



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: **February 5, 2018.**

Open Items

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Antibioticos do Brasil Rod. Professor Zeferino Vaz, Km135-SP332, Cosmopolis, Sao Paulo, Brazil 13150-000	<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
Apotex Research Private Limited (ARPL) Plot No. 1 and No. 2, Bommasandra Industrial Area, 4th Phase, Jigani Link Road, Bangalore, India	<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
Bayer S.A Km 14.5 Calzada Roosevelt, Zona 3 De Mixco, Guatemala, N/A, 1901, Guatemala	<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
Bend Research Inc 20503 Builders Street, Bend, Oregon, USA, 97701	<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) • Removed Terms and Conditions from Canadian importer(s) • No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity General GMP observations
Continental Manufacturing Chemist, Inc. 912 S. State St., Madrid, Iowa	<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
Cheng Fong Chemical Co. Ltd. No. 19, Gong 4th Road, Dayuan district, Taoyuan City 337, Taiwan	<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
Hospira S.P.A Via Frosse Ardeatine 2 Liscate Italy	<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
Intas Pharmaceuticals Limited (IPL) Plot No. 423 / P / A Sarkhej – Bavla Highway Village Moraiya, Taluka Sanand Ahmedabad – 382213 Gujarat, India	<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
Interpharm Praha A.S. Komoranska 955, Praha, Modrany	<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
Lupin Limited Unit 2-Plot No. 2, SEZ Phase-II, Misc., Apparel Park, District Dhar, Pithampur, Indore, Madhya Pradesh, India	<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
Malladi Drugs & Pharmaceuticals Ltd. Plot 67, 68, Sipcot Industrial Complex, Vellore, Ranipet, Tamil Nadu, India	<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
Micro Labs Tamil Nadu 92 Sipcot Industrial Complex Hosur - Tamil Nadu, India	<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
Micro Labs Bangalore Plots No. 113 to 116, 4th Phase, KIADB, Bommasandra Industrial Area, Jigani Link Road, Anekal Taluk, Bangalore, India	<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
Minsheng Group Shaoxing Pharmaceuticals Co. 315 Tanggong Road, Paojiand Industrial Zone. Shaoxing, Zhejiang, China 312071	<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 	Regulatory Partner(s) Canadian importer(s)	Data integrity General GMP observations
Pharmaceutics International Inc. 10819 Gilroy Rd, Hunt Valley, MD, USA, 21031	<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
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
Yicheng Goto Chemical Co.Ltd. 1 Group of Gaokeng, Xiaohe, Xiaohe, Yicheng, Hebei, 441003, China	<ul style="list-style-type: none"> Canadian importer(s) contacted by Health Canada for information 	Regulatory Partner(s)	General GMP observations

Closed Items

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>AGILA SPECIALTIES PRIVATE LTD., SPECIALTY FORMULATION FACILITY (SFF) 19A, Plot No. 284-B/1 Bommasandra Jigani Link Road, Anekal Taluk, Bangalore India - 560 105</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 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
<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"> Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Presence of Foreign Particulate Matter 	Regulatory Partner(s) Canadian importer(s)	General GMP observations
<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 	Regulatory Partner(s)	General GMP observations
<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 	Regulatory Partner(s)	General GMP observations
<p>Apotex Pharmachem India Private Limited (APIPL) Plot No. 1A, Bommasandra Industrial Area, 4th Phase, Jigani Link Road, Bangalore, Karnataka, India</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) 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 set aside import restrictions on APIPL and ARPL products, ordered a retraction of statements and declared amended terms and conditions on Apotex's Establishment Licence unlawful. <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> Health Canada puts measures in place for medically necessary products affected by import restriction from 3 facilities in India Apotex Product Recall (2015-04-10) Expanded recall of Apo-Candesartan Health Canada puts in place new oversight of Apotex Inc. imports from APIPL and ARPL Summary Report <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>	Health Canada Regulatory Partner(s)	Data integrity General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Apotex Research Private Limited (ARPL) Plot No. 1 and No. 2, Bommasandra Industrial Area, 4th Phase, Jigani Link Road, Bangalore, India</p>	<ul style="list-style-type: none"> Voluntary quarantine was in place until further assessment was completed Import restrictions imposed 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"> Health Canada requests quarantine of products for Canadian market from Apotex facility in Bangalore, India Health Canada puts measures in place for medically necessary products affected by import restriction from 3 facilities in India Apotex Product Recall (2015-04-10) Expanded recall of Apo-Candesartan Recall of Apo-Candesartan-HCTZ Apo-Risperidone (2015-06-03) Losartan-HCTZ (2015-06-03) Health Canada puts in place new oversight of Apotex Inc. imports from APIPL and ARPL Summary Report <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>	Health Canada Regulatory Partner(s)	Data integrity General GMP observations
<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 	Regulatory Partner(s)	General GMP observations
<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 	Regulatory Partner(s)	Data integrity General GMP observations
<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>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) 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
<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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Divi's Laboratories Ltd. Unit 2, Chippada Village, Bheemunipatnam, Visakhapatnam, Andhra Pradesh, 531 162, India	<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) <ul style="list-style-type: none"> Medically necessary products identified Issued terms and conditions to Canadian importer(s) Health Canada on-site inspection [November 13, 2017] No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity General GMP observations
Dr. Reddy's Laboratories APIIC Ind. Est, Unit VI Pydibhimavarma (Village) Ranasthalam Mandal, Srikakulam District, India	<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 Related recalls and alerts: <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
Dr. Reddy's Laboratories Unit V Peddadevulapalli, Tripuraram Mandal, Nalgond District, Andhra Pradesh	<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
Dr. Reddy's Laboratories Unit VII Plot No. P1 to P9, Phase III, Duvvada, VSEZ, Visakhapatnam, Andhra Pradesh IN	<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 timeNo further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity General GMP observations
Emcure Pharmaceuticals Limited Plot No. P-1 & P-2,, IT-BT Park Phase II, MIDC, Hinjwadi, Hinjwadi, Pune, Maharashtra INDIA	<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
EVERLIGHT CHEMICALS INDUSTRIAL CORPORATION 12, Industrial Third Rd, Kuanyin Industrial District, Kuanyin Hsiang, Taoyuan Hsien, 32853, Taiwan	<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
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	<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
Granules India Limited Plot No. 160/A, 161/E, 162 & 174/A, Gagillapur Village, Qutbullapur Mandal, Ranga Reddy District, Telangana state, Hyderabad, 500043, India	<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
HEBEI YUXING BIO-ENGINEERING CO. LIMITED Xicheng District, Ningjin county, Ningjin, Hebei China	<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
Hetero Labs Limited Unit V Sy.No.439-441, 458 TSIIC Formulation SEZ Polepally Village, Jadcherla Mandal Mahaboobnagar, Telangana India 509301	<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
Hospira Inc. 1776 North Centennial Drive, McPherson, KS, United States, 67460-9301	<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
Hubei Hongyuan Pharmaceutical Technology Co. Ltd. No. 428 Yishui North Road, Luotian County, Huanggang City, China-438 600, Fengshan Town, Hubei Province	<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
Hubei Hongyuan Pharmaceutical Technology Co. Ltd. No.8 Fengshan Road, Industrial and Economic Development Zone, Luotian County, China 438 600, Huanggang City, Hubei Province	<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 General GMP observations
Ind-Swift Laboratories Limited Barwala Road, Bhagwanpur Village - Derabassi District Mohali, 140 507 Punjab, India	<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)	Data integrity General GMP observations
Indoco Remedies Limited Plants II & III, L-32, 33, 34 Verna Industrial Estate Area, Verna, Goa, India	<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
INTERQUIM, S.A., C/ Joan Buscalla, 10 Sant Cugat del Valles Barcelona, Spain	<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
IPCA Laboratories Ltd. P.O. Box No. 33 Village Sejavta Ratlam, Madya Pradesh, India	<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"> Health Canada requests quarantine of products from IPCA Laboratories following falsification and manipulation of data issues Health Canada puts measures in place for medically necessary products affected by import restriction from 3 facilities in India 	Regulatory Partner(s)	Data integrity General GMP observations
IPCA Laboratories Ltd Plot 65 & 99, Dandudyog Industrial Estate, Piparia, Silvassa, Dadra & Nagar Haveli (U.T.), 396 230, India	<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
IPCA Laboratories Ltd. 1 Pharma Zone, SEZ Phase II, Sector 3, District Dhar, Pithampur, India	<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
Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin Industrial Park, China-330 700, Fengxin, Jiangxi Province	<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

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Jinan Jinda Pharmaceutical Chemistry Co. Ltd. No. 6121 Longquan Road Zhangqiu, Shandong Province 250 20, China	<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)	<ul style="list-style-type: none"> Data integrity General GMP observations
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)	<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
Mahendra Chemicals B-1, 217, 218/2, G.I.D.C. Estate, Naroda Ahmedabad, Gujarat India	<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
Marksans Pharma Limited Plot No. L-82, L-83, Verna Industrial Estate, Verna, Goa- India 403722	<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)	Data integrity General GMP observations
MEGAFINE PHARMA (P) LIMITED 48 - 51/201 Plot No 31 - 35, Lakhmapur, Maharashtra INDIA	<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
Meridian Medical Technologies 2555 Hermelin Dr., Brentwood, MO, 63144, United States	<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
Micro Labs Goa Plot No. S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa India	<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"> Health Canada takes action to restrict import of products from three Micro Labs facilities in India 	Regulatory Partner(s)	Data integrity General GMP observations
Mylan Laboratories Limited F-4 & F-12, Malegaon MIDC, inner, Nashik-422113 India	<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
Novacyl (Thailand) 321 Bangpoo Industrial Estate Praeska, Muang Sanutprakam, 10280 Thailand	<ul style="list-style-type: none"> Canadian importer(s) contacted by Health Canada for information No medically necessary products identified at this time No critical risks identified to date Compliant rating issued No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
Novacyl Wuxi Pharmaceutical Co. Ltd. 8 Guang Shi Xi Road, Wuxi, Jiangsu, 214185, China	<ul style="list-style-type: none"> Canadian importer(s) contacted by Health Canada for information No medically necessary products identified at this time No critical risks identified to date Compliant rating issued No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
Noven Pharmaceuticals Inc. 11960 S.W. 144 Street - Miami, Florida, USA, 33186	<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 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
Pharmaceutics International Inc. 103 Beaver Court, Cockeysville, MD, USA, 210303	<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)	General GMP observations
Polydrug Laboratories Pvt. Ltd. Plot no. 37, Anand Nagar, M.I.D.C., India - 421 506 Ambernath (East), Maharashtra	<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 Related recalls and alerts: <ul style="list-style-type: none"> Health Canada requests quarantine of products imported for Canadian market from Polydrug Laboratories due to data integrity concerns 	Regulatory Partner(s)	Data integrity General GMP observations
Qinhuangdao Zizhu Pharmaceutical Co., Ltd No 10, Longhai Road, Economic & Technological Development Zon, Qinhuangdao, Hebei China	<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
Resonance Laboratories Private Limited No. 8C & 9A, K1ADB Industrial Area, Bashettihalli, Doddaballapur, Bangalore, India 561203	<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
Sage Products Inc. 3909 Three Oaks Road, Cary, Illinois, USA	<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
Sancilio & Company Inc. 3874 Fiscal Ct Ste 200, Riviera Beach Florida, USA, 33404	<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
Sato Kogyo Co., Ltd 9-2, Kannonji-Cho, Kashihara City, Nara Prefecture, Japan	<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
Sekisui Medical Co., Ltd. 4-115 Matsuo, Hachimantai, Iwate Japan	<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 General GMP observations
Shanghai Desano Chemical Pharmaceutical Co., Ltd. No.417 Binhai Road, Laogang Town, Pudong District, Shanghai, China	<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
Sri Krishna Pharmaceuticals Ltd UNIT II A-35, IDA Nacharam Hyderabad 500 076 India	<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 Issued Terms and Conditions to Canadian importer(s) Health Canada on-site inspection [July 11, 2016] Terms and Conditions removed No further action required by Health Canada at this time Related recalls and alerts: <ul style="list-style-type: none"> Health products from Sri Krishna Pharmaceuticals quarantined due to data integrity concerns Release of medically necessary and non-medically necessary products according to terms and conditions 	Regulatory Partner(s)	Data integrity General GMP observations
SmithKline Beecham Limited Clarendon Road, Worthing, West Sussex, England, UK, BN14 8QH	<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)	General GMP observations
Srikem Laboratories Pvt. Ltd. Plot No. 17/24, MIDC Talaja, Navi Mumbai, India	<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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Svizera Laboratories Private Limited Plot D-16/6 TTC Industrial Area, MIDC Turbhe, Navi Mumbai, India	<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 No Canadian importers (s) importing from this facility No further action required by Health Canada at this time 	Regulatory Partner(s) Canadian importer(s)	Data Integrity General GMP observations
Tai Heng Industry Co., Ltd., 2715 Long Wu Road, Building 2, Shanghai Juke Biotech Park, Shanghai, China 200231	<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 General GMP observations
Teva Pharmaceutical and Chemical (Hangzhou) Co. Ltd No 1889 Jingliu Road, Linjiang Industrial Zone, Zhejiang China	<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
UNIMARK REMEDIES LIMITED 337 Kerala Nalsarovar Road, Kerala Village, Bavla, Ahmedabad District 530 049, India	<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 No Canadian importers (s) importing from this facility. No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity
Unimark Remedies Limited (Vapi) Plot 41/42, Phase 1 – GIDC District Valsad Pardi, Gujarat, India	<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) Removed Terms and Conditions from Canadian importer(s) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations
USV Private Limited H-17/H-18, OIDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman	<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 General GMP observations
VUAB PHARMA a.s Vltavska 53, Roztoky, CZECH REPUBLIC	<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 Issued Terms and Conditions to Canadian Importer(s)No further action required by Health Canada at this time 	Regulatory Partner(s)	Data Integrity General GMP observations
Wockhardt Limited Plot No. 138, G.I.D.C, Industrial Estate, District: Bharuch, Ankleshwar, Gujarat, 393002, India	<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 General GMP observations
YUNNAN HANDE BIO-TECH. Co.Ltd No. 3 Platform Jinding Tech-Zone, Kunming, Yunnan Province, China	<ul style="list-style-type: none"> Canadian importer(s) contacted by Health Canada for information Medically necessary products identified No critical risks identified to date 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 General GMP observations
ZHEJIANG HISOAR PHARMACEUTICAL CO. LTD. No. 100 Waisha Branch Rd, Jiaojiang, Taizhou City, Zhejiang Province CN	<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 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
Zhejiang Hisun Pharma Company Ltd. 46 Waisha Road, Jiaojiang District, Taizhou City, Zhejiang, China Binhai Site - Yantou Campus 56 Binhai Road, Jiaojiang District, Taizhou City, Zhejiang, China	<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 for 2 importers • Voluntary quarantine not accepted by 1 importer due to alternate risk mitigation measures being implemented by importer Issued Terms and Conditions to Canadian importer(s) Health Canada on-site inspection [July 18, 2016] • No further action required by Health Canada at this time Related recalls and alerts: <ul style="list-style-type: none"> • <u>Health Canada requests quarantine of products imported for Canadian market from Zhejiang Hisun Pharma due to data integrity concerns</u> 	Regulatory Partner(s) Canadian importer(s)	Data integrity General GMP observations
Zhejiang Hisun Pharmaceutical Co. Ltd. 1 Haizheng Road, Jiaojiang District, Taizhou City, Zhejiang, 9999, China	<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 • Health Canada on-site inspection [May 29, 2017] • No further action required by Health Canada at this time 	Regulatory Partner(s) Canadian importer(s)	Data integrity General GMP observations
Zhejiang Medicine Co. Ltd. Xinchang Pharmaceutical Factory, 98 East Xinchang Dadao Road, Xinchang, Zhejiang, 312500 China	<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) Canadian importer(s)	Data integrity General GMP observations

Date modified:

2018-02-05