

## ***Do you import Active Pharmaceutical Ingredients that may be used in veterinary drugs?***

## ***Are you a pharmacist or veterinarian who compounds antimicrobial drugs on [List A](#) for animals?***

If so, **regulatory changes to the [Food and Drug Regulations](#) coming into force** may affect you.

May 2018:

- You may need to be inspected by Health Canada.
- You may need to comply with Good Manufacturing Practices (GMP).
- You may need a Drug Establishment Licence (DEL).

March 31, 2019:

- If you are a manufacturer, importer or compounder of antimicrobial drugs for veterinary use that contain an active pharmaceutical ingredient on List A, you will need to [report annual sales data to Health Canada](#). This means you will need to collect data throughout 2018 and report by March 31, 2019.

### **Contact Health Canada today and stay informed!**

You will find additional information on these new rules on the [Canada.ca](#) page. [GMP](#) and [DEL](#) guidance documents for human active pharmaceutical ingredients (APIs) can be applied to veterinary APIs and are being updated as needed.

Health Canada will be offering webinars in French and English in February 2018. To receive important updates by email, including invitations to the upcoming webinars, send an email to [DEL\\_Questions\\_LEPPP@HC-SC.GC.CA](mailto:DEL_Questions_LEPPP@HC-SC.GC.CA) using the subject line "AMR Info Request".

#### **WEBINAR DATES:**

**February 13, 2018** – "Session 1: A introduction to the new requirements under the Food and Drug Regulations affecting all health care practitioners who compound veterinary API" – A session for those who want to confirm that the activities they conduct require a DEL under the new rules, as well as to receive information on the sales reporting rules.

**French - 10:30 AM to 11:30 AM (EST)**

**English - 1:30 PM to 2:30 PM (EST)**

**February 15, 2018** – "Session 2: How to submit an application or an amendment to a Drug Establishment Licence veterinary active pharmaceutical ingredients" – A session for those who are applying for a DEL for the first time or who are amending their current DEL to be in compliance with new rules, as well as to receive information on the sales reporting rules.

**French - 10:30 AM to 12:00 PM (EST)**

**English - 1:30 PM to 3:00 PM (EST)**