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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: **July 24, 2019**

Open Items

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	<ul style="list-style-type: none"> • 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. 1222 West Grand Ave Decatur, IL USA, 62522-1412	<ul style="list-style-type: none"> • 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
<p>Akorn Inc. New 72 Veronica Ave, Somerset NJ, 08873, USA</p>	<ul style="list-style-type: none"> • 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
<p>Aurobindo Pharma Ltd, Unit 11, Pydibhimavaram, Ranasthalam (Mandal), Srikakulam District, AP, 532409, India</p>	<ul style="list-style-type: none"> • 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
<p>Hetero Labs Ltd. Unit I Survey No 10 I.D.A., Gaddapotharam Village, Jinnaram Mandal, 502 319, Medak District, Telangana, India</p>	<ul style="list-style-type: none"> • Canadian importer(s) contacted by Health Canada for information • Health Canada has completed a GMP assessment and assessed the site as non-compliant. • Medically necessary products identified. • Importers cannot import active pharmaceutical ingredients or drug products that contain active pharmaceutical ingredients from this site. • Health Canada is continuing to review information as it becomes available 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<p>Jubilant Generics Limited (Roorkee) Village Sikandarpur Bhainswal, Roorkee Dehradun Highway, Bhagwanpur, Roorkee District Haridwar, Uttarakhand, 247 661, 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 <p>New</p>	Regulatory Partner(s)	General GMP observations
<p>Laboratoires Clarins New 5 rue Ampère, Pontoise, 95300, France</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>Pharmasol Corporation New 1 Norfolk Avenue, South Easton, Massachusetts, 02375, 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) 	Regulatory Partner(s)	General GMP observations

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
Vital Laboratories Pvt Ltd (Plant I) 1416-21, 1507 1 and 2 Phase III GIDC, Vapi, 396195, 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
Zhejiang Huahai Pharmaceutical Co., Ltd. - Chuannan Site Coastal Industrial Zone, Duqiao, Linhai, Zhejiang, 317016, China	<ul style="list-style-type: none"> • 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

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Closed Items

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>

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

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

Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
<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) 	Health Canada Regulatory Partner(s)	Data integrity General GMP observations

Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
	<ul style="list-style-type: none"> • 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</u> 		

Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
	<p><u>restriction from 3 facilities in India</u></p> <ul style="list-style-type: none"> • <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 Area, 4th</p>	<ul style="list-style-type: none"> • Voluntary quarantine was in place until further assessment was completed 	Health Canada Regulatory Partner(s)	Data integrity General GMP observations

Phase, Jigani Link Road, Bangalore, India Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
	<ul style="list-style-type: none"> • 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 of statements and declared amended</u> 		

Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
	<p><u>terms and conditions on Apotex's Establishment Licence unlawful.</u></p> <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</u> 		

Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
	<p><u>Inc. imports from APIPL and ARPL</u></p> <ul style="list-style-type: none"> • <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>		

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"> • 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>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

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Baxter HealthCare Corp Jayuya Plant, 250 State, Road 144, Jayuya, PR, 664, United States	<ul style="list-style-type: none"> • Canadian importer 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

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