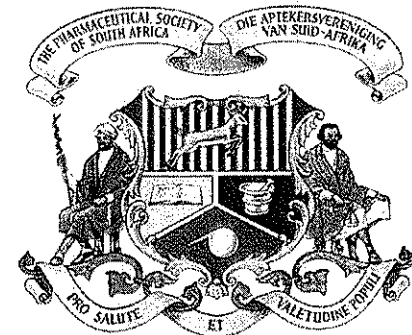


# **Medicines and Related Substances Amendment Bill [B6-2014]**

***Lorraine Osman***

***Head: Public Affairs  
Pharmaceutical Society of South Africa***

***31 October 2014***





# Pharmaceutical Society of South Africa

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- Voluntary professional association of pharmacists
- More than 7000 members
- Pharmacists who are employers and those who are employees
- Sectors
  - Community (retail)
  - Hospital
  - Manufacturing industry
  - Distribution



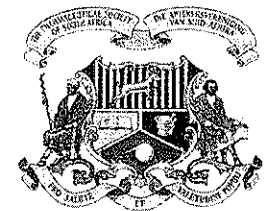


# The bottom line ....

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The PSSA supports the intention of  
the Bill

but ... we appreciate the opportunity  
to highlight some of our members'  
concerns



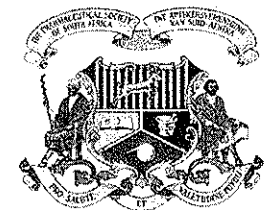


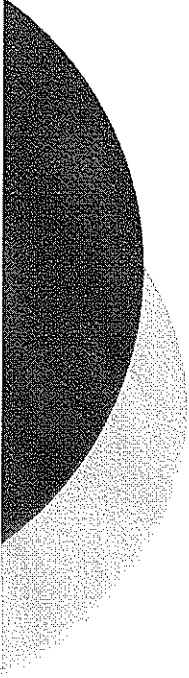
# Editing technicality

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Please note:

The intention to replace the word  
“**products**” with the word  
“**medicines**” and the expression  
“**Scheduled substances**” in the  
Act has been inconsistently applied  
in the Amendment Bill





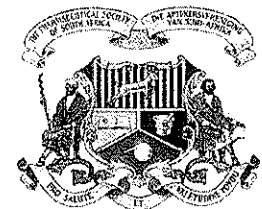
## Sections 6 and 7 – amendment of sections 13 and 14 of Act 101 05 1965

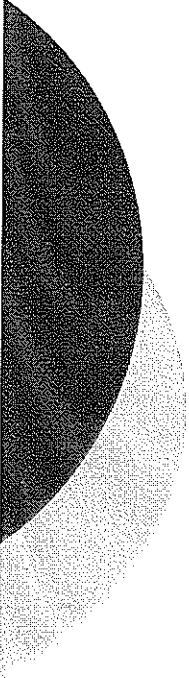
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- Section 6 – registers for “medicines, **scheduled substances**, medical devices and IVDs”

VS

- Section 7 – registration of ‘medicine medical device or IVD’

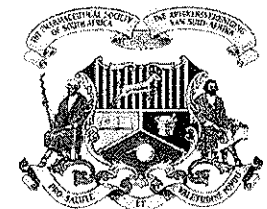


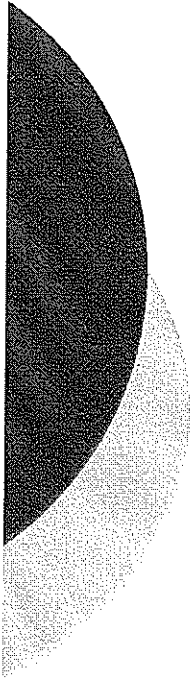


## Sections 6 and 7 – amendment of sections 13 and 14 of Act 101 05 1965

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- Registration of **scheduled substances**
  - Onerous and confusing
  - Who would apply – manufacturer of medicine or manufacturer of the API?
  - What about generic products?



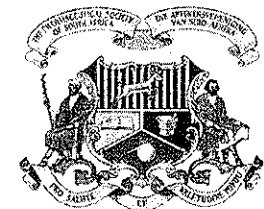


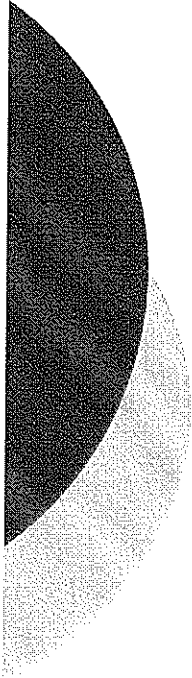
## Sections 6 and 7 – amendment of sections 13 and 14 of Act 101 05 1965

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### **PSSA recommendation**

- Simplify
- Align sections 6 and 7 by omitting the phrase “Scheduled substances” from section 6



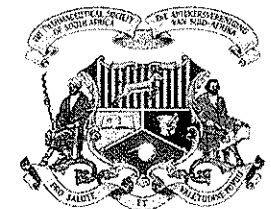


## **Section 15(a) – amendment of Section 22C(1)(a) of Act 101 of 1965**

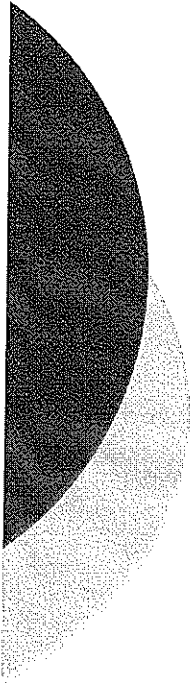
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PSSA supports the re-introduction of practitioners into this section

But ... veterinarians are not included or regulated in the same way as all the other health professionals who sell and dispense medicines







# **Section 15(a) – amendment of Section 22C(1)(a) of Act 101 of 1965**

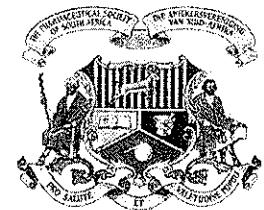
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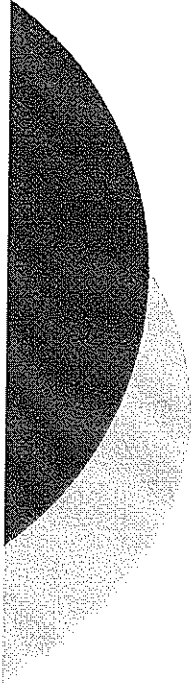
## **PSSA recommendation**

- Include veterinarians in section 22C(1)

Note:

If this is done, section 22G, which deals with pricing, will also apply to veterinarians





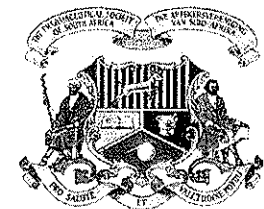
# **Section 15(a) – amendment of Section 22C(1)(b) of Act 101 of 1965**

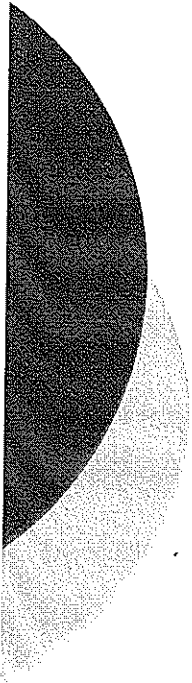
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Potential conflict:

Section 22A(11)(b) – permit for import or export of scheduled substance or medicine issued by DG

Section 15(a) – introduces licences for import and export, to be issued by the Authority



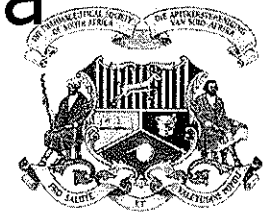


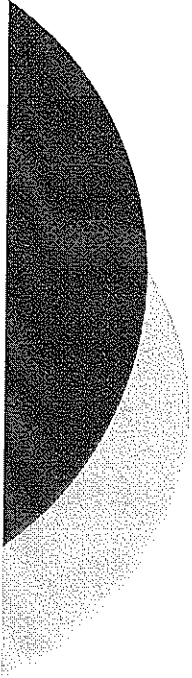
## **Section 15(a) – amendment of Section 22C(1)(b) of Act 101 of 1965**

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Unintended consequence on some  
wholesalers and distributors?

If schedule 0 medicines are not  
exempted from this section,  
distributors and wholesalers such as  
Makro or Cash and Carry will be  
obliged to comply with the  
requirements of the Pharmacy Act as  
well, i.e. to register and employ a  
Responsible Pharmacist



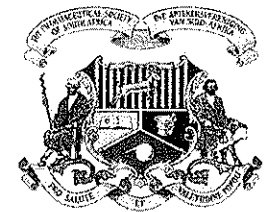


# **Section 15(a) – amendment of Section 22C(1)(b) of Act 101 of 1965**

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PSSA recommendation

Insert the words “schedule 1 and higher” before the word “medicines



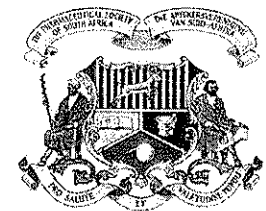


# Section 16 – amendment of section 22H

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Steps should be taken to facilitate the export of medicines by South African wholesalers to SADC countries.

This service to neighbouring countries should be supported.

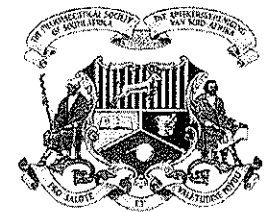


# Section 16 – amendment of section 22H

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PSSA recommendation

Section 22H(1)(b) should be amended by adding s22H(1)(b)(iii):  
“The provisions of this section do not prohibit export by wholesalers in possession of a permit issued in terms of section 22C(1)(b)



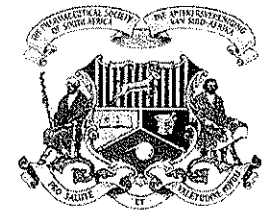


# The way forward

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Today's presentation and the PSSA's submission to the committee address only those aspects to be amended by the Amendment Bill.

But ... there are still aspects of Act 101 of 1965 that need attention on future



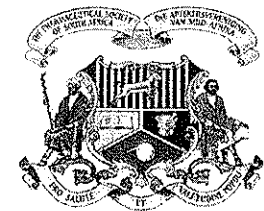


# The way forward

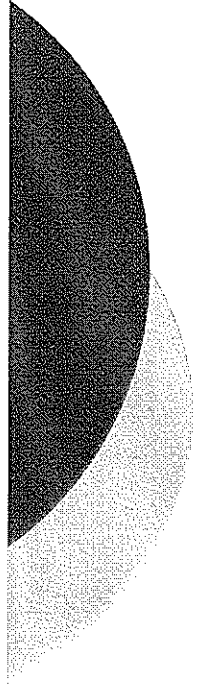
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The PSSA believes that this Committee will support the National Department of Health in ensuring that, at the appropriate time, the amended Act 101 of 1965 will be scrutinised and amended so that it becomes

clear, unambiguous,  
implementable and effective







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# Thank you!

