Manitoba
Health, Seniors and Active Living

Information for Canadian Pharmaceutical and Device Companies

Notice – Updated Product Submission Criteria and Ongoing Listing Requirements

December 1, 2017

Manitoba has conducted a review of the current product submission criteria, and have made a number of updates which can be found here: http://www.gov.mb.ca/health/mdbif/sub.html

The criteria have been revised to consider:

- The pan-Canadian Pharmaceutical Alliance (pCPA) negotiations for brand products;
- The pCPA Centralized Price Confirmation Process for generic drug products;
- Regulatory requirements to report drug shortages;
- Removal of the requirement to execute a written agreement (commonly known as a Drug Utilization Management Agreement) between the company and the Government of Manitoba for multisource and Self-Monitoring Blood Glucose (SMBG) strips, lancets, and needles; and
- Increased transparency for product pricing changes and company-sponsored Patient Access Programs (PAPs), also known as Compassionate Programs;

Provincial Drug Programs (PDP) will transition to the new submission criteria in the following manner:

- New or amended submissions are not required for products that are currently in queue with PDP;
- Companies can send submissions under the old or new submissions until January 2, 2018; and
- Companies must follow the new submission criteria after January 2, 2018.

The "Ongoing Listing Requirements" will replace "SECTION 8.00 – MANITOBA PRODUCT PRICE" and "SECTION 3.00 – COMMUNICATION PLANS AND LEARNING PROGRAMS, PRESCRIPTION ASSISTANCE PROGRAMS" in all Drug Utilization Management Agreements effective immediately.

Provincial Drug Programs will not be amending existing Drug Utilization Management Agreements.

If your questions are not answered by reviewing the Product Submission Criteria and Ongoing Listing Requirements posted at:
http://www.gov.mb.ca/health/mdbif/sub.html

Please send an e-mail to PDPInfoAudit@gov.mb.ca