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December 20, 2013

## Notice

Our file number: 13-119778-430

### *Prescription Drug List (PDL): Multiple Additions*

The purpose of this Notice of Amendment is to notify the addition of more than 120 drugs on the Prescription Drug List (PDL). With coming into force of the regulations to establish the PDL (*Regulations Amending Certain Regulations Concerning Prescription Drugs (Repeal of Schedule F to the Food and Drug Regulations)*) on December 19, 2013, Health Canada is now revising, effective immediately, the PDL. The drug and supporting qualifier in italics are the additions to the PDL.

The following drugs have been added to both the Human and Veterinary lists as single medicinal ingredients:

- *Aflibercept*
- *Belimumab*
- *Brentuximab vedotin*
- *Canakinumab*
- *Catumaxomab*
- *Certolizumab pegol*
- *Clofarabine*
- *Denosumab*
- *Dimethylfumarate*
- *Dirlotapide*
- *Efinaconazole*
- *Enzalutamide*
- *Eplerenone*
- *Firocoxib*
- *Galsulfase*
- *Gamithromycin*
- *Ibafloxacin*
- *Idebenone*
- *Idursulfase*
- *Ipilimumab*
- *Ocriplasmin*

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- *Ofatumumab*
- *Perampanel*
- *Pertuzumab*
- *Remestemcel-L*
- *Romidepsin*
- *Sevoflurane*
- *Spinosyn A and D isoforms*
- *Stiripentol*
- *Tocilizumab*
- *Trastuzumab emtansine*
- *Urokinase*
- *Velaglucerase Alfa*
- *Vismodegib*
- *Zucapsaicin*

The following drugs have been added to both the Human and Veterinary lists as medicinal ingredients along with their salts (for example, *Aclidinium or its salts* or *Colesevelam or its salts* and *Colesevelam hydrochloride* will appear in the including (but not limited to) column):

- *Aclidinium*
- *Afatinib*
- *Aripiprazole*
- *Besifloxacin*
- *Clevidipine*
- *Colesevelam* including but not limited to *Colesevelam hydrochloride*
- *Dabrafenib*
- *Desvenlafaxine* including but not limited to *Desvenlafaxine succinate*
- *Dolutegravir*
- *Eltrombopag* including but not limited to *Eltrombopag olamine*
- *Emamectin* including but not limited to *Emamectin benzoate*
- *Exenatide*
- *Fesoterodine* including but not limited to *Fesoterodine fumarate*
- *Glycopyrrolate* including but not limited to *Glycopyrronium bromide*
- *Imidapril*
- *Liraglutide*
- *Lurasidone*
- *Maropitant*
- *Mirabegron*
- *Nesiritide*
- *Olodaterol*

- *Palonosetron* including but not limited to *Palonosetron hydrochloride*
- *Pasireotide*
- *Pazopanib*
- *Plerixafor*
- *Prasugrel*
- *Prucalopride* including but not limited to *Prucalopride succinate*
- *Regorafenib*
- *Robenacoxib*
- *Ruxolitinib* including but not limited to *Ruxolitinib phosphate*
- *Sapropterin*
- *Saxagliptin*
- *Simeprevir*
- *Toceranib*
- *Tramadol*
- *Vilanterol* including but not limited to *Vilanterol trifenate*
- *Zolmitriptan*

The following drugs have been added to both the Human and Veterinary lists as medicinal ingredients along with their derivatives (for example, *Abiraterone* or its derivatives):

- *Abiraterone*
- *Apixaban*
- *Boceprevir*
- *Fidaxomicin*
- *Ingenol mebutate*
- *Ivacaftor*
- *Lacosamide*
- *Macitentan*
- *Pirfenidone*
- *Riociguat*
- *Rufinamide*
- *Telaprevir*
- *Tepoxalin*
- *Ticagrelor*
- *Tolvaptan*
- *Trametinib* including but not limited to *Trametinib dimethylsulfoxide*

The following drugs have been added to both the Human and Veterinary lists as medicinal ingredients along with their salts or derivatives (for example, *Alitretinoin or its salts or derivatives*):

- *Alitretinoin*
- *Alogliptin*
- *Asenapine* including but not limited to *Asenapine maleate*
- *Axitinib*
- *Azacitidine*
- *Azilsartan medoxomil*
- *Bendamustine* including but not limited to *Bendamustine hydrochloride*
- *Crizotinib*
- *Degarelix*
- *Eribulin* including but not limited to *Eribulin mesylate*
- *Ezogabine*
- *Fampridine*
- *Febuxostat*
- *Fingolimod* including but not limited to *Fingolimod hydrochloride*
- *Guanfacine*
- *Indacaterol*
- *Linaclotide*
- *Leflunomide* including but not limited to *Teriflunomide*
- *Linagliptin*
- *Moclobemide*
- *Nebivolol*
- *Rifaximin*
- *Rilpivirine* including but not limited to *Rilpivirine hydrochloride*
- *Roflumilast*
- *Rotigotine*
- *Silodosin*
- *Toltrazuril* including but not limited to *Ponazuril*
- *Trabectedin*
- *Triptorelin*
- *Ulipristal* including but not limited to *Ulipristal acetate*
- *Vandetanib*
- *Vemurafenib*

The following drugs have been added to only the Human list:

- *Avermectin or its derivatives* including but not limited to *Ivermectin, Selamectin, Doramectin*
- *Diffloprednate* as an adrenocortical hormone derivative
- *Doxycycline monohydrate* as a salt of doxycycline
- *Tulathromycin* as a derivative of erythromycin
- *Permethrin or its derivatives*
- *Phenylpropanolamine or its salts or derivatives*
- *Podophyllotoxin when recommended for topical use*

The following drugs have been added to only the Veterinary list:

- *Avermectin or its derivatives, including but not limited to Ivermectin, Selamectin, Doramectin, with the qualifier Ivermectin when recommended for intramuscular injection for horses, or for oral administration to dogs and cats; except doramectin*
- *Azithromycin or its salts or derivatives*
- *Desoxycorticosterone pivalate*
- *Diffloprednate*
- *Doxycycline or its salts or derivatives, including but not limited to Doxycycline hyclate, Doxycycline monohydrate, when recommended for intramuscular injection for caged birds or for subgingival administration to dogs*
- *Gonadotropin releasing factors or their analogues*
- *Hydrocortisone aceponate*
- *Hyoscine butylbromide when recommended for parenteral use*
- *Mebendazole when sold to treat dogs only*
- *Permethrin or its derivatives when recommended for use in cats*
- *Polysulfated glycosaminoglycan*
- *Progesterone or its derivatives, except when recommended for use in Progesterone implants indicated for growth promotion, or when recommended for use as Melengestrol acetate in feed for the suppression of estrus in beef heifers*
- *Tulathromycin*

The following drugs are added to both lists with a qualifier:

- *Acetaminophen when recommended for administration by intravenous injection*
- *Collagenase when recommended for the debridement of severe burns and skin ulcers*
- *Hydroxocobalamin or its salts when recommended as an antidote for cyanide poisoning*
- *Immunogenic substances including but not limited to *Dactylis glomerata* L. (cocksfoot), *Anthoxanthium odoratum* L. (sweet vernal grass), *Lolium perenne* L. (rye grass), *Poa pratense* L. (meadow grass), *Phleum pratense* L. (timothy grass) when recommended for sublingual use*
- *Potassium Citrate when recommended for the treatment of renal tubular acidosis and kidney stones*

The following drugs were previously captured under a general heading on both lists but are being added to the including (but not limited to) column:

- *Alprostadil, Travoprost* as derivatives of prostaglandins
- *Benazepril hydrochloride* as a salt of benazepril
- *Candesartan cilexetil* as a derivative of candesartan
- *Cefuroxime, Ceftazidime* as derivatives of Cephalosporin C
- *Divalproex sodium* as a salt of Valproic acid
- *Dronedarone* as a derivative of amiodarone
- *Ferumoxytol* as an iron derivative
- *Fosaprepitant* as a derivative of aprepitant
- *Levofloxacin* as a derivative of Ofloxacin
- *Levothyroxine sodium* as a salt of thyroxin
- *Mesalazine* as a derivative of 5-Aminosalicylic Acid
- *Netilmicin* as a derivative of gentamicin

**Rationale:**

A scientific review of these drugs against the former factors for listing drugs in Schedule F indicates they meet one or more of these factors and should only be available through a prescription.

While the drugs contained in this Notice were assessed against the factors for listing on Schedule F, future amendments to the PDL will be based on the criteria set out in C.01.040.3 of the *Food and Drug Regulations*. These criteria encompass and will now replace the Schedule F factors, which Health Canada has used for the past 20 years, when making decisions regarding prescription status. Additional information on how Health Canada now determines prescription

status (or non-prescription status) is available in the *Guidance Document: Determining Prescription Status for Human and Veterinary Drugs*.

Should you have any questions on these amendments to the Prescription Drug List please contact:

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