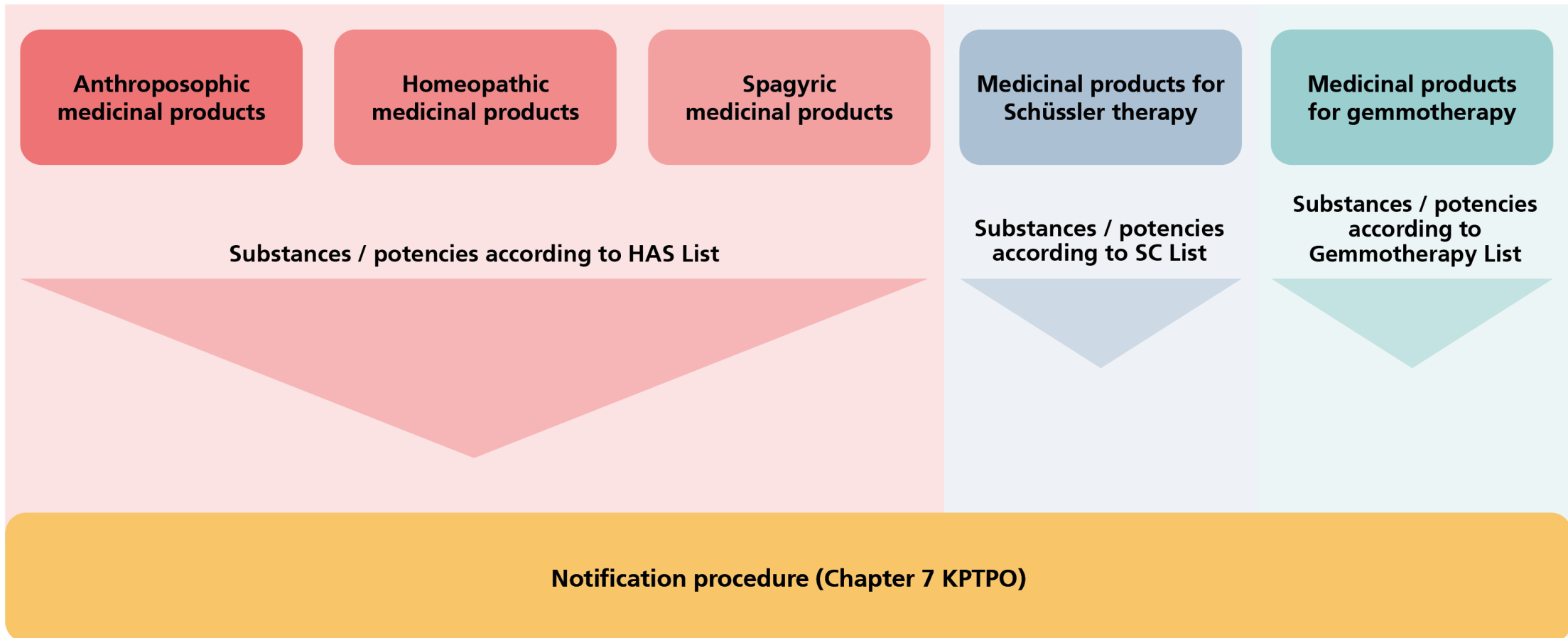


Notification procedure for homeopathics/anthroposophics – efficient submissions

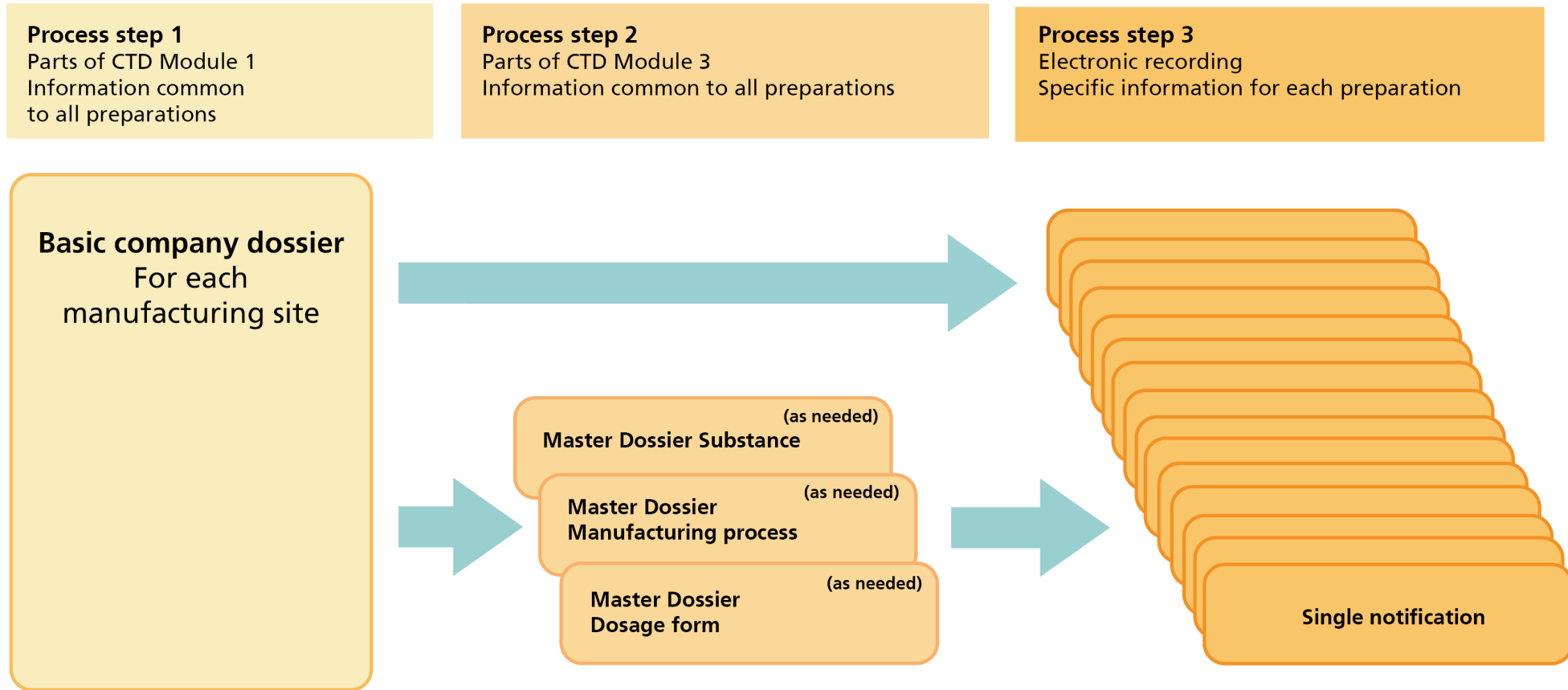
Conwitha Lapke, Quality Assessor / Regulatory Manager Homant

Structure of authorisation without indication by means of notification (notification procedure)



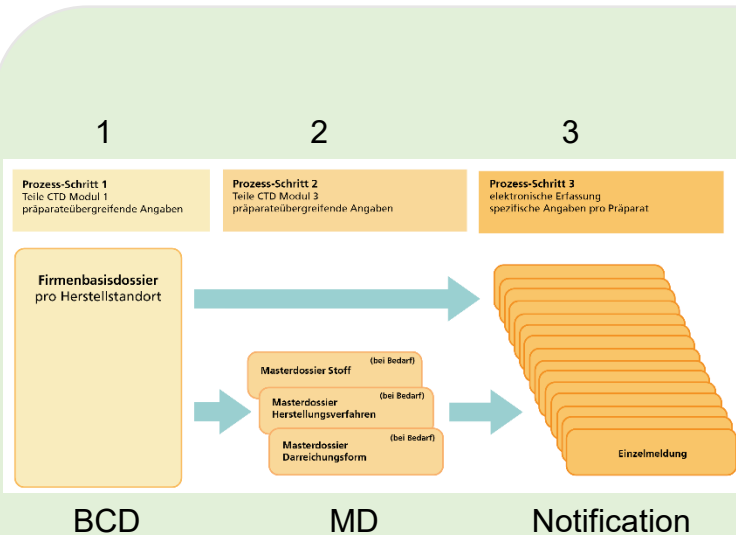
[www KPA website: Authorisation without indication by means of notification \(notification procedure\) \(swissmedic.ch\)](http://www.kpa.ch)

Structure of authorisation without indication by means of notification (notification procedure)



[www KPA website: Authorisation without indication by means of notification \(notification procedure\) \(swissmedic.ch\)](http://www.kpa.ch)

Efficiency of notification procedure?



“Range” of similar medicinal products

- Manufacturing site
- Treatment
- Dosage form
- Plannable
- Process steps, e.g. 1, 2, 3, 3, 3, 3, etc.

“Range” is heterogeneous

- Manufacturing sites -> *several BCD*
- Treatments -> *modified BCD*
- Dosage forms -> *modified BCD*
- Developing
- Process steps, e.g. 1, 2, 3, 1, 3, 2, 3, etc.

Reduced dossiers¹?

- (only) 1 application per medicinal product
- BCD, MD may be referenced
- May be modified

Efficient preparation of single notifications

Questions

- Treatment new?
- Dosage form new?
- TSE form¹ required?
(starting material, excipient lactose)
- etc.

Application submission

- ⇒ Modify basic company dossier
- ⇒ Modify basic company dossier
- ⇒ New / mod. master dossier TSE forms^{1, 2}



Swissmedic:
Approval decision

Single notifications, entered into HOMANT software

- Correct basic company dossier number selected?
- Correct dropdown for manufacturing process and pharmacopoeia (monograph)

selected?

¹ Form(s) *Substances of animal and human origin HMV4*

² Art. 39 para. 1 let. a KPTPO (SR 812.212.24)