

27 OCT 2014

**PROPOSED HEALTH PRODUCTS (LICENSING OF RETAIL PHARMACIES)
REGULATIONS 2015**

CONSULTATION PERIOD: 27 October 2014 – 23 November 2014

INTRODUCTION

1. The retail sale of pharmaceutical products which are not on the General Sale List are regulated under the Medicines Act with respect to the classes of persons who are allowed to supply and the premises at which such products can be supplied. These include the Prescription Only Medicine and Pharmacy Only Medicine. The controls on the premises are administered through the registration of retail pharmacies under the Medicines Act.

2. With the transfer of controls for pharmaceutical products from existing laws to the Health Products Act (HPA), the corresponding controls on premises will similarly be provided under the HPA.

SUMMARY OF CHANGES

3. Fundamentally the controls under the Medicines Act remain relevant and adequate for the regulatory oversight of retail pharmacies. Hence, the proposed regulations under the HPA are effectively a lateral transfer of controls from the existing regulations with streamlining of the licensing requirements.

4. With this, the control under the pharmacy registration and Form A Poisons Licence will now be consolidated into a single licence, *Retail Pharmacy Licence*, while preserving the key elements of control such as the requirement for a registered pharmacist holding an active Practising Certificate to be in charge of managing the retail pharmacy.

5. There is no major change to the licensing regime. Retail pharmacies registered under the existing regime need not re-apply for a licence under the HPA. A summary of the changes are as follows:

a) Change in Licence Name

The Certificate of Registration of a Pharmacy will be re-named to Retail Pharmacy Licence.

b) Form A Poisons Licence No Longer Required

With the dis-application of Poisons Act & Rules to “therapeutic products” (i.e. pharmaceutical products), Form A Poisons Licence is no longer required for wholesaling of pharmaceutical products containing a listed poison under HPA licensing regime. However, Form A Poisons Licence will continue to be required for the handling of Active Pharmaceutical Ingredients (APIs), laboratory reagents and/or veterinary products containing listed poisons under the Poisons Act.

c) Provisions on Telepharmacy Service

The regulatory requirements for telepharmacy service currently imposed as licensing conditions will be prescribed in the proposed regulations for better clarity and transparency.

6. The licensing fees for retail pharmacies remain the same under HPA.