My comments as follows:

Currently, the Product Information (PI) leaflet contains detailed information for health professionals , in the TGA-approved structured format, which contains summaries of indications, precautions, contraindications, and documented summaries on safety and risks.

The CMI leaflets contain plain English warnings for consumers. These include various aspects relating to the safe use of a medication, under the headings of

"before you are given it", "when you must not receive it", "taking other medicines", "side-effects,"

"while you are receiving it", "things to be careful of", and a separate list of side effects.

I believe boxed warnings are a most useful tool for reinforcing to health professionals and consumers, precautions and specifically-identified therapeutic adverse effects related to the use of various medications.

I would favour option 1, because if there is a significant concern regarding risks of specific medications, resulting in potential adverse effects, the relevant details need to be brought to the attention of health professionals and consumers, utilising all the available information sources, including promotional material, and I do not believe that a reference, prominent or otherwise, at the beginning of promotional material is sufficiently reinforcing in such cases.

I cite as one example of the need for a black-boxed warning, recognition of the dimensions of risk of which has occurred many years after marketing and approval of a specific medication.

I refer to the risks of congenital abnormality when sodium valproate is taken in early pregnancy, and the use of this medication in pregnancy for non-seizure indications in women of childbearing age.

- Whilst this medication has always been categorised at a Category D risk in pregnancy, it is only following international studies over the past 5-10 years that we have sufficient accumulated data to now recommend that if its use is essential to control otherwise uncontrolled epilepsy, we need to be cognizant of the *established dose-dependent gradation of teratogenic risk, with a current recommended daily dose threshold of 600mg.(1)*

Reference cited:

1.Tomson. T et.al..Valproic acid after five decades of use in epilepsy: time to reconsider the indications of a time-honoured drug. *Lancet Neurol* 2016; 15: 210–18

Ronald Batagol,

PhC,FSHP, AGIA, Dip.Jnl.

Pharmacist and Medicines in Pregnancy and Medication Safety Consultant