the pharmacy."*[1]

Extemporaneous dispensing allows a physician and pharmacist, using his/her professional judgement, to access the most appropriate treatment for a patient when commercially manufactured options may be unavailable or unsuitable. The use of extemporaneously prepared medicines is an essential part of effective medical management of patients. The British Pharmacopoeia 2007 includes a supplementary chapter on unlicensed (compounded) medicines in response to this role and recognises their increasing use in primary care settings.[2] The BP2007 cites a number of reasons for this increased use including:

1. requirements for liquid formulations for paediatric and geriatric populations;
2. discontinued supply of licensed medicines;
3. specialist products used in hospitals;
4. novel therapies in hospitals and clinics;
5. low demand critical care products.

To the best of our knowledge, our member pharmacies are not engaged in the supply of compounded medicines to impotence clinics. Extemporaneously prepared products that are <u>not</u> prepared for an individual patient and supplied from the compounding pharmacy to that patient are not exempt from product registration and TGA licensing of the manufacturing premises.

From documents available on the Australian Stock Exchange website relating to the proposed purchase by a public company of a company supplying compounded medicines to an impotence clinic in Australia, it appears that the clinic employing medical practitioners who prescribe impotence medicines may derive significant profit from the sale of those impotence medicines. We believe it is this incentive rather than the fact that the medicines are compounded that is the driver of this activity. That treatment for conditions like impotence is allegedly initiated after a very brief telephone discussion and no physical examination is very concerning. Removal of the profit incentive for prescribing any medicine may be one way of discouraging such practices.

Reports of Adverse Reactions

In Australia, there have been few adverse reactions associated with extemporaneous products although there have been incidents in the United States. However, the operation of pharmacies in Australia is not the same as the United States where pharmacies may be owned by non-pharmacists and advertising of prescription products to the public is allowed. The range of available manufactured products is however smaller in Australia than in many countries and extemporaneous compounding allows individual patients access to medicines prescribed by their medical practitioner in a timely and cost effective manner.

Conclusion

In summary, the extemporaneous compounding of medicines for specific patient needs is a traditional and valued part of pharmacy practice.

Extemporaneous products prepared for an individual patient based on an existing relationship between pharmacist, patient and prescriber is recognised internationally as part of the practice of pharmacy and medicine, and should not be subject to excessive regulation to the detriment of optimal patient care.

The alleged profit incentive for clinics to prescribe impotence medicines is at the core of some of the reported undesirable impotence clinic practices and removal of this incentive would address many of the Committee's and community's concerns.

References

1. Pharmaceutical Society of Australia. Compounding. *Professional Practice Standards Version 3.* 3 ed. Canberra: Pharmaceutical Society of Australia, 2006:77-83.
2. British Pharmacopoeia Commission. Supplementary Chapter V Unlicensed Medicines. *British Pharmacopoeia 2007.* London: Stationery Office, 2007.