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Inspection Tracker: Drug Manufacturing Establishments

As part of Health Canada's ongoing commitment to openness and transparency, the Department is publishing information regarding emerging issues identified through our drug inspection program.

This tracker provides a snapshot of the potential health and safety issues Health Canada is tracking with companies that fabricate, package/label, test, wholesale, distribute or import drugs for sale in Canada. The information in the chart will expand to eventually include details about affected Canadian companies and products.

How the Inspection Tracker Works

- Health Canada responds to potential risks as soon as we hear about them whether from our own inspections, the companies themselves, adverse reaction reports or from our regulatory partners.
- The tracker highlights actions Health Canada is taking such as: requests for voluntary quarantine, stop sales, import restrictions, or product recalls. It also indicates those circumstances where no action has been warranted.
- Even if a company is listed on the tracker, it doesn't necessarily mean there is an immediate risk to the health of Canadians. It means Health Canada is looking into a potential issue.
- Health Canada will continue to take action to manage risks identified to the health of Canadians using the most appropriate level of intervention, proportional to the risk to health.
- This tracker currently doesn't list specific drugs and health products affected but links to [Recalls & Safety Alerts](#) if a risk has been linked to specific products on the Canadian market.
- This tracker is updated regularly.
- Once an item is listed in the closed section, it indicates that there is no further action being taken by Health Canada at this time and there will be no more updates regarding this item.

- Last update: **October 11, 2017.**

Open Items

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Antibioticos do Brasil Rod. Professor Zeferino Vaz, Km135-SP332, Cosmopolis, Sao Paulo, Brazil 13150-000</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • Issued terms and conditions to Canadian importer(s) 	Regulatory Partner(s)	General GMP observations
<p>Bayer S.A Km 14.5 Calzada Roosevelt, Zona 3 De Mixco, Guatemala, N/A, 1901, Guatemala</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Medically necessary products identified • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Issued terms and conditions to Canadian importer(s) 	Regulatory Partner(s)	Data Integrity General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Bend Research Inc 20503 Builders Street, Bend, Oregon, USA, 97701</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • Issued terms and conditions to Canadian importer(s) 	Regulatory Partner(s)	Data Integrity General GMP observations
<p>ChemRite CoPac Inc. 19725 W. Edgewood Dr., Lannon, WI, USA</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	Regulatory Partner(s)	General GMP observations
<p>Cheng Fong Chemical Co. Ltd. No. 19, Gong 4th Road, Dayuan district, Taoyuan City 337, Taiwan</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Issued terms and conditions to Canadian importer(s) 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Divi's Laboratories Ltd. Unit 2, Chippada Village, Bheemunipatnam, Visakhapatnam, Andhra Pradesh, 531 162, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • Issued terms and conditions to Canadian importer(s) • Health Canada on-site inspection [November 13, 2017] 	Regulatory Partner(s)	Data Integrity General GMP observations
<p>Evertogen Life Sciences Limited PLOT NO: S-8, S-9, S-13/P & S-14/P TSIIC, Pharma Sez Green Industrial Park, Polepally (V), Jadcherla (M), Mahabubnagar, Telangana, IN-509 301, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Hospira S.P.A Via Frosse Ardeatine 2 Liscate Italy</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Medically necessary products identified • Requested voluntary quarantine • Voluntary quarantine not accepted due to products being medically necessary • Issued Terms and Conditions to Canadian importer(s) <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Health Canada restricts imports of drugs from Hospira S.P.A, Italy due to data integrity concerns</u> 	Regulatory Partner(s)	Data integrity General GMP observations
<p>Intas Pharmaceuticals Limited (IPL) Plot No. 423 / P / A Sarkhej – Bavla Highway Village Moraiya, Taluka Sanand Ahmedabad – 382213 Gujarat, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	Regulatory Partner(s)	General GMP observations
<p>Interpharm Praha A.S. Komoranska 955, Praha, Modrany</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e. corrective actions, information from regulatory partner) • Issued Terms and Conditions to Canadian importer(s) 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Micro Labs Tamil Nadu 92 Sipcot Industrial Complex Hosur - Tamil Nadu, India</p>	<ul style="list-style-type: none"> • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner). • No medically necessary products identified at this time • Requested voluntary quarantine • Voluntary quarantine in place • Issued Terms and Conditions to Canadian importer(s) <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Health Canada takes action to restrict import of products from three Micro Labs facilities in India</u> 	Regulatory Partner(s)	Data integrity General GMP observations
<p>Micro Labs Bangalore Plots No. 113 to 116, 4th Phase, KIADB, Bommasandra Industrial Area, Jigani Link Road, Anekal Taluk, Bangalore, India</p>	<ul style="list-style-type: none"> • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • Requested voluntary quarantine • Voluntary quarantine in place • Issued Terms and Conditions to Canadian importer(s) <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Health Canada takes action to restrict import of products from three Micro Labs facilities in India</u> 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Minsheng Group Shaoxing Pharmaceuticals Co. 315 Tanggong Road, Paojiand Industrial Zone. Shaoxing, Zhejiang, China 312071</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e. corrective actions, information from regulatory partner) • Medically necessary products identified • Requested voluntary quarantine • Voluntary quarantine not accepted due to products being medically necessary 	<p>Regulatory Partner(s) Canadian importer(s)</p>	<p>Data integrity General GMP observations</p>
<p>Pharmaceutics International Inc. 10819 Gilroy Rd, Hunt Valley, MD, USA, 21031</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • Issued terms and conditions to Canadian importer(s) 	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>
<p>Sage Products Inc. 3909 Three Oaks Road, Cary, Illinois, USA</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Vital Lab Private Limited Plant II Plot No.1710 & A1-2208, Phase III GIDC Estate, Vapi, Gujarat	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	Regulatory Partner(s)	General GMP observations

Closed Items

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
AGILA SPECIALTIES PRIVATE LTD., SPECIALTY FORMULATION FACILITY (SFF) 19A, Plot No. 284-B/1 Bommasandra Jigani Link Road, Anekal Taluk, Bangalore India - 560 105	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • Requested voluntary quarantine of non-medically necessary products • Voluntary quarantine in place • Issued terms and conditions to Canadian importer(s) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Agila Onco Therapies Ltd. Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore, Kamataka, India</p>	<ul style="list-style-type: none"> • Non-compliant rating issued • No further action required by Health Canada at this time <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Presence of Foreign Particulate Matter</u> 	<p>Regulatory Partner(s) Canadian importer(s)</p>	<p>General GMP observations</p>
<p>AGILA SPECIALTIES PRIVATE LTD. Opp II M, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka, India - 560 076</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • No critical risks identified to date • No further action required by Health Canada at this time 	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>
<p>Anuh Pharma Ltd E-17/3 & E 17/4 M.I.D.C. Tarapur, Taluka Palghar, District Thane, India-401 506 Boisar, Maharashtra</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • No further action required by Health Canada at this time 	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>
<p>Apotex Pharmachem India Private Limited (APIPL) Plot No. 1A, Bommasandra Industrial Area, 4th Phase, Jigani</p>	<ul style="list-style-type: none"> • Requested stop sale • Import restrictions imposed • On September 30, 2014, Issued Terms and Conditions to Canadian importer(s) 	<p>Health Canada Regulatory Partner(s)</p>	<p>Data integrity General GMP observations</p>

<p>Link Road, Bangalore, Karnataka, India</p> <p>Establishment</p>	<p>Status of Issue</p>	<p>Source of Information under Review</p>	<p>Primary Reason for Action</p>
	<ul style="list-style-type: none"> • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • HC onsite (June 5-10) to verify implementation of corrective actions • On August 31, 2015, amended Terms and Conditions to Canadian importer based on HC onsite corrective actions inspection conducted on June 5-10 • Judgments of the Federal Court <u>set aside import restrictions on APIPL and ARPL products</u>, ordered a <u>retraction of statements and declared amended terms and conditions on Apotex's Establishment Licence unlawful</u>. <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Health Canada puts measures in place for medically necessary products affected by import restriction from 3 facilities in India</u> • <u>Apotex Product Recall (2015-04-10)</u> • <u>Expanded recall of Apo-Candesartan</u> • <u>Health Canada puts in place new oversight of Apotex Inc. imports from APIPL and ARPL</u> • <u>Summary Report</u> <p>March 14, 2016: Health Canada issued a new decision which imposed no terms and conditions on Apotex's Establishment Licences for products fabricated at APIPL and ARPL. As such, products fabricated at these two sites are not subject to any import restrictions. This decision was based on all available information, including new information provided by Apotex.</p>		
<p>Apotex Research Private Limited (ARPL) Plot No. 1 and No. 2, Bommasandra Industrial</p>	<ul style="list-style-type: none"> • Voluntary quarantine was in place until further assessment was completed • Import restrictions imposed 	<p>Health Canada Regulatory Partner(s)</p>	<p>Data integrity</p>

<p>Area, 4th Phase, Jigani Link Road, Bangalore, India</p> <p>Establishment</p>	<p>Status of Issue</p>	<p>Source of Information under Review</p>	<p>Primary Reason for Action</p>
	<ul style="list-style-type: none"> • On September 30, 2014, issued Terms and Conditions to Canadian importer(s) • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • HC onsite (June 1-4) to verify implementation of corrective actions • On August 31, 2015, amended Terms and Conditions to Canadian importer based on HC onsite corrective actions inspection conducted on June 1-4. • Judgments of the Federal Court <u>set aside import restrictions on APIPL and ARPL products</u>, ordered a <u>retraction</u> of statements and <u>declared amended terms and conditions on Apotex's Establishment Licence unlawful</u>. <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Health Canada requests quarantine of products for Canadian market from Apotex facility in Bangalore, India</u> • <u>Health Canada puts measures in place for medically necessary products affected by import restriction from 3 facilities in India</u> • <u>Apotex Product Recall (2015-04-10)</u> • <u>Expanded recall of Apo-Candesartan</u> • <u>Recall of Apo-Candesartan-HCTZ</u> • <u>Apo-Risperidone (2015-06-03)</u> • <u>Losartan-HCTZ (2015-06-03)</u> • <u>Health Canada puts in place new oversight of Apotex Inc. imports from APIPL and ARPL</u> • <u>Summary Report</u> 		<p>General GMP observations</p>

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
	<p>March 14, 2016: Health Canada issued a new decision which imposed no terms and conditions on Apotex's Establishment Licences for products fabricated at APIPL and ARPL. As such, products fabricated at these two sites are not subject to any import restrictions. This decision was based on all available information, including new information provided by Apotex.</p>		
<p>B. Braun Medical Inc. 2525 McGaw Avenue Irvine, CA, 92614-5895 United States</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • No further action required by Health Canada at this time 	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>
<p>Biocon Limited, Works Unit II Plot Nos 2-4, Phase IV, Bommasandra-Jigani Link Road Bangalore, Karnataka India 560099</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified • No further action required by Health Canada at this time 	<p>Regulatory Partner(s)</p>	<p>Data integrity General GMP observations</p>

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Beijing Taiyang Pharmaceutical Industry Co Ltd No. 1 Shuangqiao (E) Road, Chaoyang, Beijing China</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity
<p>Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate, Ankleshwar, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • No critical risks identified to date • Health Canada on-site inspection [July 18, 2016] • Health Canada on-site re-inspection [January 23, 2017] • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>Chongqing Pharma Research Institute Co., Ltd. No. 565 Tushan Road, Nanan District, Chongqing, China</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Concord Biotech Limited 1482-1486 Trasad Road, Dholka Ahmedabad, Gujarat 387810, India</p>	<ul style="list-style-type: none"> Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>CTX Life Sciences Pvt. Ltd. 251-252 Sachin-Magdalla Road, G.I.D.C, Sachin, Surat, Gujarat, India, 394230</p>	<ul style="list-style-type: none"> Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>Dr. Reddy's Laboratories APIIC Ind. Est, Unit VI Pydibhimavarma (Village) Ranasthalem Mandal, Srikakulam District, India</p>	<ul style="list-style-type: none"> Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)No medically necessary products identified at this time Requested voluntary quarantine Voluntary quarantine in place Issued terms and conditions to Canadian importer(s) Health Canada on-site inspection [September 19, 2016] No further action required by Health Canada at this time <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> <u>Health products quarantined from two sites in India as Health Canada assesses data integrity concerns</u> 	Regulatory Partner(s)	Data Integrity General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Dr. Reddy's Laboratories Unit V Peddadevulapalli, Tripuraram Mandal, Nalgond District, Andhra Pradesh</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity General GMP observations
<p>Dr. Reddy's Laboratories Unit VII Plot No. P1 to P9, Phase III, Duvvada, VSEZ, Visakhapatnam, Andhra Pradesh IN</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity General GMP observations
<p>Emcure Pharmaceuticals Limited Plot No. P-1 & P-2,, IT-BT Park Phase II, MIDC, Hinjwadi, Hinjwadi, Pune, Maharashtra INDIA</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e. corrective actions, information from regulatory partner) • Medically necessary products identified Health Canada on-site inspection [June 14, 2016] • No further action required by Health Canada at this time 	Regulatory Partner(s) Canadian importer(s)	Data Integrity General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>EVERLIGHT CHEMICALS INDUSTRIAL CORPORATION 12, Industrial Third Rd, Kuanyin Industrial District, Kuanyin Hsiang, Taoyuan Hsien, 32853, Taiwan</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • No medically necessary products identified at this time • Health Canada on-site inspection (November 9-13) • Non-Compliant rating issued • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity
<p>Granules India Limited Plot No. 160/A, 161/E, 162 & 174/A, Gagillapur Village, Qutbullapur Mandal, Ranga Reddy District, Telangana state, Hyderabad, 500043, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>HEBEI YUXING BIO-ENGINEERING CO. LIMITED Xicheng District, Ningjin county, Ningjin, Heibei China</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • Requested voluntary quarantine of non-medically necessary products • Voluntary quarantine in place • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Hetero Labs Limited Unit V Sy.No.439-441, 458 TSIC Formulation SEZ Polepally Village, Jadcherla Mandal Mahaboobnagar, Telangana India 509301</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>Hospira Inc. 1776 North Centennial Drive, McPherson, KS, United States, 67460-9301</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • Issued Terms and Conditions to Canadian importer(s) • Health Canada on-site inspection [July 24, 2017] • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>Hubei Hongyuan Pharmaceutical Technology Co. Ltd. No. 428 Yishui North Road, Luotian County, Huanggang City, China-438 600, Fengshan Town, Hubei Province</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Hubei Hongyuan Pharmaceutical Technology Co. Ltd. No.8 Fengshan Road, Industrial and Economic Development Zone, Luotian County, China 438 600, Huanggang City, Hubei Province</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	<p>Data integrity</p> <p>General GMP observations</p>
<p>Ind-Swift Laboratories Limited Barwala Road, Bhagwanpur Village - Derabassi District Mohali, 140 507 Punjab, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No critical risks identified to date • No further action required by Health Canada at this time 	Regulatory Partner(s)	<p>Data integrity</p> <p>General GMP observations</p>
<p>Indoco Remedies Limited Plants II & III, L-32, 33, 34 Verna Industrial Estate Area, Verna, Goa, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e. corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>INTERQUIM, S.A., C/ Joan Buscalla, 10 Sant Cugat del Valles Barcelona, Spain</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e. corrective actions, information from regulatory partner) • Issued Terms and Conditions to Canadian importer(s) • Terms and Conditions removed • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>IPCA Laboratories Ltd. P.O. Box No. 33 Village Sejavta Ratlam, Madya Pradesh, India</p>	<ul style="list-style-type: none"> • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • Requested voluntary quarantine • Voluntary quarantine in place • Import restrictions imposed • Issued Terms and Conditions to Canadian importer(s) • Health Canada on-site inspection [September 26, 2016] • No further action required by Health Canada at this time <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Health Canada requests quarantine of products from IPCA Laboratories following falsification and manipulation of data issues</u> • <u>Health Canada puts measures in place for medically necessary products affected by import restriction from 3 facilities in India</u> 	Regulatory Partner(s)	Data integrity General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>IPCA Laboratories Ltd Plot 65 & 99, Dandudyog Industrial Estate, Piparia, Silvassa, Dadra & Nagar Haveli (U.T.), 396 230, India</p>	<ul style="list-style-type: none"> • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Terms and Conditions for IPCA Ratlam apply to the Piparia products. • Health Canada on-site inspection [August 19, 2016] • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data integrity General GMP observations
<p>IPCA Laboratories Ltd. 1 Pharma Zone, SEZ Phase II, Sector 3, District Dhar, Pithampur, India</p>	<ul style="list-style-type: none"> • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • Requested voluntary quarantine • Voluntary quarantine in place • Issued terms and conditions to Canadian importer(s) Health Canada on-site inspection [October 3, 2016] • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data integrity General GMP observations
<p>Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin Industrial Park, China-330 700, Fengxin, Jiangxi Province</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No critical risks identified to date • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Jinan Jinda Pharmaceutical Chemistry Co. Ltd. No. 6121 Longquan Road Zhangqiu, Shandong Province 250 20, China</p>	<ul style="list-style-type: none"> • No medically necessary products identified at this time Non-compliant rating issued • No further action required by Health Canada at this time 	Regulatory Partner(s)	<p>Data integrity</p> <p>General GMP observations</p>
<p>Kores (India) Limited (Plot Nos. 58/1, 58/2, 59A, 65A, 65B, 65C & 66A M.I.D.C. Industrial Area Dhatav, District Raigad, Roha, Maharashtra, India - 402 116)</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e. corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>Mahendra Chemicals B-1, 217, 218/2, G.I.D.C. Estate, Naroda Ahmedabad, Gujarat India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information. • No medically necessary products identified • Non-Compliant rating issued • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Marksans Pharma Limited Plot No. L-82, L-83, Verna Industrial Estate, Verna, Goa- India 403722</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • No medically necessary products identified at this time • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No Canadian importers (s) importing from this facility. • No further action required by Health Canada at this time 	Regulatory Partner(s)	<p>Data integrity</p> <p>General GMP observations</p>
<p>MEGAFINE PHARMA (P) LIMITED 48 - 51/201 Plot No 31 - 35, Lakhmapur, Maharashtra INDIA</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • Requested voluntary quarantine • Voluntary quarantine in place for 6 importers • Voluntary quarantine not accepted by 4 importers due to alternate risk mitigation measures being implemented by importer • Health Canada on-site inspection [April 12, 2016] • Health Canada inspection completed • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Meridian Medical Technologies 2555 Hermelin Dr., Brentwood, MO, 63144, United States</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • Medically necessary products identified • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
<p>Micro Labs Goa Plot No. S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa India</p>	<ul style="list-style-type: none"> • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No medically necessary products identified at this time • Requested voluntary quarantine • Voluntary quarantine in place • Issued Terms and Conditions to Canadian importer(s) • Health Canada on-site inspection [September 19, 2016] • No further action required by Health Canada at this time <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> • <u>Health Canada takes action to restrict import of products from three Micro Labs facilities in India</u> 	Regulatory Partner(s)	Data integrity General GMP observations
<p>Mylan Laboratories Limited F-4 & F-12, Malegaon MIDC, inner, Nashik-422113 India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) • No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations