Workshop session 2

– Legislation and guidance –

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5th Global Animal Health Conference and Workshop 2016

Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

Organising Committee:

NVAL

MAFF
Ministry of Agriculture, Forestry and Fisheries

1. Legislation (Act/Ordinance/Notice)

Structure, development and revision;

Difference between regulations and guidelines (GLs)

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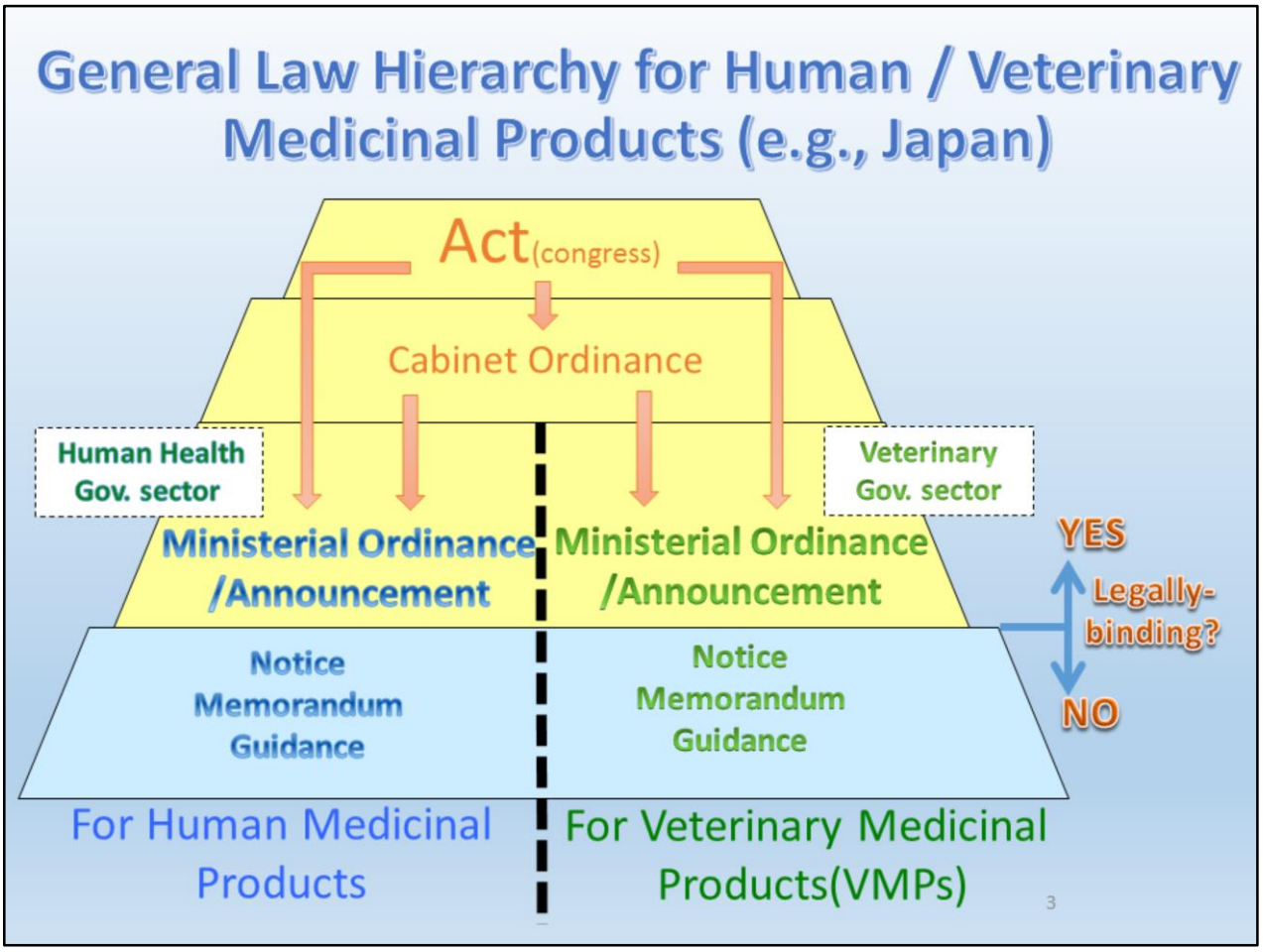
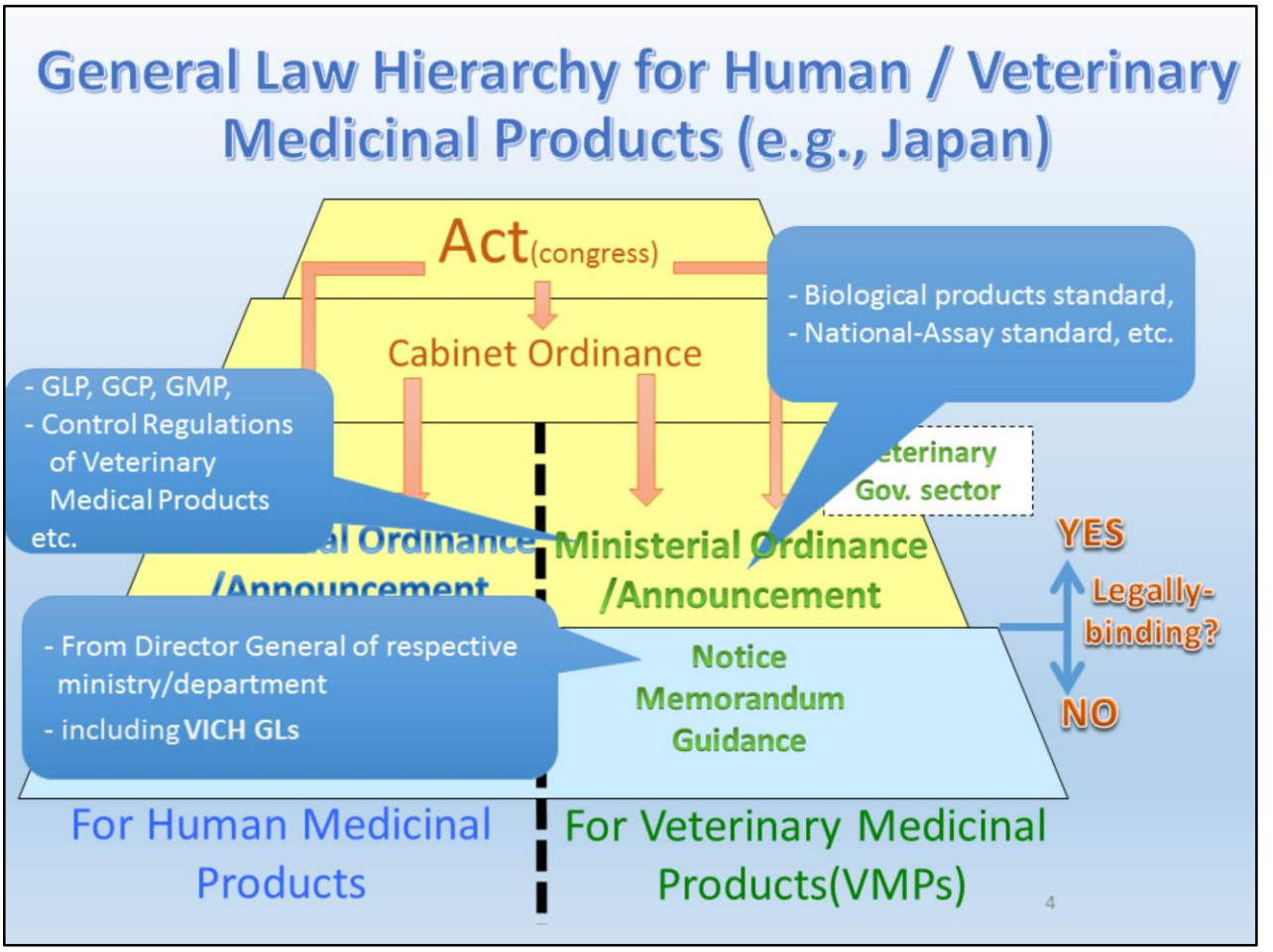


All medicinal products (for human and veterinary use) are regulated under the single Pharmaceutical Act.

The Act and the subsequent Cabinet Ordinance provide higher rules applicable for both human and veterinary medicinal products, and delegate to human health or veterinary government sector for detailed regulatory rules (Ministerial Ordinance/Announcement).

Each sector communicates with respective stakeholders on the operational or technical aspects, employing “Notice/Memorandum/Guidance” which are legally non-binding (soft law).

[definition]
Legally-binding : things or matter that is restricted by law in the respective country



- Good Laboratory Practice (GLP)
- Good Clinical Practice (GCP)
- Good Manufacturing Practice(GMP)

Issues to be discussed in this part

- Ideally, Agricultural/Veterinary government sector should regulate VMPs.
- However, in many countries, human medicine sector also regulates VMPs.

- What is your current situation?
- Do you know the different actors involved in elaboration of regulation in your country ?

Notes

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail
Connaître, évaluer, protéger

2. International standards (OIE, Codex, PIC/S)

codes and guidelines;

what is their relation with regional or national regulation?

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“One World, One Health” Concept

The “ONE HEALTH” concept ensures **political support in coordinated prevention** of high public health and animal impact diseases **at the human-animal interface**

➢The VMPs policy is part of the animal health policy :
Vet Drugs shall be sure, secure and efficient

- To protect **Animal health**
- To protect **Human Health** (residue, zoonosis, AMR)
- For **Environmental safety**

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The solution

- A holistic and coordinated management across the animal, food and human sectors
- Improved intersectoral collaboration where regulations of medicines are managed by different entities

What do we need?

- International standards (to harmonise protocols and methodologies)
- Legislation on access to quality drugs and restricted use
- Good governance of all sectors related to authorisation and use of VMPs

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What do we need?

- International standards (to harmonise protocols and methodologies)
- Legislation on access to quality drugs and restricted use
- Good governance of all sectors related to authorisation and use of VMPs
    - E.g. lab expertise, international standards and legislation development and implementation, surveillance and control

Major International Standards for VMPs

- OIE standards for a **good governance** of VMPs:
  - Specific part of terrestrial code concerning VMPs legislation,
  - Standards for Antimicrobial resistance
  - Standards for manufacturing and quality control
- OIE **specific program**: OIE PVS pathway for capacity building

⇨ *OIE standards*

- CODEX international **food safety standards**, guidelines and related texts such as;
  - Maximum residue limits (MRLs) of veterinary drugs
  - Codes of practice to protect consumers and ensure fair practices in the food trade

⇨ *Codex food standards*

Both OIE standards and Codex food standards are recognized by ***WTO as references for international trade***

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Major International Standards for VMPs

OIE

- OIE develops different standards for a **good governance** of VMPs :
  - Specific part of terrestrial code concerning VMPs legislation (chap.3.4.11),
  - Standards for Antimicrobial resistance
  - Standards for manufacturing and quality control
- OIE develops a **specific program** : OIE PVS pathway for capacity building (PVS evaluation, PVS Gap analysis and veterinary legislation audit …)

⇨ *OIE standards*

CODEX

- Develops international **food safety standards**, guidelines and related texts such as;
  Maximum residue limits (MRLs) of veterinary drugs in foodstuffs from animal origin
  Codes of practice to protect consumers and ensure fair practices in the food trade

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Issues to be discussed in this part

- Are international standards included in your national regulation ?
- How do you implement international standards ?
- Do you participate to elaboration of international standards ?

Notes

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3. Guidelines(VICH, OECD, Local)

What can they provide?
where can they be found?

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Notes

Guidelines contribute to faster development and approval of new VMPs

Issues on development	GLs
• Difficult to assess the efficacy due to new mechanism of action	• Show assessment index for efficacy
• Quality /stability evaluation methodology unknown due to new physicochemical characteristics	• Show method for establishing specification / stability

For Applicant: Encourage new research & development by reducing time, costs & animal testings

For Regulators: Shorten reviewing period

Ensure product quality, safety and efficacy

Increase options for veterinary services

Improve animal/public health and food safety

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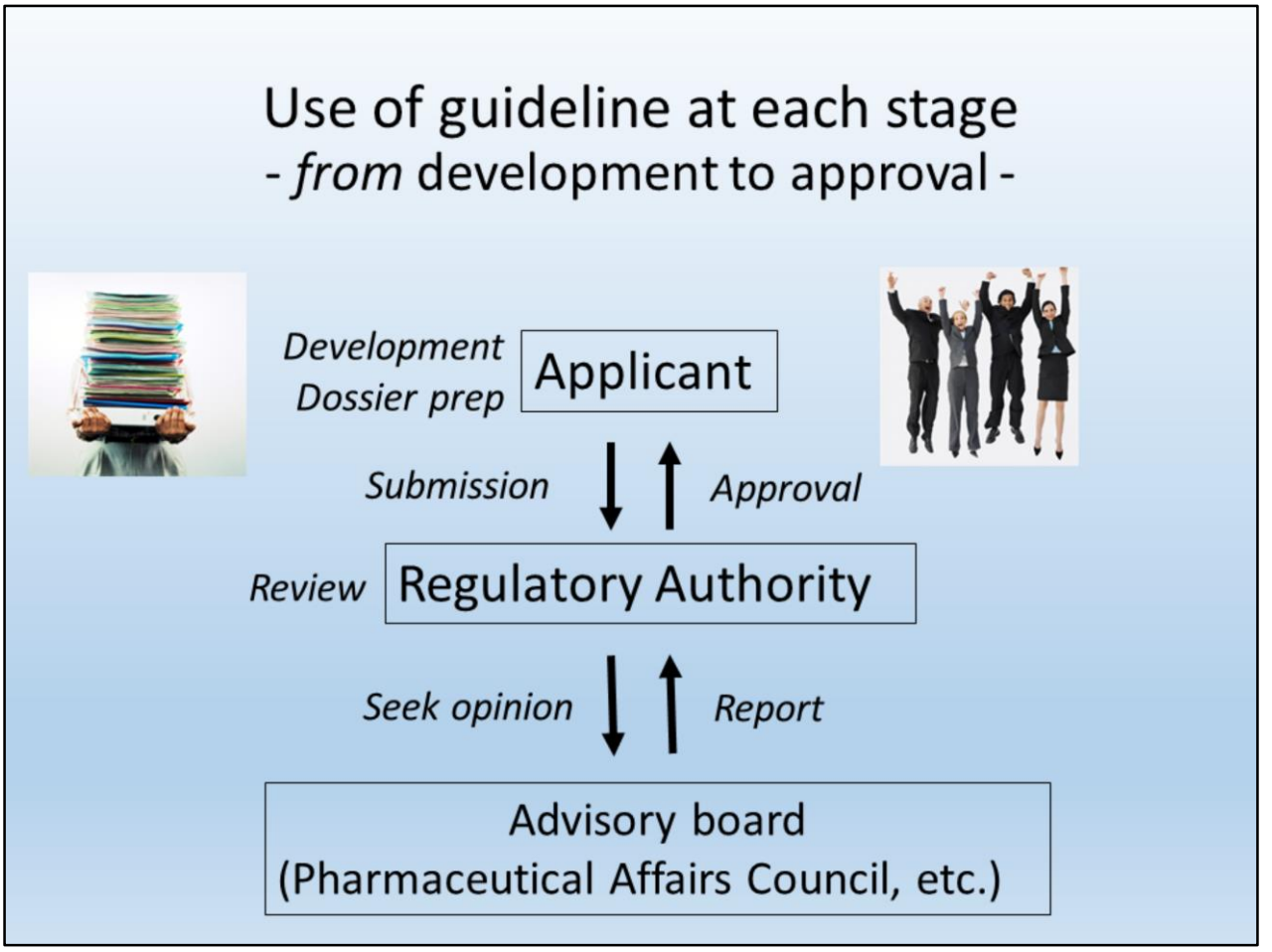

Technical and/or administrative guidelines (GLs) will be used, when;

- Applicant develops a new product and prepares application dossier,
- Regulatory authority (RA) reviews the dossier,
- Advisory board is sought for opinion from the RA and
- RA finally make decision on the marketing approval.

VICH guidelines

- Regulators and Industry work together as equal partners
  - A mutual agreement between regulators and industry
- Published as Notices
  - Legally non-binding (recommendation)
  - Maximum study design (require not any more)
- Lead both applicant and reviewer to the goal
  - Faster approval
  - Benefit also to veterinarians & consumers

VICH guidelines

- Regulatory Authority and Industry work together as an equal partner
  - A mutual agreement between regulatory authorities and industry
- The VICH guidelines are published with an accompanying Notice
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Issues to be discussed in this part

- Do you have legally non-binding guidance system in your country?
- Do you have industry organization which could work with Regulators as an equal partner?

- Are you using internationally harmonized guideline , such as VICH-GLs, in your country?
- Are you familiar with VICH Outreach Forum initiative?

Notes

4. Preparing guidelines

Flexibility versus clarity;
Development and public consultation;
Access to scientific/legislative advice;
How is animal welfare protected(3Rs)?

Notes

The guidelines(GLs) should be on Consensus

- GLs should follow the current science
- Mutual acceptance of data
  - prevents unnecessary repetition of animal testing
- Needs occasional update (flexibility)

- GLs are legally non-binding (soft law)
- A recommendation from the Regulator

- Needs support by All STAKEHOLDERS

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VICH guideline creation process

Step	Stage
1: SC agrees to start a topic and appoints an EWG 2: EWG elaborates a draft GL 3: SC approves the draft GL for public consultation	Drafting
4: Draft GL is circulated to stakeholders and public 5: EWG prepares a revised GL 6: SC approves the revised GL	Fine-tuning
7: Final GL is circulated to authorities of VICH region 8: Final GL is implemented in VICH region	Publishing
9: SC monitors, maintains and reviews the GL	Maintenance

SC: Steering Committee
EWG: Expert Working Group

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VICH guideline creation process
9 Step procedure (with 4 stages)

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- 8: Final GL is implemented in VICH region

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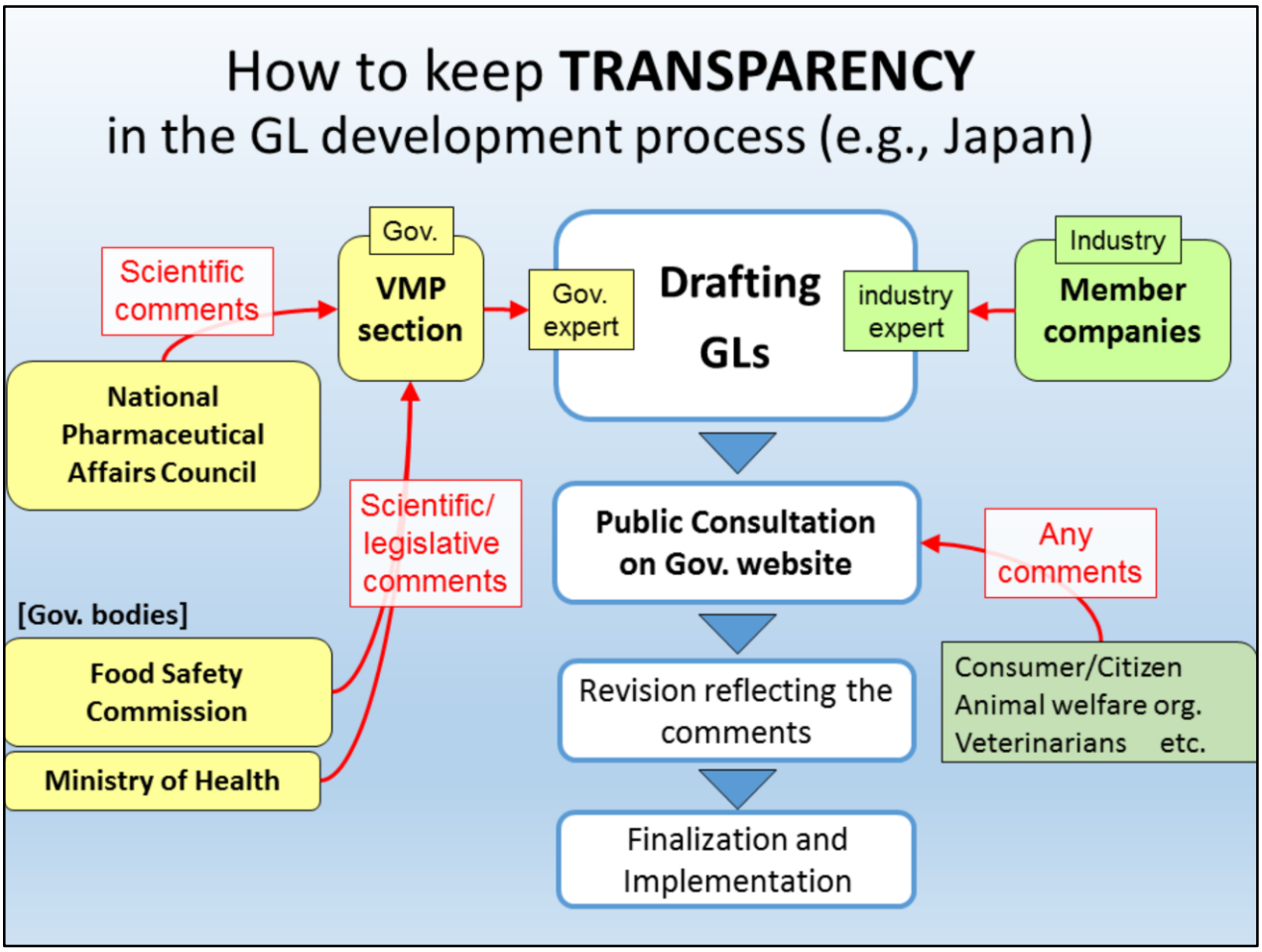

How to keep **TRANSPARENCY** in the GL development process in Japan

When drafting GLs, an expert from government side receive scientific and legislative comments from the advisory boards through VMP section in the government.
Also, an Industry expert collect the comments from the member companies..

Then, the draft GL will be published for **public consultation** on government website.
The EWG revises the draft guidelines based on comments from consumer, citizen, animal welfare org, veterinarians, etc. before implementation.

Issues to be discussed in this part

- Do you have scientific/legislative advisory board?
- Are you keeping good relationship with industry organization?
- Do you have a sound public consultation system that is open for all the people in your country?

Notes

Appendix

Where to find International guidelines
VICH guidelines
OECD guidelines

and local guidelines and related legislation

European Union

International guidelines

- VICH GLs: http://www.vichsec.org
- OECD GLs: http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm

Local GLs and related legislation (EU)

- European Medicines Agency website. Scientific guidelines for veterinary medicinal products.
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000173.jsp

- European Commission.
  EudraLex - Volume 5 - Pharmaceutical legislation Medicinal Products for veterinary use
  http://ec.europa.eu/health/documents/eudralex/vol-5/index_en.htm
  EudraLex - Volume 6 Notice to Applicants and Regulatory Guidelines for Medicinal products for Veterinary use
  http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm

- European Directorate for the Quality of Medicines and Healthcare (EDQM).
  http://www.edqm.eu/en/

Where to find local guidelines and related legislation

Japan
USA

Local GLs related legislation (Japan)

- Outline of Regulation System of Veterinary Drugs in Japan".
  http://www.maff.go.jp/nval/english/pdf/outline130325.pdf
- Standards for Veterinary Biological Products, Notification of the Minister of Agriculture, Forestry and Fisheries (Notification No.1567; October 3, 2002).
  http://www.maff.go.jp/nval/kijyun/index.html
- "Pharmaceutical Affairs Law*" and "Ministerial Ordinances for Veterinary Medicinal Products".
  http://www.maff.go.jp/nval/hourei_tuuti/index.html
  *English translation is available from: Yakuji Nippo, Ltd.
  http://www.yakuji.co.jp/english_publications#others

Local GLs related legislation (USA)

- Guidelines:
  http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm
- Regulations for Animal Drugs:
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=514&showFR=1
- Food, Drug and Cosmetic Act:
  http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm
- 9 C.F.R. PART 102—LICENSES FOR BIOLOGICAL PRODUCTS
  http://law.justia.com/cfr/title09/9-1.0.1.5.41.html

Where to find local guidelines and related legislation

Australia
Canada
New Zealand

Australia

- Agricultural and Veterinary Chemicals (Administration) Act 1992
  http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/593357AE6E2C5699CA257308003366D3?OpenDocument
- Agricultural and Veterinary Chemicals Code Act 1994
  http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/current/bytitle/A06DDA96E680781ECA2573120082EBE6?OpenDocument&mostrecent=1
- Agricultural and Veterinary Chemicals Code Regulations 1995
  http://www.comlaw.gov.au/ComLaw/legislation/legislativeinstrumentcompilation1.nsf/current/bytitle/D46CF53F85578946CA25768D0012F0A3?OpenDocument&mostrecent=1

Canada

- Food and Drugs Act and Regulations
  http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/act-loi_reg-eng.php
- Health of Animals Act and Regulations
  http://laws.justice.gc.ca/en/H-3.3/

New Zealand

- Registration
  http://www.foodsafety.govt.nz/industry/acvm/vet-medicines/authorisation/registration.htm

Links to web pages of regulatory authorities of VICH member countries and regions

EU
Japan
USA

EU

- European Commission, Directorate General Health and Consumers (SANCO)
  http://ec.europa.eu/health/index_en.htm
- European Medicines Agency, Veterinary Medicines
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/veterinary_medicines_regulatory.jsp&mid
- regulatory authorities for veterinary medicines in member States of the EU:
  http://www.hma.eu/

Japan

- Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries
  http://www.maff.go.jp/j/syouan/tikusui/yakuzi/index.html
- National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries
  http://www.maff.go.jp/nval/english/

USA

- Center for Veterinary Medicine/Food and Drug Administration
  http://www.fda.gov/AnimalVeterinary/
- Center for Veterinary Biologics
  https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics

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Australia
New Zealand
Canada

Australia

- Australian Pesticides and Veterinary Medicines Authority (APVMA)
  www.apvma.gov.au

New Zealand

- New Zealand Food Safety Authority (NZFSA) http://www.nzfsa.govt.nz/

Canada

- Veterinary Drugs Directorate Health Canada
  http://www.hc-sc.gc.ca/dhp-mps/vet/index-eng.php
- Canadian Centre for Veterinary Biologics, Canadian Food Inspection Agency
  http://www.inspection.gc.ca/english/anima/vetbio/vbpbve.shtml