

The following information is a follow up to Item 4.2 of the minutes from the June 8-9, 2008 meeting of the National Drug Scheduling Advisory Committee.

Item 4.2 Guidelines for Scheduling Status Submissions

During the course of preparing this policy recommendation for presentation to the NAPRA Board of Directors, it was noted that implementation of the policy as written, (i.e. requiring the NOC before even initiating the scheduling process) would result in significant delays for scheduling applicants. This matter was brought to the attention of the Chair and Vice Chair, and on their authority, all committee members were consulted.

It was agreed that the process should not be amended as previously discussed. Instead, committee members agreed that the final text of the Product Monograph available at the time the NOC is issued would need to be made available as part of the information package considered during the course of making scheduling recommendations. This would allow for initiation of the scheduling process prior to the release of the NOC.

This information was presented to the NAPRA Board of Directors during the November 1-2, 2008 meeting.