

Government of Canada

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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 <u>Recalls & Safety Alerts</u> 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: July 17, 2020

Open Items

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Acharya Chemicals W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India	 Canadian importer 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Akorn Inc. 1222 West Grand Ave Decatur, IL USA, 62522-1412	 Canadian importer 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
Akorn Inc. 72 Veronica Ave, Somerset NJ, 08873, USA	 Canadian importer 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
Cipla Limited Unit IV L-139, S-103 & M-62 Verna Industrial Estate, Verna, Salcette, Goa, 403 722, India	 Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Cipla Limited Unit VIII, S-103 To S-105, S- 107 To S-112, L-147, L-147/1 & L-147/3 (NEW)	 Canadian importer 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
Cipla Limited Unit X, Plot No. L139, S-103, & M-62, Verna Industrial Estate, Verna, Salcette, Goa, 403722, India (NEW)	 Canadian importer 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
Cipla Limited Unit III (Plot No. L-139 to L-146), Verna Industrial Estate, Verna, Salcette, Goa, 403 722, India (NEW)	 Canadian importer 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
CTX Lifesciences Private Ltd. Block No. 251-252 Sachin-Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat, India	 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
Glenmark Pharmaceuticals Limited Village Kishanpura Baddi Nalagarh Road Baddi Solan, Himachal Pradesh, India	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Guangzhou Tinci Materials Technology Co. Ltd. No.8 Kangda Road, Yunpu Industrial Zone, Huangpu Region	 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
LNK International Inc. 22 Arkay Drive, Hauppauge, NY, 11788, United States	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
LNK International Inc. 40 Arkay Drive, Hauppauge, NY, 11788, United States	 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
LNK International Inc. 60 Arkay Drive, Hauppauge, NY, 11788, United States	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
LNK International Inc. 100 Ricefield Lane, Hauppauge, NY, 11788, United States	 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
LNK International Inc. 145 Ricefield Lane, Hauppauge, NY, 11788, United States	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Lupin Limited Unit 1 Unit 1, 198-202 New Ind Area No 2, Mandideep Madhya Pradesh, India	 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
Lupin Limited Unit II Plot No. M-2 & M-2-A, Special Economic Zone Phase II, Misc. Zone, Apparel Park, Pithampur, Dist Dhar, Madhya Pradesh, 454775, India	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Mylan Laboratories Limited Unit 8, G. Chodavaram, POO Sapatirega Mandal, Vizianagaram District, Andhra Pradesh, 535204, India	 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
Pfizer Healthcare India Pvt. Ltd. Plot No. 111 (Part), 116, 117, 118, 119 and 123 (Part), Jawaharlal Nehru Pharma City, Special Economic Zone, Parawada Mandal, India	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Pharmasol Corporation 1 Norfolk Avenue, South Easton, Massachusetts, 02375, United States	 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
Sentiss Pharma Private Limited Village Khera Nihla, Tehsil Nalagarh, Dist: Solan Khera Nihla, Himachal Pradesh 174101, India	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Shandong Xinhua Pharmaceutical Co., Ltd Hutian Chemical Industrial Zone, Zibo, Shandong, 255075, China	 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
Stason Pharmaceuticals Inc. 11 Morgan, Irvine, CA, 92618, United States (NEW)	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Strides Pharma Science Limited Unit-II, R. S. No.: 32, 33 & 34 PIMS Road Periyakalapet, Puducherry	 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
Symbiotec Pharmalab Pvt. Ltd. 385/2 Pigdamber, Near Hotel Mashal, Off A.B. Road, Rau, Indore, Madhya Pradesh, 453331, India	 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

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Teligent Pharma US, LLC 105 Lincoln Avenue, Buena, NJ, 08310, United States	 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
Torrent Pharmaceuticals Limited Ahmedabad-Mehsana Highway, Taluka-Kadi, Indrad, Gujarat	 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
Zhejiang Huahai Pharmaceutical Co., Ltd Chuannan Site Coastal Industrial Zone, Duqiao, Linhai, Zhejiang, 317016, China	 Canadian importer(s) contacted by Health Canada for information Health Canada has completed a GMP assessment and assessed the site as non-compliant. Importers cannot import drugs that contain active pharmaceutical ingredients from this site. Health Canada is continuing to review information as it becomes available. 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
Zhejiang Hisun Pharmaceutical Co., Ltd. 1 Haizheng Road, Jiaojiang District, Taizhou City, Zhejiang, 318 000, China Inspection start date: 2019- 03-26	 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
Zhejiang Hisun Pharmaceutical Co., Ltd. 56 Binhai Road, Jiaojiang District, Taizhou City, Zhejiang, 318 000, China Inspection start date: 2019- 03-26	 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

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Closed Items

		Source of Information	Primary
		under	Reason for
Establishment 🚹 🖶	Status of Issue ↑ ↓	Review 1	Action ↑ ↓

Establishment ↑ ↓	Status of Issue	Source of Information under Review	Primary Reason for Action
Actavis Laboratories, FL. Inc., 4955 Orange Drive, Davie, Fort Lauderdale, Florida, USA, 33314	 Canadian importer 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) No further action required by Health Canada at this time 	• Regulatory Partner(s)	General GMP observations
Agila Onco Therapies Ltd. Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore, Kamataka, India	 Non-compliant rating issued No further action required by Health Canada at this time Related recalls and alerts: 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

Establishment ↑ ↓	Status of Issue	Source of Information under Review	Primary Reason for Action
AGILA SPECIALTIES PRIVATE LTD. Opp II M, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka, India - 560 076	 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

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	 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 nonmedically 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
AllerQuest LLC 10 Farmington Valley Drive, Suite 106 Plainville, Connecticut 06062-1182, United States	 Canadian importer contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) Medically necessary products identified Terms and Conditions applied 	Regulatory Partner(s)	General GMP observations

Establishment 🚹 🖶	Status of Issue	Source of Information under Review	Primary Reason for Action
Amanta Healthcare Ltd. Plot No 876 NH No 8, Hariyala Matar Kheda, Gujarat, 387411, India	 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) 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
Antibioticos do Brasil Rod. Professor Zeferino Vaz, Km135-SP332, Cosmopolis, Sao Paulo, Brazil 13150-000	 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

Establishment 🚹 🖶	Status of Issue	Source of Information under Review	Primary Reason for Action
Anuh Pharma Ltd E-17/3 & E 17/4 M.I.D.C. Tarapur, Taluka Palghar, District Thane, India-401 506 Boisar, Maharashtra	 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
Apotex Pharmachem India Private Limited (APIPL) Plot No. 1A, Bommasandra Industrial Area, 4th Phase, Jigani Link Road, Bangalore, Karnataka, India	 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 	Health Canada Regulatory Partner(s)	Data integrity General GMP observations

Establishment 🚹 🖶	Status of Issue	Source of Information under Review	Primary Reason for Action
	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.		
	 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) 		

Establishment 🚹 🖶	Status of Issue	Source of Information under Review	Primary Reason for Action
	 Expanded recall of Apo-Candesartan Health Canada puts in place new oversight of Apotex Inc. imports from APIPL and ARPL Summary Report 		
	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.		
Apotex Research Private Limited (ARPL) Plot No. 1 and No. 2, Bommasandra Industrial Area, 4th Phase, Jigani Link Road, Bangalore, India	 Voluntary quarantine was in place until further assessment was completed Import restrictions imposed On September 30, 2014, issued Terms 	Health Canada Regulatory Partner(s)	Data integrity General GMP observations

Establishment ↑↓	Status of Issue	Source of Information under Review	Primary Reason for Action
	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 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.		

Establishment	Status of Issue ↑↓	Source of Information under Review	Primary Reason for Action
	 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 Recall of Apo-Candesartan Health Canada puts in place new oversight of Apotex Inc. imports from APIPL and ARPL Summary Report March 14, 2016: Health Canada issued a new decision which imposed no terms and conditions 		

Establishment 🚹 🖶	Status of Issue	Source of Information under Review	Primary Reason for Action
	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.		

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2020-07-17