



## Notice

Our file number: 14-101822-970

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

The purpose of this Notice of Amendment is to notify the addition of eight drugs to both the Human and Veterinary Prescription Drug List (PDL). The drug and supporting qualifier in italics are the additions to both the human and veterinary PDL.

*Dibotermine alfa (Veterinary PDL only);*

*Lidocaine when in a preparation containing an equal amount of Tetracaine and recommended for topical use on the skin, in concentrations of 7% or higher;*

*Lomitapide or its salts;*

*Mitratape;*

*Pomalidomide or its salts;*

*Sofosbuvir or its salts;*

*Tetracaine when in a preparation containing an equal amount of Lidocaine and recommended for topical use on the skin, in concentrations of 7% or higher;*

*Umeclidinium or its salts or derivatives.*

### **Rationale:**

A scientific review of these drugs against the former factors for listing drugs in Schedule F ([http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/schf\\_annf\\_fact\\_pol-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/schf_annf_fact_pol-eng.php)) 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* ([http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl\\_gd\\_ord\\_ld-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_gd_ord_ld-eng.php)).

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

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