

Veterinary Oversight of Medically Important Antimicrobials

Prepared by Jean Szkotnicki

President, Canadian Animal Health Institute



Topics for Discussion

1. Medically Important Antimicrobials
2. Regulatory Changes (red titles)
3. Policy Changes (blue titles)
4. Changes as of December 1 – move from over the counter to prescription status for MIA
5. Discussion

Medically Important Antimicrobials (MIA)

- Categorized based on a importance in human medicine – preferred drug for treatment of serious infections and whether there are alternatives to treat a disease
- List A identifies the antimicrobials
- MIA – include Categories I, II and III
- Category IV are antimicrobials not important in human medicine and not associated with AMR e.g. ionophores

Own Use Importation

- New regulation allows for import of 90-day supply of a product based on label use
- Antimicrobials exempt from the program
- List B – identifies the products that can be imported by an animal owner
- Product cannot be resold

Oversight on Quality of Veterinary APIs

- Pharmacists or veterinarians or those compounding a drug under supervision of a licensed veterinarian must hold a DEL when importing MIA's (List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients)
- Producers cannot import MIA APIs for direct use in food animals



New Pathway for Veterinary Health Products (VHP) – November 13, 2017

- List C: permitted active homeopathic and traditional medicines substances used to make a VHP inclusive of important conditions such as; route of administration, species, mandatory label statements & qualifiers.
- New rules are founded on the success of the Interim Low Risk Program and will apply to both companion & food animals
- VHP's to be notified to Health Canada;
 - 30 days before selling a VHP for the 1st time
 - 30 days before making a change to an already notified VHP
 - Before importing a VHP to Canada

Website Information on List A, B & C

- **List A: Medically Important Antimicrobial (Category I, II and III)**

<https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/lists-incorporated-by-reference/about-list-a.html>

- **List B: Own Use Importation Eligible Products**

<https://canada-preview.adobecqms.net/en/public-health/services/antibiotic-antimicrobial-resistance/animals/personal-importation-certain-drugs-food-producing-animals/list-b.html>

- **List C: Veterinary Health Products (Low Risk)**

<https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-health-products/list-c.html>

- **New Substance Application also permitted**

Reporting of Veterinary Antimicrobial Sales Volumes

- By end of March 31st sales volumes by species must be reported for the previous calendar year
- What is to be reported?
 - Quantity sold or compounded of List A products used in veterinary medicine
 - Approximate quantity sold or compounded for each intended species

Prudent Use & Growth Promotion Claims

- Phase out of the non-therapeutic purposes such as growth & weight gain
- No GP claims approved since 2004 for MIA
- About 65 products are implicated
- Labels of all in-feed & in-water MIA's to include responsible use statements

New Prudent Use Statements

- **In-Feed**

- *“To reduce the development of drug-resistant bacteria & maintain effectiveness, use this antibiotic prudently.”*

- **In-Feed & In-Water with undefined duration for use**

- *“To reduce the development of drug-resistant bacteria & maintain effectiveness, use this antibiotic prudently & for the shortest duration required to achieve the desired clinical outcome.”*

Increasing Veterinary Oversight

- All MIA to have prescription status (via the Prescription Drug List) since supervision by licensed veterinarians in treatment decisions is an important part of antimicrobial stewardship
- Veterinary, Client, Patient Relationship (VCPR) a requirement of veterinary licensing bodies (knowledge of animals, management & ability to provide services)
- In-Feed MIA to be included in the Compendium of Medicating Ingredients Brochure
- About 340+ products implicated in all dosage forms (75 in-feed MIA's)

MIA Implicated in Switch from OTC TO PR

- Apramycin
- Bacitracin
- Erythromycin
- Lincomycin
- Neomycin
- Penicillin G
- Spectinomycin
- Streptomycin/Dihydrostreptomycin
- Sulphonamides
- Tetracycline/Chlortetracycline/Oxytetracycline
- Tilmicosin
- Tiamulin
- Tylosin/Tylvalosin
- Virginiamycin
- Or their salts or derivatives



Poultry

Pigs

Sheep

Dairy Cattle

Goats

Horses

Fish &
Shellfish

Fur Species

Antimicrobials Requiring a Veterinary Prescription

as of December 1, 2018

the antimicrobial categorizations determined by Health Canada in relation to their importance to human

	Licensed Drug	Brand Names				
	Ceftiofur	No change. These products already require a veterinary prescription. Includes products such as:				
	Danofloxacin					
of ns ited	Enrofloxacin	Baytril	Excenel	Ceftiofur	Spectramast	Special Formu
	Polymixin B					

Terminology is Important

- **Drug premix** is defined in the Food and Drug Regulations [C.01A.001] – it means a drug for veterinary use to which a drug identification number (DIN) has been assigned, where the directions on its label specify that it is to be mixed with feed.
- **Wholesaler** is defined in the Food and Drug Regulations [C.01A.001] – it means a person who **sells** a prescription drug other than at retail sale.
- **Wholesale druggist** does not have a regulatory definition. Health Canada's definition of a wholesale druggist includes wholesalers and commercial feed mills (who may access DIN drug premixes to support their operations).
- **Commercial feed mill** does not currently have a regulatory definition. Health Canada defines a commercial feed mill as a wholesale druggist and is a facility that mixes and manufactures feed for commercial sale in accordance with the Feeds Act and Regulations.
- **Retail stores** include facilities such as livestock medicine outlets, farm supply stores or feed stores – it does not include pharmacies or veterinary clinics.
- **Dispensing** is the provision of a drug as set out properly on a lawful prescription

Terminology is Important

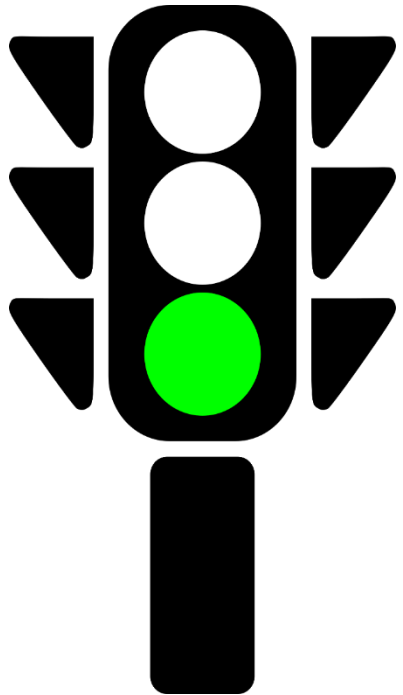
Commercial Feedmill Extensions

- **Cross Docking** – facilitates the sale of feed (including prescription medicated feed) by providing storage and delivery services between the commercial feedmill and the end user of producer. Particularly important in remoted locations.
- **Toll Manufacturing** – is the manufacturing of a feed (including prescription medicated feed) that is contracted out from the commercial feedmill (who received the order) to another separate facility . This helps when there is a capacity challenge or need for special equipment.

Prescription Drug Access as of December 1st , 2018

In-Feed Prescription Products

COMMERCIAL FEEDMILLS

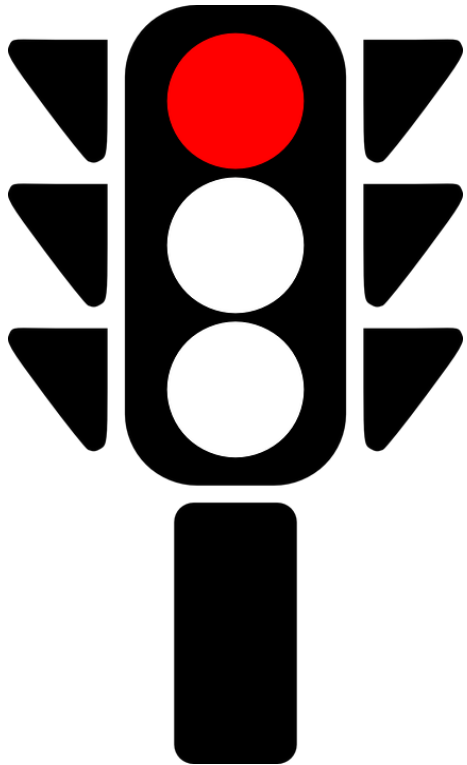


- can purchase prescription DIN Drug Premix for manufacture of medicated feed (complete feed, supplement, macro and micro premix)
- can manufacture and floor stock a prescription medicated feed as per the CMIB prior to a veterinary feed prescription being on file
- must ensure a Veterinary Feed Prescription is in hand before sale of the medicated feed to an end-user

Prescription Drug Access as of December 1st , 2018

In-Feed Prescription Products

COMMERCIAL FEEDMILLS

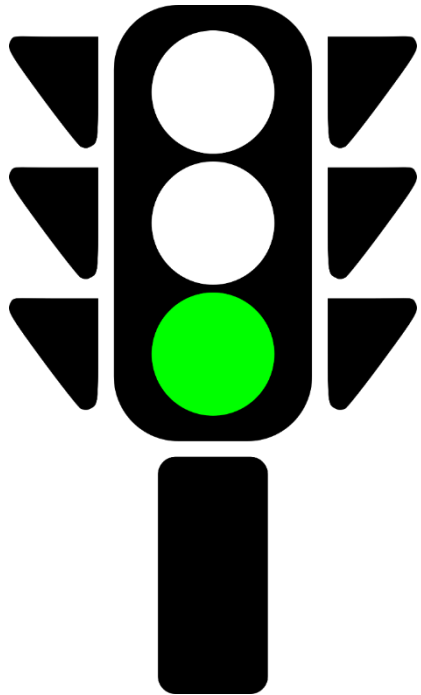


- cannot floor stock prescription medicated feeds that are off-label e.g. not as per the CMIB
- cannot sell a DIN Drug Premix to an end user unless otherwise authorized under provincial law (e.g. Quebec)

Prescription Drug Access as of December 1st , 2018

In-Feed Prescription Products

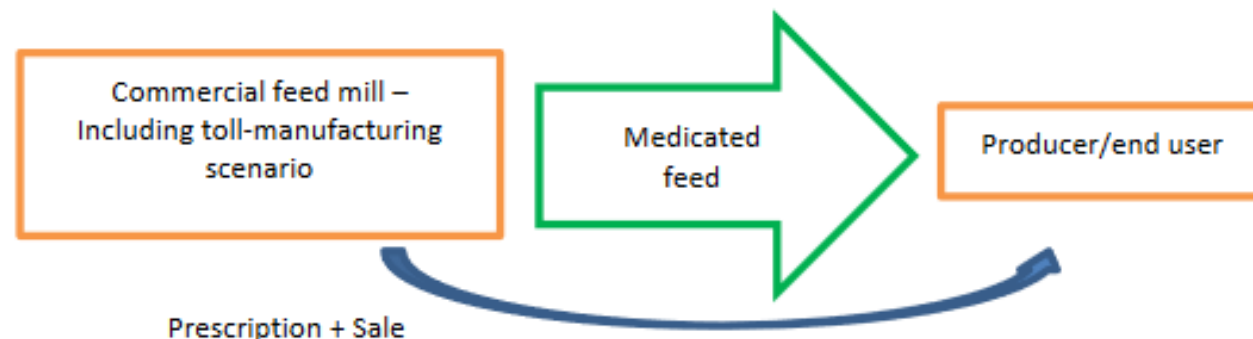
RETAIL STORES



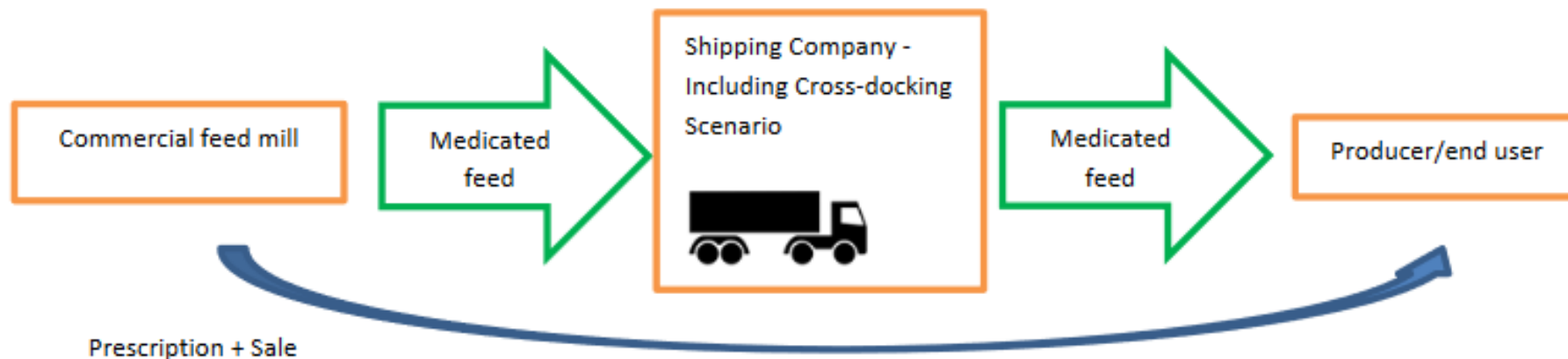
- can sell a prescription medicated feed to an end-user unless otherwise authorized under provincial law (e.g. Quebec)
- can purchase or sell a DIN Drug Premix to an end-user unless otherwise authorized under provincial law (e.g. Quebec)

CURRENT PATHWAYS AND CONDITIONS FOR SELLING PRESCRIPTION MEDICATED FEED**

Pathway 1: Direct sales between a CFM and producer



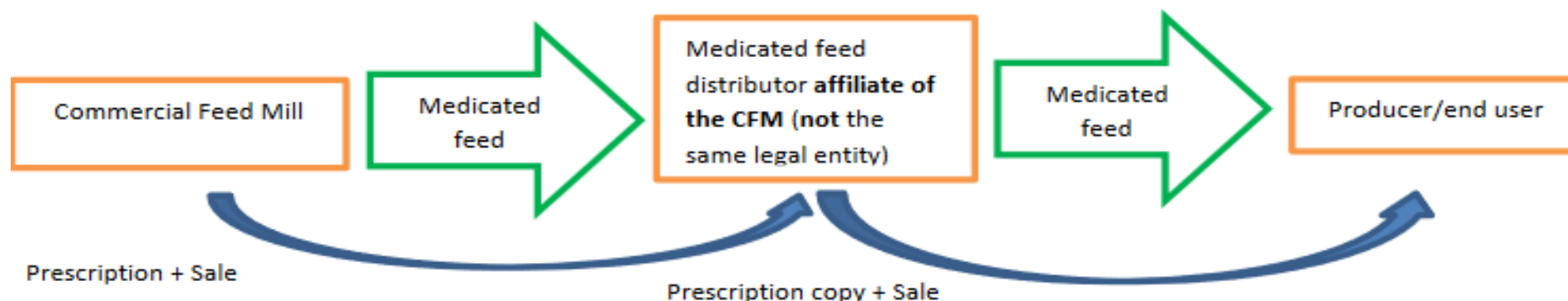
Pathway 2: Sales that are facilitated by a shipping company



Pathway 3: Sales that are facilitated from a CFM by another facility that is the same legal entity as the CFM



Pathway 4: Sales that are facilitated from a CFM by a third party distributor

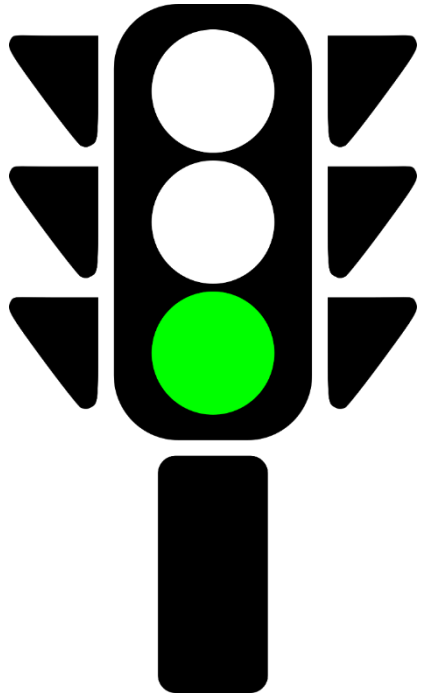


****It is important to note that these pathways have not changed, they are simply now applicable to a wider range of in feed medications that have been given prescription status.***

Prescription Drug Access as of December 1st , 2018

In-Feed Prescription Products

VETERINARIANS AND PHARMACISTS

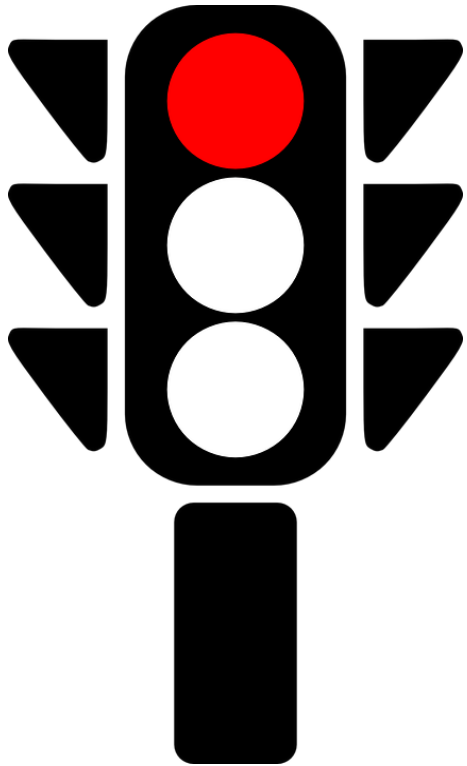


- can purchase DIN Drug Premixes and sell to an end-user with a veterinary prescription

Prescription Drug Access as of December 1st , 2018

Other Pr Products including Water Solubles & Injectables

COMMERCIAL FEEDMILLS

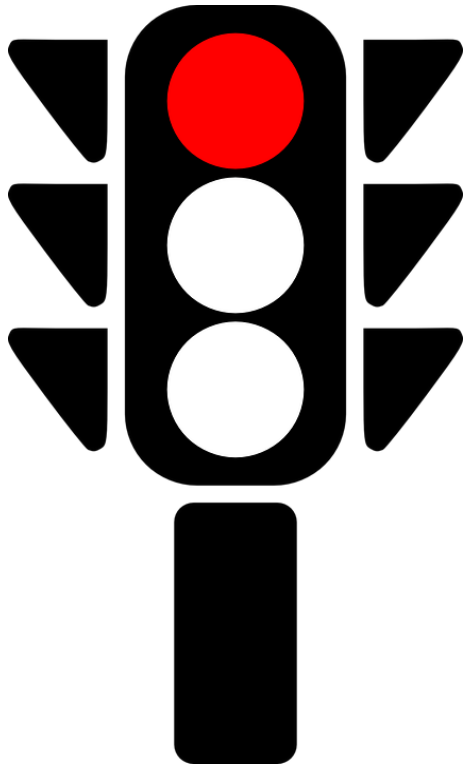


- cannot purchase or dispense any Prescription drugs to an end-user unless otherwise authorized under provincial law (e.g. Quebec)

Prescription Drug Access as of December 1st , 2018

Other Pr Products including Water Solubles & Injectables

RETAIL STORES

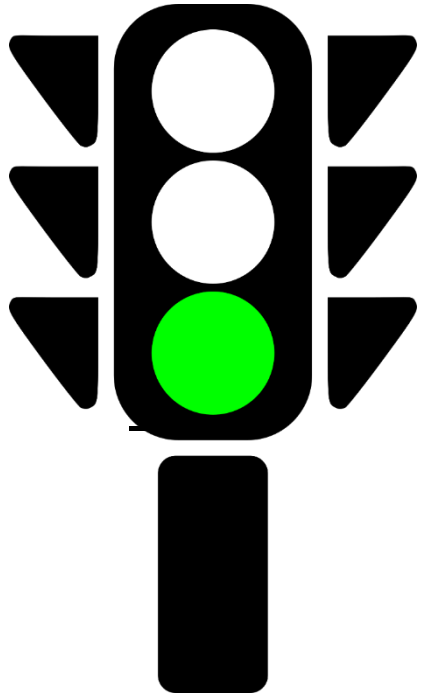


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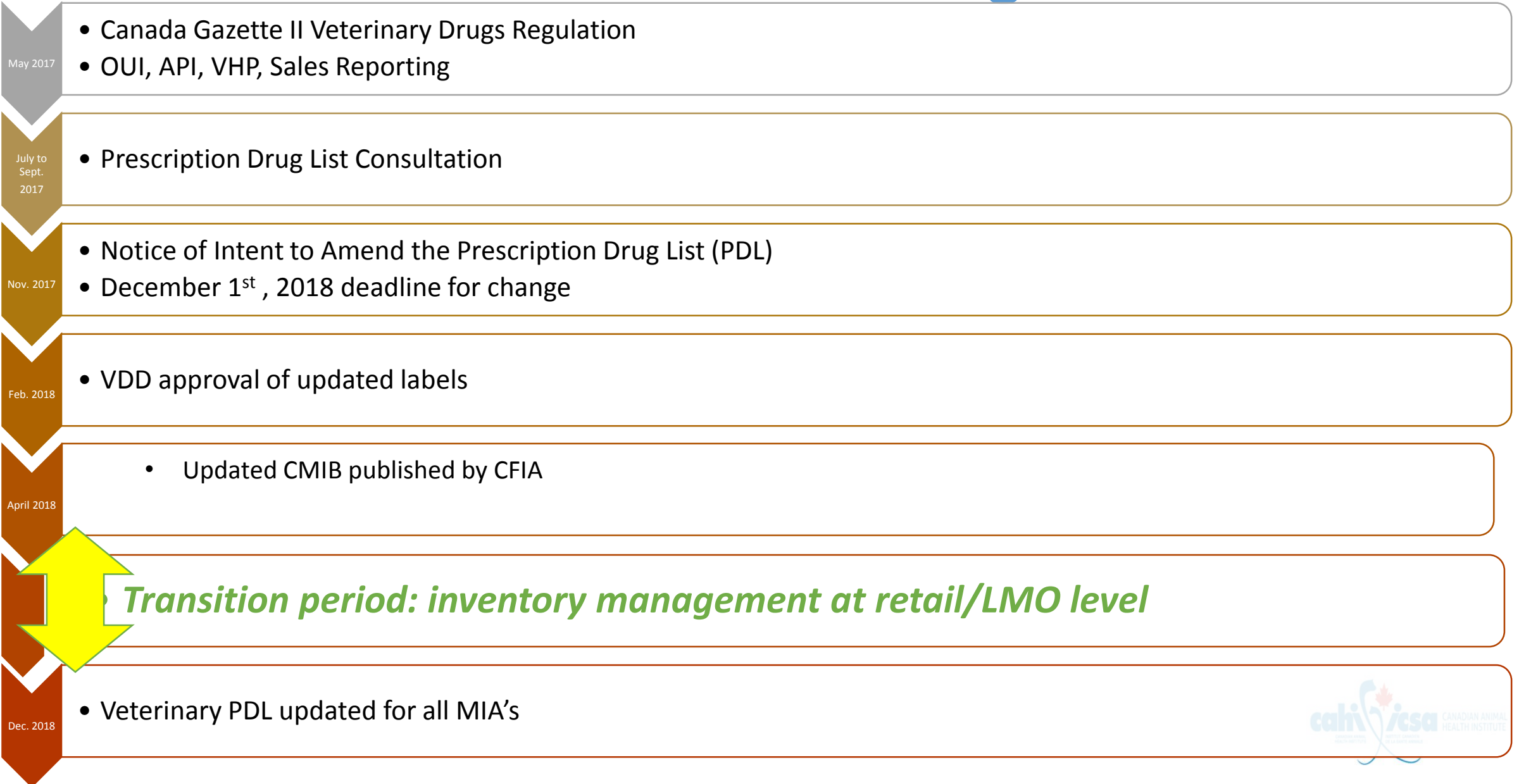
Other Pr Products including Water Solubles & Injectables

VETERINARIANS AND PHARMACISTS



- can purchase and dispense these prescription drugs to end-users with a veterinary prescription
- must be prescribed by a veterinarian under a Veterinary Client Patient Relationship

Timelines for Change



Is the future antibiotic free production?

- Prevention and good biosecurity are not enough
- Diseases will not disappear

3 in 4 cattle have respiratory disease

9 in 10 chickens exposed to coccidiosis

1 in 3 pig herds experience ileitis

1 in 4 cows face mastitis

