

PROGRAM PLAN FOR THE MANITOBA MEDICATIONS RETURN PROGRAM

Submitted to

Green Manitoba An Agency of the Manitoba Government

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Pharmaceutical and Health Products Plan Renewal

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Medications Program Plan

1. Executive Summary

The Household Hazardous Material and Prescribed Material Stewardship Regulation (MR 16/2010) under the Waste Reduction and Prevention Act (WRAP Act) creates a set of requirements and criteria for two categories; pharmaceutical products category and natural health products category, both captured under the Manitoba Medications Return Program (MMRP). Since 2011, the Health Products Stewardship Association (HPSA) has administered the MMRP for prescriptions drugs, over-the-counter medications and natural health products sold for use in the province of Manitoba but limited to the "consumer/residential" waste stream. The program is designed to ensure that the collection service is available to all regions of the province and products returned are packaged, handled, transported and disposed of in a safe, compliant and environmentally responsible manner. Collection of "pharmaceutical" waste is in place at more than 319 pharmacies licensed by the Manitoba College of Pharmacists across the province.

This program provides a collective strategy for the health industries producers to comply with the Manitoba Regulation 16/2010. The MMRP plan will cover a five-year period from January 1, 2017 to December 31, 2021, at which time the plan will need to undergo a review.

The MMRP plan renewal has been shared with our network of pharmacies (319) including the Pharmacists Manitoba Inc., Manitoba College of Pharmacists, Neighbourhood Pharmacy Association of Canada, HPSA membership (161) and key stakeholders for comments and input during the HPSA consultation period.

This plan was posted on the HPSA web site (<u>www.healthsteward.ca</u>) for the general public and other interested stakeholders to review during the consultation period (45 days) held in the fall of 2015. Comments received as part of a public consultation are recorded in Appendix E.

2. Glossary of Acronyms and Definitions

Glossary

CAP:	Canada-Wide Action Plan for EPR
CAPDM:	Canadian Association for Pharmacy Distribution Management
CCME:	Canadian Council for Ministers of the Environment
CWS	Minister of Conservation and Water Stewardship
EPR:	Extended Producer Responsibility
FDA	Food and Drugs Acts & Regulations (Canada)
GMES:	Green Manitoba Eco Solutions
HHM	Household Hazardous Material
HPSA:	Health Products Stewardship Association
ISO:	Industry Stewardship Organization
MCP:	Manitoba College of Pharmacists
MMRP:	Manitoba Medications Return Program
NHP	Natural Health Products Regulations
MR (16/2010):	Household Hazardous Material and Prescribed Material Stewardship
	Regulation
NPAC:	Neighbourhood Pharmacies Association of Canada
PM:	Pharmacists Manitoba Inc.
RCC:	Retail Council of Canada
WRAP Act:	Waste Reduction and Prevention Act

Terms and Definitions

- a) Collection Location(s): A location, typically a retail pharmacy, at which the collection of pharmaceutical and natural health products are provided for. In the case of a retail pharmacy, it must have a dispensary that is accessible to the general public during normal business hours to be eligible as a collection location.
- b) Consumer: Means an individual acting for personal, family or household purposes.
- c) Medications: For the purposes of the MMRP, the pharmaceuticals product and natural health products categories are defined in three sub-categories:
 - All prescriptions drugs
 - Over-the-Counter Medications
 - Natural Health Products
- d) Natural Health Products (Designated Material): Under the *WRAP Act*, a natural health product as defined in The Natural Health Products Regulation under The Food and Drugs Act (Canada). *This category is limited to household quantities of natural health products*.
- e) Pharmaceutical Products (Designated Material): Under the *WRAP Act*, a pharmaceutical product is a substance or mixture of substances manufactured, sold or represented for use in:
 - i. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms; or,

 restoring, correcting or modifying organic functions; including, but not limited to, medications available with or without a prescription, but not including contact lens disinfectants, antidandruff products and shampoos, cosmetics, antiperspirants, antiseptic or medicated skin-care products, sunburn protectants, mouthwashes, fluoridated toothpastes, and veterinary medications and products.

This category is limited to household quantities of pharmaceutical products.

- f) Program Plan: A document that provides producers with a strategy for individually or collectively managing the extended producer responsibility of their products including any safety, environmental and regulatory requirements.
- g) Producer: means the steward of designated material. For the purposes of the industry stewardship plan, the steward for pharmaceutical and natural health products is:
 - i. the first person who, in the course of business in Manitoba, supplies a designated material to another person; or
 - ii. a person who, in the course of business in Manitoba, uses a designated material obtained in a supply transaction outside of Manitoba.

For the purpose of this Plan, a producer will be deemed to be the brand-owner or first importer into Manitoba when applicable.

In compliance with the *MR 16/2010*, producers must demonstrate participation in an approved program in order to do business in Manitoba. Producers deemed to be in non-compliance with program requirements will be subject to enforcement of the Regulation which is the responsibility of the Government of Manitoba.

3. Introduction

The purpose of this document is to apply for plan renewal for the pharmaceuticals and natural health product material categories under the Government of Manitoba's MR 16/2010. The primary objective of this document is to ensure, through a detailed program plan, that HPSA members with pharmaceutical and/or natural health products are in compliance with the Manitoba *WRAP Act*.

3.1 Designated material categories and sub-categories:

Pharmaceuticals and Natural Health Products are regulated by Health Canada under the *Food and Drugs Act and Regulations* and the *Natural Health Products Regulations*.

For the purposes of the MR 16/2010 the pharmaceuticals product category will be limited to 2 sub-categories:

- All prescriptions drug All dosage forms
- Over-the-Counter drug Limited to medications that are absorbed through the bloodstream. Including patches, antibiotics or anti-fungal agents.

A pharmaceutical does not include the following:

- A substance or mixture used as a disinfectant for premises
- A food within the meaning of section 2 of the *Food and Drugs Act* (Canada).
- A cosmetic within the meaning of section 2 of the *Food and Drugs Act* (Canada).
- is limited to household quantities

For the purposes of the MR 16/2010 the Natural Health Products category are all natural health products (NHPs) sold in Canada subject to the *Natural Health Products Regulations*. The NHP is limited to medications that are absorbed through the bloodstream.

• Natural Health Products Limited to medications that are absorbed through the bloodstream.

A Natural Health Products does not include the following

- food and beverage products,
- is limited to household quantities.

4. Health Products Stewardship Association

The Health Products Stewardship Association (HPSA) is a non-profit organization that is funded by leading suppliers in the health products industry to administer Medications Return Programs and Sharps Collection Programs throughout the country. As a Producer Responsibility Organization (PRO), the HPSA administers the regulated Extended Producer Responsibility (EPR) programs for health products in Canada.

Originally started in the province of British Columbia, today there are several regulated programs offered in Manitoba, Ontario and Prince-Edward-Island. There are also voluntary programs in Alberta and Nova Scotia. All of these programs provide excellent value for Canadians, with brand owners covering the full costs of safely disposing of the medications and sharps collected. Pharmacies also play a key role in the success of the programs by serving as collection sites voluntarily and without compensation. Pharmacies are not legally required to act as collection sites, but owners and operators have found the environmentally-friendly, community-minded service creates customer loyalty.

The HPSA was established in 1999 as a federal not-for-profit corporation, and is guided by a board of directors whose members are leaders from Canada's prescription drugs, consumer health products and medical devices (sharps) industries. Our member producers have been engaged, active and supportive participants in these programs.

Today, the HPSA draws on more than 15 years of experience as a national Producer Responsibility Organization. The knowledge and network we have built helps us promote our programs and educate Canadians on material collection, end of life material management and the regulatory framework for take-back programs in this country. We represent more than <u>161 health products brand-owners</u> in Canada and collect and safely dispose of 600 tons of medications and sharps every year, helping to protect Canadians and the Canadian environment.

VISION:	To be the National Steward for environmental waste management programs of post-consumer health products.
MANDATE:	To manage health products from the public in a cost efficient and environmentally acceptable manner that meets government policy or legislation for our members.
PRINCIPLES:	Meet stewardship obligations in the most cost-effective manner.
	Ensure a level playing field among the health products industries.

GOALS

As we work with our members to improve our existing programs and develop new programs, we are guided by the following goals:

- 1. **Set High Environmental Standards:** We will ensure materials are disposed of in a responsible manner that safeguards the environment and worker health and safety in accordance with the requirements under the Environmental Protection Act.
- 2. **Ensure Operational Efficiency:** We will ensure our programs are delivered effectively and efficiently at the lowest possible cost.
- 3. **Promote Fairness:** We will provide a level playing field (fair competition), achieve a high level of compliance, and reduce the potential for free-riders. All producers are treated equitably with no cross subsidization of product types.
- 4. Ensure Sound Fiscal Management: We will ensure that revenue from members are in balance with the expenses and fees, closely reflecting the costs of managing each obligated product.

We will also ensure sustainable management of the association by maintaining an appropriate operating contingency reserve (OCR), but not accumulating a surplus.

- 5. **Strive for Continuous Improvement:** We will adhere to recognized best practices and strive for continuous improvement in environmental and economic performance in a scalable fashion.
- 6. **Seek Harmonization:** We will seek to harmonize with other related programs to the greatest extent possible, in an effort to achieve economies of scale.
- 7. **Ensure Accessibility:** We will strive to ensure all consumers have reasonable access to collection sites.

FINANCIAL ACCOUNTABILITY

- a) **Budget:** The program will be managed and funded by members based on fees on the sale of products in Manitoba. Fees will be subject to GST. The fees will be set yearly using estimates for program costs and product sales units (NHP's). Fees may be adjusted to address surpluses or deficits, but all fees will be used for program purposes in Manitoba.
- b) **Reserve Fund:** As part of its risk management system, the program intends to build and maintain a reserve fund. The reserve fund will stabilize program funding in the case of unexpected collection volume increases, fluctuations in operating costs or reduced revenue due to economic or other factors.
- c) **Producer Compliance:** In order to maintain a 'level playing field' for the contributing members and to ensure compliance with the Regulation, the program will actively search for, identify and recruit producers of program products. If a potential member has not joined the program despite repeated notifications of their obligations, the program will refer the matter to the Manitoba Ministry of Conservation and Water Stewardship regulatory for potential enforcement proceedings.

5. Manitoba Medications Return Program

In compliance with the WRAP Act, the MMRP will provide all Manitoba residents with reasonable access to collection sites on a province-wide basis. HPSA will be responsible for strategic planning as well as overseeing program and financial operations including contracting services to managing day-to-day operations of the program. The program requirements and criteria for stewardship programs under the MR 16/2010 are outlined on the left column of Table 1 with the right column identifying the program components that address each requirement:

	Household Hazardous Material and Prescribed Material Stewardship Regulation Requirement	HPSA Program Component
1.	The establishment and administration of a waste reduction and prevention program for household hazardous material or prescribed material.	Approved program plan for the collection and safe disposal of post-consumer medications.
2.	The appropriate management of waste material in accordance with any written guidelines established by the minister.	Proper management of post-consumer pharmaceutical waste including consideration of risks associated with Controlled Substances.
3.	A province-wide, convenient collection system for waste material without user fees at the point of collection.	Reasonable and free consumer access to a province-wide retail pharmacy collection network. The network is equal to or greater than 80% of all retail pharmacies accredited by the Manitoba College of Pharmacists. No user fee is directed to the consumer at the point of purchase or at the point of collection.
4.	A system for the payment of expenditures incurred in the collection, transportation, storage, processing and disposal of waste material in connection with the waste reduction and prevention program.	Funding from the health industry covers all of the expenses incurred for the collection, transportation, storage, secure disposal, promotion activities and education in connection with the MMRP.
5.	The orderly collection of revenues from subscribers to the program in balance with expenditures for the program.	HPSA staff administers the program and its various components, including contracts with service providers.
6.	The establishment and administration of education programs for the purpose of the waste reduction and prevention program.	The development and dissemination of promotion and educational material for the program to HPSA collection sites for the public including pharmacists, municipalities, health authorities and other

Table 1: Pa	rogram F	Requirements
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	partners working in this field.
The establishment and administration of	The development and dissemination of
1 1 0	promotion and educational material for the
	proper use of medications is covered Health
prevention program.	Canada FDA and NHP to addresses
	Canadians' concerns about availability and
	safety.
The payment of salaries and other costs	HPSA will provide payment to GMES for
of government for the administration	the following documented services:
and enforcement of this regulation and	Enforcement services as requested;
of the Act as it relates to household	Interpretation of Regulations and guidelines
hazardous material or prescribed	with respect to HPSA program;
material;	Administration and compliance with the
	regulation and the Act as it relates to
	pharmaceuticals and NHP;
	Program plan renewal and amendments in
	accordance with the Wrap Act.
Ongoing consultations about the	Commitment to continuous improvement in
stewardship program with persons who	program performance and targets through
the operator considers the stewardship	ongoing consultation with other health
program may affect, including members	professionals and key stakeholders working
	with the pharmaceutical and natural health
-	material category.
0 1 0	
	a point of sale information program for the purpose of the waste reduction and prevention program. The payment of salaries and other costs of government for the administration and enforcement of this regulation and of the Act as it relates to household hazardous material or prescribed material; Ongoing consultations about the stewardship program with persons who the operator considers the stewardship

6. Program Design

The MMRP provides all Manitoba residents with reasonable access to collection locations on a province-wide basis. HPSA is responsible for strategic planning, overseeing the program and financial operations including day-to-day operations of the program. This includes:

6.1 Collection System:

The collection sites for the MMRP are community pharmacies. Registered pharmacy locations are easily identified through a web-based search engine on the HPSA website. Pharmacies are a logical and safe system for the public to return unused or expired medications. Many are open extended hours, offering a convenient place for consumer disposal year-round.

Collection locations must also meet the following requirements:

- Collection locations must provide the service to the public at no charge.
- The collection location must provide to the public the ability to drop off products during regular business hours.
- Collection locations must display, and have, awareness, promotion and educational materials for the public.
- A licensed pharmacist or pharmacy technician must be present when a consumer drops off products.
- Collection locations must have a valid provincial registration number.
- There must be an agreement with HPSA that addresses collection and storage of unused and expired products.
- If the location is offering safe disposal of unused and expired medications under the MMRP and it is not a retail pharmacy, then the location has to be approved by HPSA.

Since the voluntary participation of a pharmacist is central to the success of the program, HPSA works closely with their representatives to ensure full participation and awareness of the MMRP. Pharmacy managers interested in offering the program must complete a registration form. Specific information is provided to ensure that pharmacy managers and staff are knowledgeable on the program objective and the way the program operates. All participating collection locations receive a kit containing instructions on the program, a service request form, and sample of education material developed for this program along with a minimum of two collection containers. Once the registration form is completed and faxed to the HPSA office, the pharmacist is contacted by phone to discuss the following points:

- ✓ The program is for returns from the public and not from hospitals, institutions, doctor's offices or their own commercial pharmacy operations.
- \checkmark All employees working at the site must be knowledgeable about the program offered to the public.

- ✓ All pills should be deposited into the collection container and the original package should be recycled except for liquid medications, gels, powder, etc ... containers are to be deposited directly into the container.
- Recycle the outer container/extra packaging where facilities exist and are available in their region.
- ✓ There is no limitation on the quantity of medications that a consumer can drop off to a collection location.

Once two (2) collection containers are full, the pharmacist must complete the service request form and contact the HPSA approved service provider to schedule service. Replacement containers will be delivered and the full containers will be picked up either on a service schedule or by request.

If the location is offering collection of medications under the MMRP and it is not a retail pharmacy then the location has to be approved by the HPSA and meet collection location standards before collection of unused and expired medications, including controlled drugs, can begin.

6.2 Performance Measures:

Medications are intended to be consumed entirely to treat a specific condition or symptom. Ideally, none should be left over. Because of the practice of keeping medications for future use, there is typically a considerable lag time between its purchase and its eventual disposal.

- A year to year comparison analysis will be completed to monitor the overall progress.
- The plan will provide for an audit procedure to ensure proper tracking mechanisms, such as certificates of destruction, are in place for management of medications from point of collection to final destruction.
- The quantity of medications available for collection is difficult to estimate since medications are taken for specific conditions or symptoms and should be fully consumed unless otherwise indicated by a health professional. Prescription drugs are prescribed by a physician and in most cases given in a relatively small quantity. Patients are directed by their physician and health professional to use the medication until finished. In humans, data has shown up to 90% of the active ingredient in a product is excreted into our sewage systems.
- Prescription pharmaceutical data on sales is available by dosage. Collections under the medication return program are measured by weight (kgs) therefore there is no ability to correlate these two metrics which makes collection targets by weight inaccurate and unrealistic.

6.2.1 Number of Collection Points

Target until 2021:	• Increase the participation rate of provincially accredited retail pharmacies in the MMRP from 80% to 85% by 2021.
Performance measure:	Report percentage of participating pharmacies yearly.
Strategies: Year 1	 Promotion and information for the public available for distribution to pharmacies upon request. Developed material to promote the program in pharmacies, events and National Prescription Drug Drop-off Day, Pharmacy Awareness Month, Earth Day, Summer Ambassador Tour (MARRC) Advertise the Manitoba Medications Return Program through websites, flyers and events. Contact pharmacies that are not participating in program. Educate and promote the program to pharmacy staff with HPSA bi-annual newsletter. Monitor and contact pharmacies with a significant change in collection patterns.
Year 2	 Contact Municipalities with promotional material and key messages for their websites. Contact on a quarterly basis existing pharmacies with ownership and/or manager changes. Promote program through pharmacies, ambassador tour, Recycle Manitoba and Pharmacists Awareness Month. Monitor and contact pharmacies with a significant change in collection patterns. Continue to advertise the Manitoba Medications Return Program through websites, flyers and events
Year 3-5	 Contact Municipalities with promotional material and key messages for their websites. Educate and promote the program to pharmacy staff with bi-annual newsletter. Advertise the Manitoba Medications Return Program through websites, flyers and events.

6.3 Consumer Awareness

The Regulation requires that the plan makes adequate provision for informing consumers of the program, the location of collection facilities, as well as the environmental and benefits associated with participating in the program. The strategy will be modified over time in response to the effectiveness of the program.

6.3.1 Key Messages:

It is important that consumers are aware of the importance of returning unused or expired medications, where to return them and appropriate safety measures at home to prevent drug abuse and reduce the potential for diversion and misuse.

- Drug abuse among kids is a major area of concern
- Parents are the first line of defense in a drug prevention strategy
- 450,000 Canadian teens misuse prescription drugs and 70% of those kids say they stole them from home
- One in 6 teenagers admit to having taken a legal prescription drug in the past year to get high.
- Canada along with the U.S. are the biggest consumers of prescription drugs (painkillers in particular)

6.3.2 Communication Methods:

The Program will use a number of methods to create consumer awareness. These include:

• Website: The program website will have information on what items can be returned and how to return them. A map based collection location finder is available. It also includes a print-ready brochure and a system for reordering consumer information materials produced for the program.

• **Point of Return:** Any participating collection depots will be offered program signage to display and counter cards to distribute to consumers.

• Earned media and advertising: The Program targets the use of earned media (press releases etc.) and paid advertising.

• **Direct advertising and Communications:** The program will directly target commercial initiatives through dedicated mailings and partnerships with relevant associations such as Partnership for Drug Free Canada and Canadian Centre for Substance Abuse and other groups.

6.3.3 Partnerships:

The program works towards partnering with organizations interested in collaborating to promote health and safety. Collaboration strategies have been developed through discussions with potential partners and HPSA members. Some avenues currently used by HPSA are:

• **Retailers**– Point of sale materials including shelf-talkers, counter cards, consumer brochures and/or program posters, provided at no cost to retailers.

• Other Stewardship Programs – Opportunities to combine communication efforts with existing stewardship programs such as MARR ambassador tour used since 2013.

• **Municipal and District Partnerships** – The program will seek opportunities to partner with local governments, including advertising in municipal calendars; links from local government websites to Program website and inclusion of program information in recycling/how to disposed of specific web pages; inclusion of program information with local government householder communications.

• Others –Brand owners (161) and other agencies (++) with an interest in health and safety have links to our website (www.healthsteward.ca) to educate the public on proper disposal of medications.

Target until 2021:	 10 % increase in public awareness compared to 2016 results: In the fall of 2016, HPSA will conduct a survey to set standards.
Performance measures:	• Measure changes in awareness.
Strategies: Year 1	Work with Manitoba Stewards to increase exposure through communications and other events.
	• Promote program through advertising and special events and provincial/territorial or national initiatives.
Year 2 - 3	• Secure publicity in annual recycling calendars and continue to support special initiatives.
Year 4	Measure awareness of program with public survey.
Year 5	• The consumer awareness strategy will be modified over time based on the results of the methods employed and ongoing surveys in year 4.

6.3.4 Consumer Awareness Targets

7. Dispute Resolution Procedure

The Program will contract with suppliers and service providers to the program by the use of commercial agreements.

Any person or organization believing that the responsibilities of parties participating in the MMRP do not meet the program plan should immediately provide a detailed description of their concerns to HPSA:

By e-mail to admin@healthsteward.ca By fax to 613-722-1626 By phone to 613-723-7282

Within 15 business days HPSA will seek to resolve the dispute through a co-operative approach and voluntary resolution. In the absence of a successful resolution, HPSA will convene a three party adjudication panel within the following 30 business days. One individual will be chosen by HPSA, one individual chosen by the pharmacy and one individual chosen by the concerned party (concerned party can't be appointed). The panel will consider the dispute and offer a decision on all parties involved within 5 business days of panel adjournment. Should the decision not be accepted, commercial litigation may be pursued by the concerned party.

8. Annual Report

The reporting requirements that HPSA will provide on behalf of its members are clearly defined in the *Wrap Act* Section 16 (1). HPSA will submit an annual report on the MMRP on or before April 30th of each year to the GMES.

9. Pollution Prevention and Best Management

Over the last 5 years, HPSA members have undertaken environmental initiatives that have improved the environmental impact of health products. As a performance measure, individual stewards have also made some changes to product monographs which reflect the program's ability to influence change in a positive manner. Product monographs (patient medication information sheets) are starting to indicate safe disposal options (see example in Appendix G). In addition, all MMRP containers are reusable 23 L containers.

HPSA has also partnered with some chains (e.g.: Shoppers Drug Mart/Rexall) to distribute paper bags to help with medicine cabinet clean-up and reduce the impact of pharmaceuticals entering the environment.

9.1 Safety, Social and Environmental Impact

The MMRP is designed to help mitigate the following safety, societal and environmental risks associated with unused medications in the home.

9.1.1 Safety Risk

One in six teenagers have admitted to taking prescription drugs to get high and 70% of them say they stole them from home (Source: PDFC)). The MMRP promotes consumer awareness and education about the dangers of unused/expired medications in the home and that the proper storage and handling of these unused/expired medications is essential to avoid accidental ingestion by household members and pets. A key component of that message is promoting the use of MMRP registered community pharmacy collection locations as the proper venue for disposing of these materials.

9.1.2 Societal Risk - Abuse and Diversion

It is important for prescription drugs to be disposed of properly through the MMRP and not left in the home where they can be easily abused or diverted. Opioids, central nervous system depressants and stimulants are the most commonly misused classes of prescription drugs (Source: National Institute on Drug Abuse,

http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications) and are present in the post-consumer pharmaceutical waste stream. The 2014 the Partnership for Drug-Free Canada reported that 70% of people aged 12 or older used pain relievers non-medicinally in the past year, many of which were likely obtained from a home medicine cabinet. Unused quantities of medications in the home creates the opportunity for abuse through unauthorized consumption or the opportunity for diversion into the black market. Educating consumers on abuse and diversion, promoting community pharmacy collection locations and contracting a safe and secure service provider to collect and dispose of medications from pharmacies are all critical components of the MMRP that HPSA has put in place to create the necessary program accessibility to help prevent abuse and diversion.

9.1.3 Environment

A 2013 study by Statistics Canada showed that nearly 40% of Canadian households disposed of their unused or expired medications by dumping them down the drain, flushing them down the toilet or putting them in their curbside garbage (Source: Statistics Canada Disposal of Household Special Wastes.

http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications). Sewage treatment plants are not designed to effectively treat these kinds of substances and remove them from the waste water stream and as a result they pass through the process and are released into the environment. There is no reuse or recycling application for postconsumer unused/expired medications. Medications must be completely destroyed through incineration. The tonnages of medications collected by the MMRP has kept this material out of our landfills and wastewater treatment systems which has been beneficial to the environment.

Due to the nature of an EPR program for pharmaceuticals and Natural Health Products, an environmental performance measurement is problematic. The amount of eligible pharmaceutical, over-the-counter and natural health products introduced into Manitoba can be calculated based on prescriptions or units sold but, according to the USEPA, "...quantities of production or consumptions do not correspond with the quantities of pharmaceuticals and personal care products (PPCPs) introduced into the environment. (Source: USEPA web site http://epa.gov/ppcp/faq.html#quantities). The USEPA also notes that "To date, scientists have found no evidence of adverse human health effects from PPCPs in the environment" (Source: USEPA web site http://epa.gov/ppcp/faq.html#quantities). Additionally, aquatic species that bio accumulate pharmaceutical, personal care of veterinary products and have been subjected to toxicity tests show that lethal effects are unlikely in the environment but that long term effects are possible (Source: Pharmaceuticals and Personal Care Products in the Canadian Environment: Research and Policy Directions. Dr. Francois Gagne, p.10-11.).

Medications cannot be reused or recycled, unlike other designated products covered under this regulation.

Processing Requirements:

- Post-consumer pharmaceutical waste collected in the MMRP must be treated by high temperature incineration.
- To ensure safety, mitigate the risk of diversion and maximize the efficiency of the thermal treatment process, pharmaceutical waste will be contained in leak-resistant and diversion-resistant secondary packaging (i.e.: plastic pharmaceutical waste pails and/or liners).
- Waste-to-Energy is the preferred treatment method for post-consumer pharmaceuticals.
- Processors must be licensed by the appropriate provincial government authority and have a provincial registration number where required.
- A certificate of destruction, as well as 3rd party verification will be obtained by HPSA.

10. Conclusion

Since 1997, HPSA has administered and operated provincially regulated *Medications Return Programs* that allows consumers to return (at no charge) their unused or expired medications to participating retail pharmacies. As a result, in 2015, HPSA diverted approximately 452,000 kg of unused or expired medications from landfills or waterways of which approximately 19,000kg collected in Manitoba.

11. Appendices

11.1 Appendix A: HPSA Membership in 2015

AA Pharma Inc. Abbott Diabetes Care Abbott EPD AbbVie Corporation Actavis Pharmaceuticals Company Actelion Pharmaceuticals Canada Inc. Advanced Orthomolecular Research (AOR) Advanced Sales and Marketing Canada Inc Alcon Canada Inc. Allergan Inc. Amgen Canada Inc. Amway Canada Apotex Inc. Aptalis Pharma Canada Inc. Aspri Pharma Canada Inc Astellas Pharma Canada Inc. AstraZeneca Canada Inc. Auro Pharma Inc Auto Control Medical Aventix Animal Health Baxter Canada Bayer Inc. **BD** Medical Bimeda-MTC Animal Health Inc. Bioforce Canada Inc. Biogen Idec Canada Inc Blistex Body Plus Nutritional Products Inc. Boehringer Ingelheim Canada Ltd. Boiron Canada Inc. Bristol-Myers Squibb Pharmaceutical Group Canada Safeway Ltd. Canadian Custom Packaging Company Celex Laboratories Inc. Champion Alstoe Animal Health Inc. Church & Dwight Canada **Cipher Pharmaceuticals** Combe Incorporated Costco Wholesale Canada Ltd. Covidien **Cubist Pharmaceuticals Canada Inc** Cytex Pharmaceutical Inc. D Drops Company

Diversified Nutrition Lifestyle Canada Ltd. Domrex Pharma Inc. Duchesnay Elanco Eli Lilly Canada Inc. EMD-Serono Canada Inc. Enzymatic Therapy Euro-Pharm International Canada Inc. Ferring Inc. Fresenius Kabi Canada Ltd. Galderma Canada **General Nutrition Centres Canada** Generic Medical Partners Inc. **Genuine Health Inc** Gilead Sciences Canada, Inc. GlaxoSmithKline Consumer Healthcare Inc. GlaxoSmithKline Inc. Groupe Jean Coutu (PJC) inc Health First Network Association Inc Herbal Magic Inc. Herbalife of Canada Hospira Healthcare Corporation HPI Health Products/Lakota Indivior Intervet Canada Corp (dba Merck Animal Health) Jamieson Laboratories Janssen Inc. Katz Group Canada Ltd. Laboratoires Atlas Inc. Leo Pharma Inc. Les Laboratoires Nicar Inc LifeScan Canada Ltd. Loblaw Companies Ltd London Drugs Limited Lundbeck Canada Inc. Mannatech Incorporated Marcan Pharmaceuticals Inc. McKesson Canada McNeil Consumer Healthcare a division of Johnson & Johnson Mead Johnson Nutrition (Canada) Co. Medexus Inc **Medical Futures Inc**

Medtronic Merck Canada Inc. Merial Canada Inc. Methapharm Inc. Mint Pharmaceuticals Inc Mylan Pharmaceuticals ULC Natural Factors Nutritional Products Ltd. Nature's Sunshine Products of Canada Ltd. Nature's Way Canada Ltd Nestlé Canada Inc. Norbrook Laboratories Inc. Novartis Consumer Health Canada Inc. Novartis Pharmaceutical Inc. Novo Nordisk **Omega Alpha Pharmaceuticals** Organika Health Products Inc. Otsuka Canada Pharmaceuticals Inc. Overwaitea Food Group Ltd Partnership Paladin Labs Inc. Pascoe Canada Pfizer Canada Inc Pfizer Consumer Healthcare, Division of Pfizer Canada Inc. PharmaChoice Pharmasave National (Drugs) Ltd. Pharmascience Inc. Platinum Naturals **Preferred Nutrition** Procter & Gamble Inc. Purdue Pharma Puresource Inc Purity Life Health Products Rafter 8 Products Ranbaxy Pharmaceuticals Canada Inc. RBP Canada Ltd. Renew Life Canada Inc. **Roche Canada Limited Roche Diagnostics** Sandoz Canada

Sanis Health Inc. Sanofi Consumers Health Sanofi-Aventis Canada Inc. Schering Plough Canada Inc. Servier Canada Inc. Shaklee Canada Inc. Shire Canada Inc. Shoppers Drug Mart Central Sigma Tau Pharmaceuticals, Inc. SISU Inc. Sobi Inc Stericycle Inc. Sterimax Inc Sunovion Pharmaceuticals Inc. Takeda Canada Inc. Tanta Pharmaceuticals Inc. Taro Pharmaceuticals Inc. Teva Canada / Novopharm TOP Nutritionals (Natural Calm Canada) **Tremblay Harrison Inc Tribute Pharmaceuticals Canada Inc Trillium Health Care Products** UCB Canada Inc. UniPHARM Wholesale Drugs Univet Pharmaceuticals Ltd. **USANA Health Sciences** Valeant Canada LP Valeo Pharma Inc. Vertex Pharmaceuticals Incorporated Vetoquinol Canada Incorporate Virbac Animal Health Canada Vita Health Products Inc. Walmart Canada Corp. Webber Naturals Ltd. WellSpring Pharmaceutical Canada Corp. Westcoast Naturals WN Pharmaceuticals Ltd. Zoetis Canada

11.2 Appendix B: Registered Pharmacies in 2015

Aberdeen Pharmacy Apothecary of Morden Inc Arborg Pharmacy Archibald pharmacy Ashern Pharmacy Assiniboine Pharmacy Autumnwood Medical Pharmacy **Baldur Pharmacy BenefitsRx** BioScript Pharmacy Ltd. Birtle Pharmacy **Boyd Medical Pharmacy Brandon Clinic Pharmasave** Brandon South Sobey's Pharmacy Good Shepherd Pharmacy Brathwaite's Pharmacy Broadway Pharmacy **Brothers Pharmacy Ltd** Brown's Drug Store Canadadrugs.com LP CarePlus Transcona Pharmacy Carman Pharmacy Ltd CD Whyte Ridge Pharmacy **Cin Den Pharmacy** CinDen Pharmacy #2 Clayman Pharmacy Concordia Community Pharmacy Co-op Pharmacy Grant Park Corydon Village Pharmacy Costco Pharmacy #153 Costco Pharmacy #549 Costco Pharmacy #57 Crestview Pharmacy **Dakota Pharmacy Danial Pharmacy Dauphin Clinic Pharmacy** Drugstore Pharmacy #1508 **Drugstore Pharmacy #9002** Drugstore Pharmacy #9079 Drugstore Pharmacy #9081 Drugstore Pharmacy #9082 **Dueck Drug Store** East St. Paul Pharmacy **Ebbeling Pharmacy** Elie Pharmacy Ellis Pharmacy & Thrifty Meds

Emad pharmacy Emerson Pharmacy Empire Drugs Eriksdale pharmacy Express Scripts Canada Pharmacy Lundar Pharmacy Ltd Falk Pharmacy Flatland Drugs Fort Alexander Pharmacy Fort Rouge Pharmacy Friend's Pharmacy Gilbert Plains Pharmacy Ltd Gladstone Pharmacy **Glenboro Pharmacy** Grand Med Hth Science Pharm Grand Medicine Health Services Green Crest Pharmacy **Grunthal Pharmacy Guardian Pharmacy** Harbourview Pharmacy Hartford Drugs Hazelwood Drugs Health Central Pharmacy **Higgins Pharmacy** Hill's Clinic Pharmacy Hill's Drug Store Home Health Care Pharmacy Ingham Pharmacy Interlake Pharmacy Invivo Health Pharmacy Isabel Pharmacy Island Lakes Pharmacy Killarney Pharmacy Ltd. La Salle Pharmacy Ltd. Leclerc Pharmacy Leila Pharmacy Loblaw Pharmacy #1503 Loblaw Pharmacy #1505 Loblaw Pharmacy #1506 Loblaw Pharmacy #1509 Loblaw Pharmacy #1510 Loblaw Pharmacy #1511 Loblaw Pharmacy #1512 Loblaw Pharmacy #1514 Loblaw Pharmacy #1515

Loblaw Pharmacy #1516 Loblaw Pharmacy #9080 London Drugs #66 Lorette Pharmacy Dufresne Macgregor Pharmacy Machray Pharmacy Main & Luxton Co-op Pharmacy Main St. Pharmacy Mandalay Pharmacy Maples Pharmacy Marion Pharmacy Martin's Pharmacy Ltd Meadowood Pharmacy Medi North Pharmacy & AccessCa Medical Centre Pharmacy Medi-Care Pharmacy Medicine Shoppe #331 Medicine Shoppe Pharmacy #278 Medicine Shoppe Pharmacy #290 Medicine Shoppe Pharmacy #305 Medicine Shoppe Pharmacy #313 Medicine Shoppe Pharmacy #329 Medocare Pharmacy Medsafe Pharmacy Melita Super Thrifty Pharmacy Meyers Drug Store Millennium Pharmacy Miller's Pharmacy Mount Carmel Clinic Pharmacy Mountain Park Pharmacy Ltd. Munroe Pharmacy My Care Pharmacy Nations First Pharmacy Niverville Pharmacy Ltd. North Mart Pharmacy North Mart Pharmacy #176 Norway House Pharmacy Notre Dame Hospital Pharmacy **Oakbank Pharmasave Oakfield Pharmacy** Osborne Village Pharmacy Ltd. Patient Advocate Pharmacy Pharma Plus #4812 Pharma Plus #4814

Safeway Food And Drug Pharmacy Shoppers Drug Mart #0551 Pharma Plus #4815 #588 Pharma Plus #4823 Shoppers Drug Mart #0552 Safeway Food And Drug Pharmacy Shoppers Drug Mart #0553 Pharma Plus #4846 #590 Safeway Food And Drug Pharmacy Shoppers Drug Mart #0554 Pharma Plus #4854 Shoppers Drug Mart #0555 Pharma Plus #4895 #591 Safeway Food And Drug Pharmacy Shoppers Drug Mart #0556 Pharma Plus #4903 Pharma Plus #4950 #603 Shoppers Drug Mart #0557 Safeway Food And Drug Pharmacy Shoppers Drug Mart #0559 Pharma Plus #4960 #604 Pharmacie Seine Ltee Shoppers Drug Mart #0561 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2404 Pharmamir Pharmacy #623 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2406 Pharmasave #0451 Pharmasave #0455 Shoppers Drug Mart #2414 #701 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2419 Pharmasave #0469 Pharmasave #0471 #708 Shoppers Drug Mart #2421 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2422 Pharmasave Health Centre #0470 #717 Pilot Mound Pharmacy Shoppers Drug Mart #2424 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2428 **Pinawa Pharmacy** #718 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2444 **Pine Pharmacy** Plessis Pharmacy Shoppers Drug Mart #2460 #725 Point Douglas Rexall #7403 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2501 #726 Shoppers Drug Mart #2505 Police Depot Safeway Food And Drug Pharmacy Shoppers Drug Mart #2511 **Positive Health Pharmacy** #727 Shoppers Drug Mart #2514 Prana Pharmacy Safeway Food And Drug Pharmacy Shoppers Drug Mart #2516 **Providen Pharmacy Logistics &** #729 Safeway Food And Drug Pharmacy Shoppers Drug Mart #2517 Rasha Pharmacy Reavie's Pharmacv Shoppers Drug Mart #532 #731 Red River CO-OP Southdale Safeway Food And Drug Pharmacy Shoppers Drug Mart #549 Pharmacy #791 Sobey's Grant Park Pharmacy #5150 Regent Park Pharmacy Safeway Pharmacy #0359 Sobey's Kenaston Pharmacy #5166 Reston Drug Ltd Safeway Pharmacy #0586 Sobey's Northdale Pharmacy #5167 **Rexall #4813** Safeway Pharmacy #0714 Sobey's Pharmacy #5155 **Rexall #4816** Safeway Pharmacy #0720 Rexall #4887 Safeway Pharmacy #0728 Rexall #7401 Scale Drug Store Rexall #7402 Serenity Pharmacy Rexall #7404 Shoal Lake Pharmacy Rexall #7405 Shoppers Drug Mart #0530 Rexall #7406 Shoppers Drug Mart #0533 Rexall Pharma Plus #4817 Shoppers Drug Mart #0534 Rexall Pharma Plus #4994 Shoppers Drug Mart #0535 **River East Pharmacy** Shoppers Drug Mart #0537 **Riverton Pharmacy** Shoppers Drug Mart #0538 **Riverview Health Centre** Shoppers Drug Mart #0539 Rockwood Pharmacy Shoppers Drug Mart #0540 Ronald Pharmacy Shoppers Drug Mart #0542 **Rossburn Pharmacy** Shoppers Drug Mart #0544 Safety Drugs Shoppers Drug Mart #0545 Safeway Food And Drug Pharmacy Shoppers Drug Mart #0546 #334 Shoppers Drug Mart #0547

Notice of Consultation: Revised HPSA Stewardship Plan for Medication Returns in Manitoba

The Health Products Stewardship Association (HPSA), on behalf of Canada's health products industries, manages the national Medications Return Programs (MRP) within the province of Manitoba. The HPSA Stewardship Plan in Manitoba was approved by Manitoba Conservation and Water Stewardship in 2011 and recognized the MRP as the official industry stewardship program for pharmaceuticals and natural health products. HPSA is inviting stakeholder comments on the revised industry stewardship plan that is intended to highlight how the program will continue to fulfill the requirements as outlined in regards to the *Household Hazardous Material and Prescribed Material Stewardship Regulation*. The 2017-2021 program plan is available at: http://www.healthsteward.ca/sites/default/files/MBProgramPlan20162021.pdf. You may direct your questions and comments to programswest@healthsteward.ca or contact Bill Burns at 1-844-535-8899 by November 27th, 2015.

We look forward to the opportunity of continuing our commitment to provide access for responsible disposal of health products to Manitobans.

11.3.1 Program Plan Consultation Distribution List

The MMRP Program Plan was sent to the Pharmacy Managers at all of our participating pharmacy collection locations (see Appendix B) as well as the Association of Manitoba Municipalities members, HPSA member companies (see Appendix A) and other key stakeholders interested and/or involved listed below.

- Environment Resource Counselling
- Manitoba Association for Resource Recovery
- Manitoba Association of Regional Recyclers
- Manitoba College of Pharmacists
- Neighborhood Pharmacy Association of Canada
- Pharmacists Manitoba Inc
- Pharmacists Manitoba Inc Board of Directors
- Pharmasave Central Office
- Product Care Manitoba
- Rexall Central Office
- Shoppers Drug Mart Pharmacy Operations
- Stericycle
- Walmart Pharmacy Operations

11.4 Appendix D: Consultation Presentation



HPSA Overview

 National Industry Stewardship Organization representing companies that introduce health products (medications and sharps) into the marketplace as a result of EPR regulations

•Operates collection programs that focus on drugs, natural health products and sharps waste from the public

 Rely on an extensive network of community pharmacies to voluntarily collect materials

·Act as a compliance agent for producers of health products

HPSA Stewardship Programs

- British Columbia Medications Return Program (BCMRP): 1996
- Recycling Regulation 2004/16
- Manitoba Medications Return Program (MMRP): 2011
- Household Hazardous Material and Prescribed Material Stewardship Regulation
- Ontario Medications Return Program (OMRP) and Ontario Sharps Collection Program (OSCP): 2012
 EPA 298/12
- Island Medications Return Program (IMRP) and Island Sharps Collection Program (ISCP): June, 2015
 PEI Environmental Protection Act Materials Stewardship and Recycling Regulations



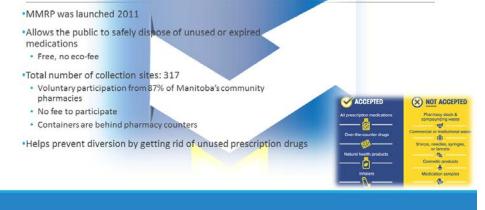
HPSA Standards



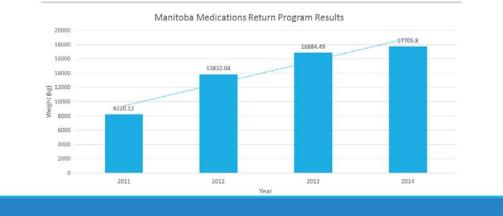
- Safety
- Diversion
 Environment
- Compliance
 - compnance
- Offer a "one-stop" for product stewards
- Central administration
- Harmonized product definitions
- Single board of directors representing industries
 Rx, OTC, NHP and sharps
- · Coordination of events and promotion



Manitoba Medication Returns Program



Collection Results





11.4.1 Public Consultation In Person – 2015 MARR Forum Attendance List

First Name	Last Name	Organization
Alan	Abraham	LGD of Pinawa
Sandra	Abuwalla	Call2Recycle
Mac	Balacano	MTS
Lisa	Baldwin	RM of Hanover
Glen	Basarowich	RM of St. Clements
Kathy	Bennett	Eastman Recycling Services
Ron	Benson	MARRC
Angela	Bidinosti	Aboriginal Affairs & Northern Development
Bob	Bodnaruk	RM of Springfield
James	Bolton	Portage & District Recycling Inc.
Sam	Brask	City of Winnipeg
Bill	Brenner	City of Dauphin
Don	Budinsky	Communities in Bloom
Bill	Burns	Health Products Stewardship Assn.
Peter	Campbell	RM of West St. Paul
Jennifer	Carlson	MARRC
Kathy	Cass	Miller Environmental
Lorne	Charney	Whitemouth-Reynolds Waste Management
Darcy	Culbertson	Miller Environmental
Greg	Currie	Louise Integrated Waste
Rosemary	Deans	MEIA
jaclyn	Diduck	CBCRA
Murray	Donald	Prairie View Municipality
Melissa	Dorota	CBCRA/Recycle Everywhere
Jerry	Drobot	RM of St. Clements
Gerry	Dube	Overton Environmental Enterprises
Brett	Eckstein	Tire Stewardship Manitoba
Pam	Elias	RM of West St. Paul
Greg	Elson	RM of Springfield
Heather	Erickson	RM of Springfield
Ken	Fargher	City of Winnipeg
Jim	Ferguson	Green Manitoba
Mike	Fernandes	StrategyMakers Consulting
Debbie	Fiebelkorm	RM of St. Clements
Heather	Francis	SWAMP Waste Authority
Ray	Frey	RM of St. Clements
Barry	Friesen	CleanFarms
Dan	Gagne	Town of Altona
Ron	Gerbrandt	Gateway Resources Inc.
Marj	Greenwood	The Pas & Area Recycling Centre
Scott	Haddow	City of Brandon
Sylvie	Hebert	Green Action Centre
Hank	Hildegbrand	SWAMP Waste Authority
Laura	Hnatiuk	MTS
Kristin	Houle	Emterra
Floyd	Houston	Town of Virden
Debbi	Hruda	RM of Springfield
Tracy	Hucul	Green Action Centre
Laurie	Hunt	RM of St. Andrews
Laune	TUIL	

11.5 Appendix E Consultation Comments, Questions and Answers

Brent Booker – Pharmacy Manager CO-OP Grant Park

These comments should not be misconstrued as unsupportive, but it should be noted that a significant amount of time is needed by pharmacy staff to deal with the volume of product returned. It is not uncommon for people to come to the pharmacy with grocery bags of unused medications. The sorting and removal of product from original packaging diverts pharmacy assistant labor on average of 1-2 hours per week, and over the course of a year this should not be taken lightly. I may be incorrect, but I am not aware of any visible or backstage remuneration for this.

Jim Harlow – Empire Drugs

It would be advantageous to have a sharps recovery program added. This would prevent a huge number of sharps from entering landfills

Marlene Hutchinson – Cycle Environment

After reading the proposed plan for the Manitoba Medications Stewardship Plan (2017-2021) we agree with the program as managed for the past five years by HPSA.

Pharmacists of Manitoba - Board of Directors

- 1. Number of inhalers is capped at 10 canisters per pail. This volume is far too low as many are returned on a daily basis. Please re-evaluate and consider removing any minimum number to be returned per pail.
 - a. This maximum is for full inhalers; empties are not subject to this minimum. We will inform our pharmacies network as this is obviously needs interpretation.
- 2. Advertising to the public requires strong messaging about what can and cannot be returned to the pharmacy (5.3).
 - b. We are developing a new piece of promotional material for the public and will make it available next year in Manitoba (see appendix E).
- 3. Information regarding sharps and the appropriate containers these can returned in to the pharmacy i.e. random jars, peanut butter jars, and coke cans are not appropriate.
 - c. Please note that HPSA is not the administrator for the sharps collection program in Manitoba we operate a sharps program in Ontario and PEI with compelling medical sharps regulations.
- 4. Two collection containers to be full before pick up is a hardship for small independent pharmacies (5.1). We have a large proportion of independent pharmacies in Manitoba.
 - d. Any pharmacies that are challenged with storage are able to be serviced more frequently and return only one item. This can be requested directly through our program coordinator at programwest@healthsteward.ca.
- 5. Consumers should be provided with a complaint line if a pharmacy refuses to take returns.
 - e. If there is an issue the public can reach us at 1-844-535-8889, this information will appear in the new rack card (see appendix E).

11.6 Appendix F: Rack Card (Front and Back)



HAVE YOUR OLD MEDICATIONS OVERSTAYED THEIR WELCOME?



1

Safely store medications in your home.



Check for unused and expired medications.



Empty all pills into a bag or container, but keep liquids, creams and inhalers in their original packaging. Remove any personal identification. Recycle all other packaging.



Take it back to a participating pharmacy.



HEALTH PRODUCTS

HPSA IS FUNDED BY THE HEALTH PRODUCTS INDUSTRY

For more information, visit: healthsteward.ca or e-mail info@healthsteward.ca Call Our Toll-Free Number: 1-844-535-8889

11.7 Appendix G: Product Monograph

Patient Medical Information

Zellers Pharmacy #472, Hamati Pharma Inc., Ottawa ON, K1H 7X6 Phone: (613) 526-4466 Fax: (613) 526-0853

Printed On: 01/12/2011 16:33:02

Brand Name:NOVAMOXIN 500 MG CAPSULE DIN:00406716 Generic Name:Amoxicillin Trihydrate AMOXICILLIN - ORAL (a-MOX-i-SIL-in)

USES

Amoxicillin is used to treat a wide variety of bacterial infections. This medication is a penicillin-type antibiotic. It works by stopping the growth of bacteria.

This antibiotic treats only bacterial infections. It will not work for viral infections (such as common cold, flu). Unnecessary use or misuse of any antibiotic can lead to its decreased effectiveness.

Amoxicillin is also used with other medications to treat stomach/intestinal ulcers caused by the bacteria H. pylori and to prevent the ulcers from returning.

OTHER USES

This section contains uses of this drug that are not listed in the approved US professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This drug may also be used by people with certain heart problems (such as heart valve disease) before medical/dental procedures (such as tooth/gum procedures) to prevent heart infection.

HOW TO USE

Take this medication by mouth with or without food as directed by your doctor, usually every 8 or 12 hours. The dosage is based on your medical condition and response to treatment.

Drink plenty of fluids while using this medication unless your doctor tells you otherwise.

Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals. To help you remember, take it at the same times each day.

Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a return of the infection. Tell your doctor if your condition persists or worsens.

SIDE EFFECTS

Nausea, vomiting, or diarrhea may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection (oral or vaginal fungal infection). Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge or other new symptoms. Tell your doctor immediately if any of these rare but serious side effects occur: dark urine, persistent nausea or vomiting, stomach/abdominal

pain, yellowing eyes or skin, easy bruising or bleeding, persistent sore throat or fever. This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

Amoxicillin can commonly cause a mild rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe allergic reaction. Therefore, get medical help right away if you develop any rash.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

- Continued -

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Continued Monograph For 00406716 (Novamoxin) PRECAUTIONS

Before taking amoxicillin, tell your doctor or pharmacist if you are aller tic to it; or to penicillin or cephalosporin antibiotics; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, a certain type of viral infection (infectious mononucleosis).

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

Amoxicillin passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS

The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring.

To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval.

Some products that may interact with this drug include: live bacterial vaccines, methotrexate.

Before taking amoxicillin, tell your doctor or pharmacist if you are also taking probenecid. Probenecid slows down the removal of amoxicillin from your body, causing higher levels of this antibiotic in your bloodstream. For certain types of difficult-to-treat infections, your doctor may prescribe these 2 medications together in order to achieve this effect. Consult your doctor or pharmacist for more details.

Although most antibiotics probably do not affect hormonal birth control such as pills, patch, or ring, some antibiotics may decrease their effectiveness. This could cause pregnancy. Examples include rifamycins such as rifampin or rifabutin. Be sure to ask your doctor or pharmacist if you should use additional reliable birth control methods while using this antibiotic.

Amoxicillin may cause false positive results with certain diabetic urine testing products (cupric sulfate-type). This drug may also affect the results of certain lab tests. Make sure laboratory personnel and your dectors know you use this drug.

This document does not contain all possible drug interactions. Keep a list of all the products you use. Share this list with your doctor and pharmacist to lessen your risk for serious medication problems.

OVERDOSE

If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: severe vomiting, persistent diarrhea, a severe decrease in the amount of urine, or seizures.

NOTES

Do not share this medication with others.

This medication has been prescribed for your current condition only. Do not use it later for another infection unless your doctor directs you to do so. A different medication may be necessary in that case.

With prolonged treatment, laboratory and/or medical tests (such as kidney and liver function, complete blood counts) may be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature according to the product labeling, away from light and moisture. Different brands of this medication have different storage needs. Check the product package for instructions on how to store your brand, or ask your pharmacist. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal contrainty for more details about how to safely discard your product. IMPORTANT: HOW TO USE THIS INFORMATION: This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

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