

**Federal agency for medicines and health
products**

Part 5

Roadmap for E-submission

22.03.2013

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EU TI Ges vet subgroup

Functioning of the group is described by its terms of reference:

- Composition, role, mission statement, vision, working methods, liasons and interactions, subgroups as the important Change Control Group

Goals of the group are described in a roadmap:

- One format for electronic dossier whatever procedure and EEA countries concerned - importance of harmonisation, stability and simplicity
- Safe transmission to all authorities whatever the procedure

-> Both documents are published

Results: Guideline, validation checklist, Q&A, correlation table

Challenge: Alignment between directive, NtA, CMDv, CVMP, VNeesS
Guideline, pragmatism and tools is very important



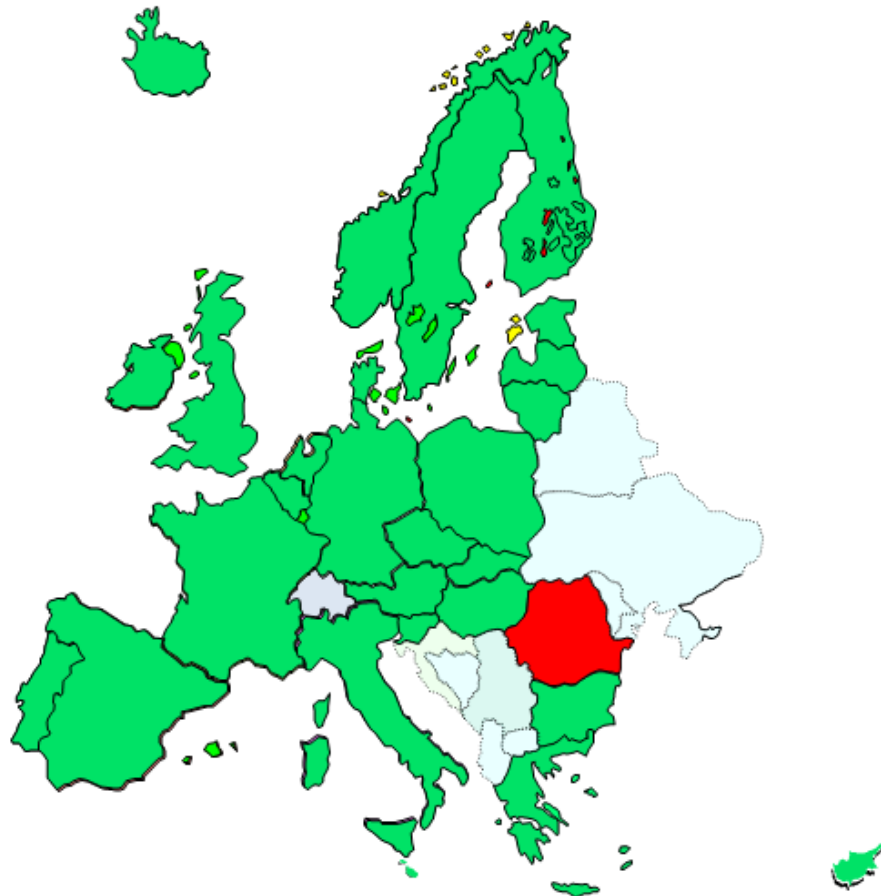
Dossier requirements in veterinary MRP/DCP and national procedures



Ready for Electronic Only dossier (Optional or mandatory)



Not ready for e-submission without paper – or no response



2012-11-14



EU Statistics 2012

	FINLAND	EMA	BELGIUM	NORWAY	GERMANY- BVL	LATVIA	SWEDEN	DANMARK	ESTONIA	SPAIN	SLOVENIA	GERMANY PEI	HUNGARY	FRANCE	NETHERLANDS
ratio elect/total															
MRP/DCP new appl variations	100,0%		98,8%	100,0%	95,4%	79,7%	93,4%	66,0%		20,0%		50,0%	82,1%	97,6%	100,0%
renewals	93,2%		68,3%	53,7%	68,9%	67,0%	40,1%			20,0%		9,9%	89,3%	92,6%	95,8%
National new appl variations	100,0%		97,8%	83,3%	75,0%	85,7%	42,1%			19,9%		0,0%	23,5%	100,0%	94,3%
renewals	0,0%	100,0%	92,9%	100,0%	1,0%	35,0%	100,0%			18,6%		20,0%	8,9%	95,2%	100,0%
	95,2%	99,2%	72,6%	51,8%	13,7%	32,1%	9,9%			19,8%		18,7%	13,1%	94,6%	93,3%
	100,0%	90,9%	72,2%	50,0%	6,3%	50,9%	0,0%			19,9%		0,0%	10,0%	99,4%	90,9%
of all elect % real VNeS															
MRP/DCP new appl variations	69,1%		92,6%	95,0%	100,0%		100,0%	90% of the electr submissions are accepted			52,0%	100,0%	94,5%	100,0%	
renewals	32,2%		45,9%	44,3%	100,0%		100,0%				11,0%	13,3%	79,5%		
National new appl variations	29,2%		55,6%	20,0%	100,0%		100,0%						50,0%		
renewals	0,0%	81,8%	92,3%	0,0%	100,0%		100,0%				0,0%	100,0%		100,0%	
	28,7%	10,3%	12,9%	33,3%	100,0%		100,0%				0,0%	8,5%			
	0,0%	20,0%	7,7%	0,0%	100,0%										



Likely future evolutions

- *Follow up of acceptance ratio electronic way of working*
- *Interest in long term archiving*
- *Use of central systems*
- *Dealing with human CTD module 3, ASMFs*
- *Introduction of context of use*



Validation score in BE february 2013 (MAA)

NA	NAT MRP/DCP	type (MR, DC, E)	compliance			
			folder	files	files in TOC	hyperlinks
0000148	DCP	DC	100	96,47	97,65	100
0000159	MRP	DC	100	100	100	97,67
0000160	DCP	DC	100	100	100	100
0000169	DCP	DC	100	100	100	98,99
0000168	DCP	DC	100	100	100	98,82
0000178	MRP	MR	97,3	90,59	98,82	100
0000178	MRP	MR	97,3	90,8	98,85	100
0000182	DCP	DC	100	100	100	100
0000182	DCP	DC	100	100	100	100
0000182	DCP	DC	100	100	100	100
0000182	DCP	DC	100	100	100	100
0000195	DCP	DC	100	100	100	100
0000209	NAT	NP	100	97,06	97,06	100
average	13		99,58	98,07	99,41	99,65



Roadmap e-submission in BE

01/01/2013 - 30/06/2013: submission of VneeS validation report recommended, not mandatory, no rejection fee

01/07/2013-31/12/2013: submission of VneeS validation report mandatory, no rejection fee

From 01/07/2014 on: full VneeS compliance required, rejection fee



questions ?



A large, stylized graphic of an eye is centered on the page. The eye is composed of several concentric, semi-transparent shapes: a light grey outer arc, a medium blue middle ring, and a white inner circle. The text is centered within the blue ring.

Your medicines and health products,
our concern