Nestlé Australia Ltd appreciate the opportunity to respond to the consultation paper on the remaking of therapeutic Goods Order NO. 78.

We have the following comments to make on the draft therapeutic Goods Order 101.

Section 19 Disintegration

TGO 101 requires all tablets and capsules to comply with a test for disintegration except that if a test for dissolution is performed a test for disintegration is not required. This is a change from TGO 78 that specifies "the requirements of the relevant test for disintegration **(if any)** of the British Pharmacopoeia, in the general monographs "Tablets" or "Capsules".

The words 'if any' in TGO 78 where included to recognise that the disintegration testing is not required by the British pharmacopeia for chewable tablets. The details of this decision are recorded in the Therapeutic Goods committee – 32nd Meeting (April 2008).

Chewable tablets are formulated to be disintegrated in the mouth by the action of chewing and are not formulated to disintegrate upon being swallowed whole. The default pharmacopoeias do not require a disintegration to be performed for chewable tablets.

TGO 101 must be amended to recognise that disintegration testing is not applicable for chewable tablets. Sponsors should not be required to reformulate existing chewable tablets so that they comply with a dissolution test requirement. The reformulation of a chewable tablet to include a disintegrant to make it pass a disintegration test that it would not otherwise pass would be very costly and time consuming for sponsors and would not provide any product benefit to consumers as the product is disintegrated by chewing before it is swallowed.

Chewable tablets for which there is an applicable monograph would not be required to comply with a disintegration test as it is not required by a pharmacopoeia, it should be the same when there is no applicable monograph.

Section 15 (2) Assays for each active ingredient

This section states that if the tablet contains an active ingredient mentioned in schedule 2 then the assay limit **for each active ingredient in the tablet or capsule** is specified in the table in Schedule 2.

This means that if a tablet or capsule contains no active ingredients in schedule 2 then the assay limits in schedule 1 apply.

If the tablet or capsule contains any active ingredient mentioned in schedule 2 then schedule 1 for the active ingredient assays no longer applies to that tablet or capsule and each of the active ingredients in the tablet or capsule must comply with the assay limit specified in schedule 2.

If a tablet or capsule has some active ingredients mentioned in schedule 2 and some active ingredients that are not mentioned in schedule 2, then for that product the active ingredients that are not mentioned in schedule 2 have no assay limits defined.

The assay limit in Schedule 2 should only apply to the active ingredients specified there, and not to all active ingredients in the tablet or capsule.

Section 21 Uniformity

A listed medicine with an applicable monograph under section 13 has the option to apply either uniformity of dosage units or uniformity of mass. However under the Australian Specific Requirements it is very prescriptive that a listed good must comply with uniformity of mass.

We request that under section 21 listed medicines be given the option of using either uniformity of dosage units or uniformity of mass. This is consistent section 13.

Sponsor of listed medicines who choose to apply uniformity of dosage units for their listed tablet or capsule should not be required to apply for an exemption from TGO 101 in order to do so.

Section 11 impurities

This section introduces the term "another pharmacopoeia". This should be limited to default standards only and not any pharmacopeia.

17 (C) Impurities

This section allows different concentration limits for impurities if each of the active ingredients are herbal materials. Some tablets and capsules contain both herbal and not herbal active ingredients. **This section should apply to products where <u>any</u> of the active ingredients are herbal materials.**