NAPRA ANORP
National Association of Pharmacy Regulatory Authorities ®
Association nationale des organismes de réglementation de la pharmacie

1800 – 130 rue Albert Street
Ottawa, ON K1P 5G4
Tel./Tél. 613-569-9658
Fax/Téléc. 613-569-9659
www.napra.ca

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Mr. Paul Gustafson
Senior Corporate Regulatory Compliance and Enforcement Advisor
Regulatory Operations and Regions Branch (RORB)
Health Canada
Government of Canada

RE: Interpretation of Policy 0051 around Dose-splitting

I am writing in regards to a critical issue that has been brought to our attention by members of NAPRA.

As you are aware, there has been increasing discussion on the issue of dose-splitting and whether dose-splitting is considered a form of manufacturing as outlined in Health Canada's *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)*.

By 'dose-splitting' we mean the process, that traditionally occurred in a hospital environment, of taking a product that is labelled for single use and breaking it into more than one dose to be administered at different times or to different patients. In today's environment, the practice is also occurring in community pharmacy. An example is when an individual draws up a number of doses from a single-use vial using the excess product (or overfill) and then ships these drawn-up syringes to another pharmacy for distribution or ships directly to a health professional for administration to patients. A specific example our members are aware of and concerned with is dose-splitting of Lucentis and Eylea for ophthalmic purposes.

As the practice of dose-splitting single-use products becomes more common and is carried out in larger quantities, the possibility of harm to a patient occurring as a result of the practice increases. Dose-splitting has raised serious concerns for patient safety and public health within a number of jurisdictions and they are urgently facing how to address the matter. In this regard, we request the following action(s).

Firstly, although we understand that Health Canada is still evaluating the appropriate regulatory safeguards for commercial compounding, we respectfully believe, given the risk of potential safety concerns right now, that Health Canada cannot wait for its analysis to be complete before providing an opinion on the practice of dose-splitting. We understand that Health Canada's Policy 0051 is still in effect and, therefore, ask Health Canada for an interpretation.

Based on the criteria outlined in Policy 0051, is dose-splitting of single-use products into multiple doses for distribution to health professionals or other pharmacies considered manufacturing by Health Canada? This interpretation is essential as our members urgently deal with this matter.

Secondly, Policy 0051 expressly states that *"in circumstances where an individual cannot clearly determine whether a particular activity is considered to be manufacturing or compounding…discussions may take place between the two jurisdictions for final determination of whether an activity is considered to be compounding or manufacturing."* We believe the spirit of this statement can be applied to the issue of dose-splitting. The lack of clarity and agreement on the issue of dose-splitting provides an opportunity to address a serious concern through meaningful and timely collaborative dialogue between federal and provincial/territorial jurisdictions.

We do primarily seek an interpretation of Policy 0051 given the urgency of the issue, but we also remain available for discussions with you on this important matter. I look forward to hearing from you at your earliest convenience.

Sincerely,

Adele Fifield, O.Ont., CAE, BA, B.Ed
Executive Director
National Association of Pharmacy Regulatory Authorities