Nordic Regualtory Authority Update on the Nordic Activities Related to the CTR

Norway

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Norwegian Medicines Agency

Norwegian Medicines Agency

Agenda

- Regulatory status
- Organization of the Ethics Committees (ECs) in Norway
- Collaboration between Norwegian Medicines Agency and ECs in Norway
- Preparedness
- Fees
- Insurance

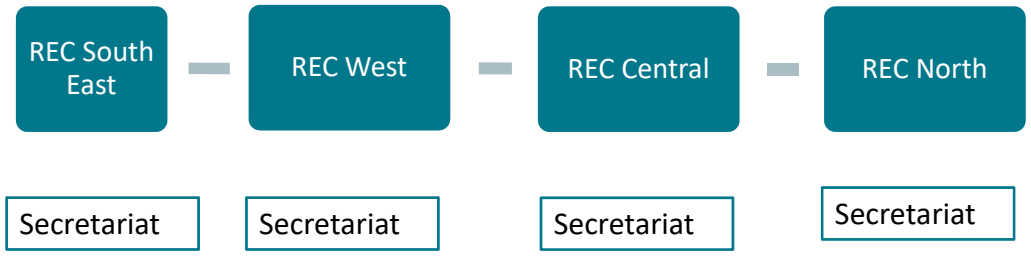
General principles

- Norway will be in line with the rest of Europe
- Participates on the same grounds as EU-members (EEC-agreement)

Regulatory status in Norway

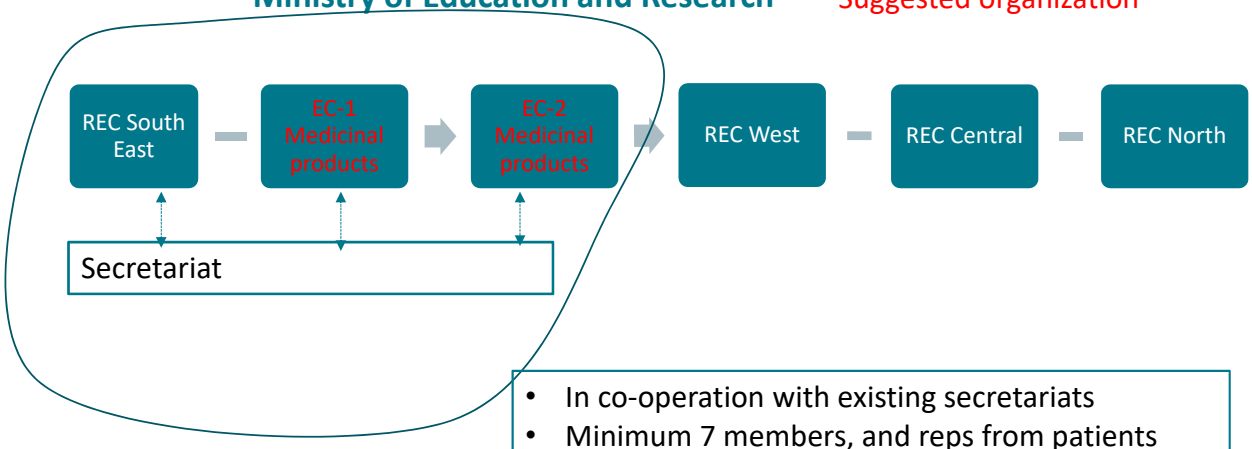
- Legemiddelforskriften – by reference to the regulation 536/2014
- The Norwegian Clinical trial regulation
  (Forskrift om klinisk utprøving)
- The Norwegian Regulation of Manufacturing and Importation
  - Need for change after publication of delegated regulation on GMP?
- Guidance document for Stakeholders operating in Norway

Ministry of Education and Research



Ministry of Education and Research

Suggested organization



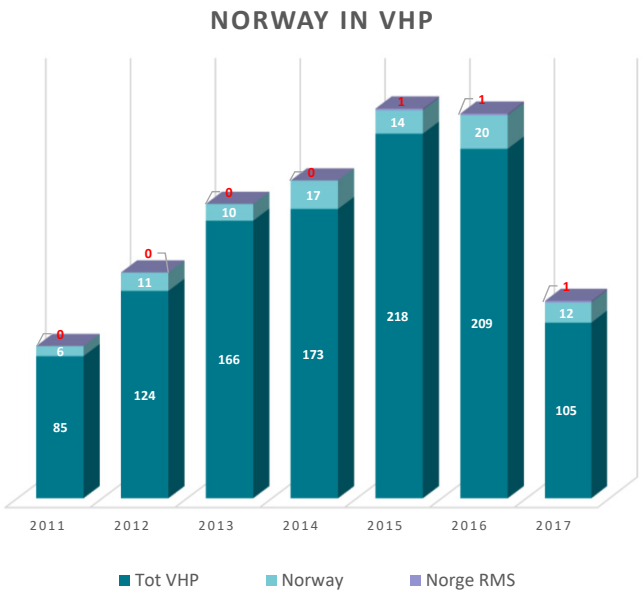
- In co-operation with existing secretariats
- Minimum 7 members, and reps from patients organization
- Meeting every 10-14 days
- Part I and part II

Co-operation EC and CA

- General principles
  - NoMACompetent Authority
  - National Contact Point = NoMA and Member of CTAG (Clinical Trial Advisory Board)
  - Facilitate the procedures in the regulation, chapter II (and II ?)
  - NoMA manages tasks/procedures when Norway is RMS
  - Appeal to Norwegian Ministry of Health
- Validation of the application
  - NoMA assess if a trail fall under the scope of the regulation
  - NoMA assess whether it is low intervention or not
- Assessment
  - Part I: EC and NoMA co operation
  - Part II: EC
  - Substantial Modification (SM) + Norway as additional MS - both EC and NoMA participate in the approval process - basically same procedure as new applications
- Still independent authorities

How to prepare?

- Voluntary Harmonisation Procedure (VHP)
  - VHP plus in 2018
- Work Sharing on Safety assessment
  - 2018 (?)
- Information to stakeholders
  - Presentations
  - Q&A
- Road show in 2019
- Updating web page 2018/2019



Fees

- Payment for non-commercial CTs(?)
- Different fees for different roles/procedures
  - Reporting MS
  - MS concerned
  - Amendment (RMS fee / MSC fee)
  - Safety assessment

Insurance – damage compensation

- National
- Norway: Norwegian Liability Association

National IT-system?

National Implementation Status August (*July)

- Litle progress, major hurdels remain
- Some progress, more activity needed
- Pregressing well, on target

	NCA - EC organisation	Ethics committees restructure	National law	National IT system	Fees	Communication and training	Pilot projects	Safety	Resources
*							N/A		
*									
				NA			NA		
*									
		N/A	N/A		N/A				
							N/A		
		N.A.					N.A.		
				N/A			N/A		
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		N/A		N/A			N/A		
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							N/A		

Summary

- Norway will implement the regulation in line with rest of Europe
  - Regulatory status on track
- EC and NoMA will co operate on part II.
  - Planning is progrssing
  - EC organization most likely in place early 2018
- Norway needs to increase the activity in VHP/VHP plus and on the safety assessment sharing
- Still big hurdles on national IT system
- Fees and insurance on track

Thank you !

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