International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VICH/19/078
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~~Draft 7~~Final

List of information on topics drawing a strong interest by the VOF members, which are currently outside the scope of VICH

Objective

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is receiving many questions as to the topics for which this international body can establish harmonised guidelines.

The purpose of the *List of information of topics drawing a strong interest by the VOF members, which are currently outside the scope of VICH* is to provide further clarity on this point. Furthermore, the VICH SC would like to provide direction as to the mechanism through which important topics raised can be addressed in case global harmonisation through VICH is not currently possible. This kind of information is not only useful to promote active communication between VOF and VICH members, but also amongst VICH SC members for better understanding ~~to recognize~~ the differences in VMP regulation leading to ~~find a perspective on~~ further harmonisation in the future.

Role and scope of VICH

One of the key roles of VICH is to establish and implement harmonised technical requirements for the registration of veterinary medicinal products (VMPs) in the VICH regions. This specifically means development of VICH Guidelines (GLs) describing the study and testing methodology in order to demonstrate product quality, safety and efficacy (including bioequivalence). In addition, Pharmacovigilance GLs describe how post-marketing safety monitoring of approved VMPs should be performed.

In this context VICH uses the following definition of VMP (VICH GL 24):
Any medicinal product with approved claim(s) to having a protective, therapeutic or diagnostic effect or to alter physiological functions when administered to or applied to an animal. The term applies to therapeutics, biologicals, diagnostics and modifiers of physiological function.
This definition includes pharmaceutical and biological products as well as medicated premixes.

While VICH uses the above definition, it is important to recognise that national competent authorities are required to respect definitions included within their legislation. In some instances, this may mean that although a particular type of product might fall within the VICH definition of a VMP, one or other VICH member may be precluded from considering it as a VMP by their national legislation.

List of information on topics drawing a strong interest by the VOF members, which are currently outside the scope of VICH

The overview presented in Table 1 lists the topics raised to VICH and considered by the VICH Steering Committee (SC) to be either outside the scope of the VICH objectives or the VICH SC concluded that harmonisation of the topic should be deferred. Accordingly, at the present time it will not be possible to elaborate a harmonised VICH position for those topics. VICH would nevertheless like to point parties interested in those topics in the direction of already existing information and documentation and to provide the contact details of organisations, who could provide further assistance.

The table below should be regarded as a "living document", which will be amended as necessary. An updated version will be made available to the public via the VICH website (www.vichsec.org).

Table 1:

Topic proposed by the VOF members: Current status on harmonisation and/or regulatory measure in the VICH country/region	**Related information on the applicable requirements from the competent regulatory authorities and international organizations**	
	Country /Region /Organisa-tion	**Title (website and/or contact)**
Requirements for updating viral strains in vaccines: Regulatory requirements are excluded from VICH and may differ between countries	EU	Data requirements for changes to the strain composition of authorised equine influenza vaccines in line with OIE recommendations
	Japan	Veterinary influenza virus vaccine strain selection committee https://www.maff.go.jp/nval/tyosa_kenkyu/animal_influenza.html
	USA	9 CFR 114.8 & 114.9; VSM 800.111- Viral Strain Changes in Equine Influenza and Swine Influenza Vaccines
	Australia	Major changes to seed strains: change to source or site or process of manufacture requires a new product application. https://apvma.gov.au/node/1044 . It some situations it may be possible to vary a viral strain through an Item 14 variation.
	(any)	
Diagnostics: Not currently included in the definition of VMP in all VICH countries (N.B.: exception Japan) - *might become a topic which could be treated at sometime in the future*	EU	Not regulated in the veterinary medicines sector at an EU level
	Japan	No.18 Guideline for performance and clinical test methods for in-vitro diagnostic drugs for veterinary use in; http://www.maff.go.jp/nval/hourei_tuuti/pdf/20200701betten2.pdf
	USA	VSM 800.73- *Diagnostic Test Kit Validation*; VSM 800.206- *General Licensing Considerations* (note: extensive rewrites & new diagnostics-specific regulations planned in next 12-24 months)
	Australia	Not regulated in the veterinary chemical products (veterinary medicines) sector

	OIE	Registration of diagnostic kits https://www.oie.int/en/scientific-expertise/registration-of-diagnostic-kits/background-information/
Autogenous vaccines : Not currently included in the scope of VMP registration in all VICH countries *- might become a topic which could be treated at sometime in the future*	EU	The control of autogenous vaccines is under the jurisdiction of the national EU member state legislation, except for some key principles that are now specified in the new EU Regulation 2019/6: definitions; limits use to inactivated autogenous vaccines; must be manufactured in accordance with "the principles" of GMP; and prohibits their advertising. Recommandations from HMA/CMDv : https://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Procedural_guidance/Miscellaneous/Recommendations_manufacture_control_use_inact_autogenous_vaccines.pdf
	Japan	Currently under consideration.
	USA	9 CFR 113.113 & 113.3(b)(8); VSM 800.69- Guidelines for Autogenous Biologics (updated version pending)
	Australia	The control of autogenous vaccines is under the jurisdiction of APVMA legislation (AgVet Code 1994 as amended), Autogenous vaccines fall under Permits as minor use and generally issued only for inactivated vaccines. Autogenous vaccines must be manufactured in accordance with the principles" of GMP and the manufacturer hold an APVMA GMP Licence. Autogenous vaccines are limited to the farm of origin unless justified.
	OIE	In line with recommendation no. 8 of the 2nd OIE Global Conference on Antimicrobial Resistance (2018), the OIE will explore the opportunity to develop standards or guidelines related to autogenous vaccines and other alternatives to antimicrobials, including guidance for quality, safety and efficacy, as tools to reduce the need to use antimicrobials.
Complementary feed, food supplements: Not currently included in the definition of VMP in all VICH countries	EU	
	Japan	
	USA	
	(Any)	

MRL extrapolation: VICH does not establish safety standards. While guidance on the design of studies needed for setting MRLs is provided in VICH metabolism and residues kinetics guidelines, responsibility for the approach used to assess the resulting data lies with the relevant national competent authority.	EU	COMMISSION REGULATION (EU) 2017/880 of 23 May 2017 laying down rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0880&from=EN There is also EU guidance that covers extrapolation of MRLs: Guideline on safety and residue data requirements for pharmaceuctical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market Note for guidance on the establishment of maximum residue limits for *Salmonidae* and other fin fish
	Japan	
	USA	
	(Any)	
Establishment of withdrawal times: While VICH has established guidance to be followed for the design of withdrawal period studies, responsibility for the approach used to assess the resulting data lies with the relevant national competent authority	EU Japan USA	"Report to the VICH OUTREACH FORUM: Withdrawal periods for veterinary medicinal products - Approach by VICH members and observers" dated August 2020 (see enclosed and link) Report on calculation of withdrawal periods
	(any)	

Commenté [B(RB1]: Hervé, could you please include the link to the document on the VICH website, once it will have been posted? Thanks.

Ectoparasiticides: Not currently considered by VICH since in the USA ectoparasiticides are regulated by the Environmental Protection Agency (EPA) and as EPA has no involvement with VICH it would not be possible to commit to apply a VICH GL on ectoparasiticides in the USA	EU	
	Japan	
	USA	
	Australia	Adopt Recommendation to refer to the guidelines (link) published by the World Association for the Advancement of Veterinary Parasitology (WAAVP) as a national regulation.
	(any)	
Medicated feed: Not currently included in the definition of VMP in all VICH countries	EU	REGULATION (EU) 2019/4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC : **https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0004&from=EN**
	Japan	
	USA	
	(any)	
~~**Borderline products (Hh**~~**erbal medicine~~)~~:** Limited/varying experience with that type of product in VICH countries	EU	
	Japan	
	USA	
	(any)	

(any new topic): (Current status on harmonisation and/or regulatory measure in the VICH country/region)	EU	
	Japan	
	USA	
	(any)	