

**CMDh Task Force
Meeting on
Self-Medication
- Non-prescription medicines -**

**‘Automatic recognition’:
how would it work in practice?**

Agenda item #3

20 June 2011

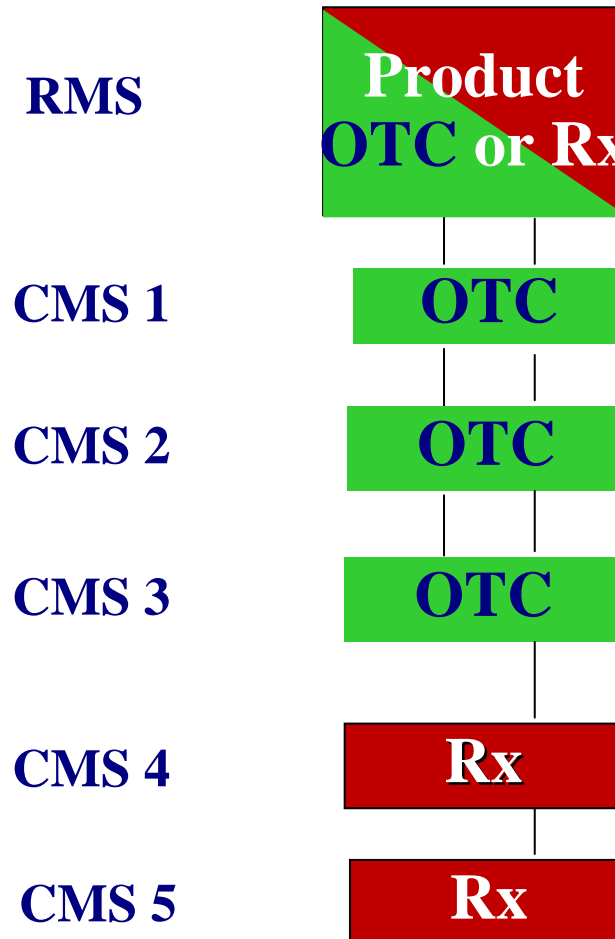
Introduction

- Automatic recognition is one of the key items of AESGP Smart Regulation 2015
- It is the end goal but a number of steps need to be in place first to ensure that the whole concept works
 - MRP/DCP with hybrid legal status possible
 - Product information sub-sets (Rx and non-Rx) as outcome of the procedure
 - Understanding and self-care specific features are part of MRP/DCP (cf. best practice guide)
 - Transparency re legal status before and after procedure

Steps to ‘automatic recognition’

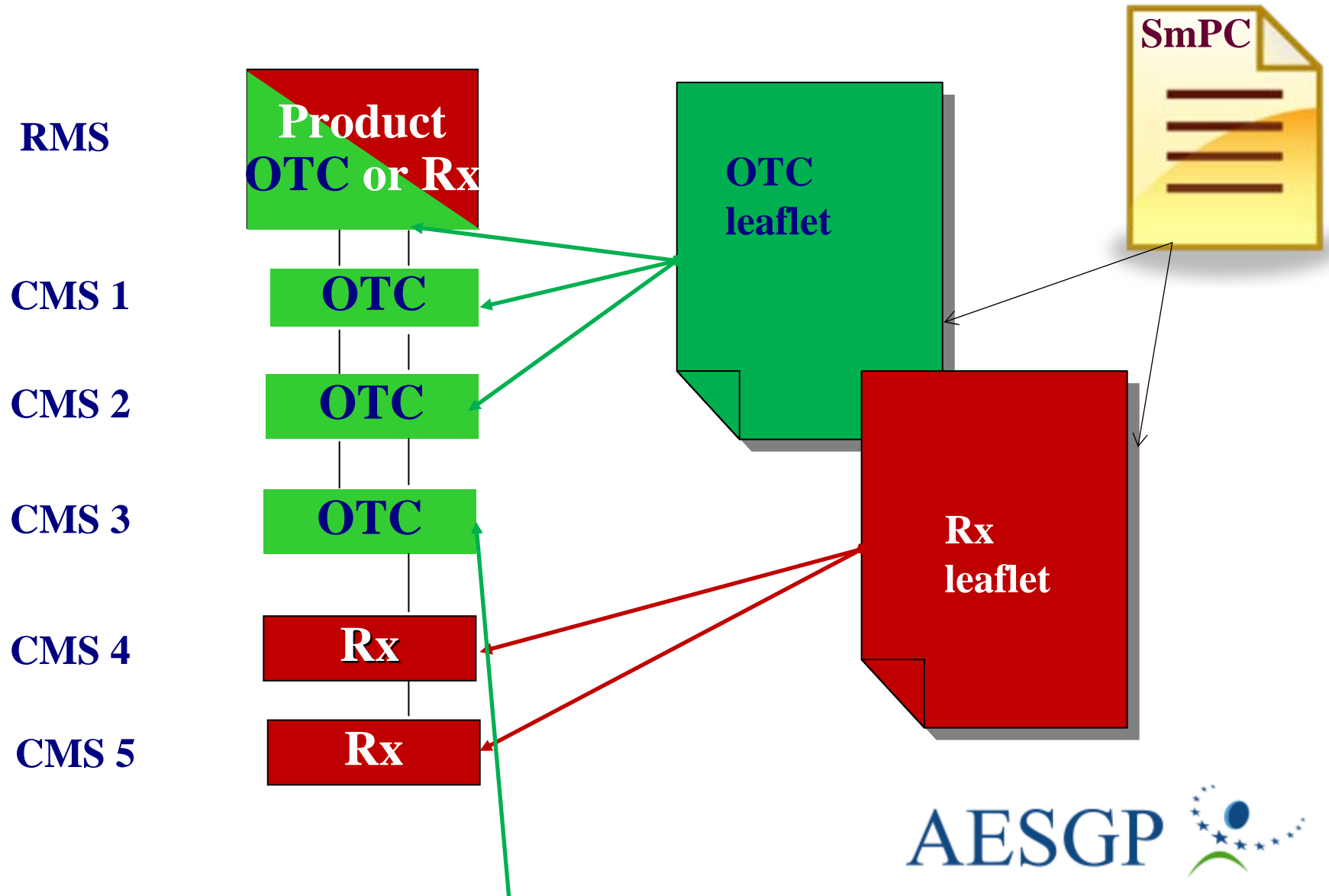
1. Mixed legal status MRP/DCP
2. Sub-sets of product information
3. Record of legal status in RMS and CMSs at the end of MRP/DCP and tracking of same; reasons why a country chose to retain Rx also to be recorded
4. ‘Automatic recognition’ of legal status

Step 1: Combined Rx/OTC MRP/DCP



There are a number of real examples of MR/DC procedures with such outcome

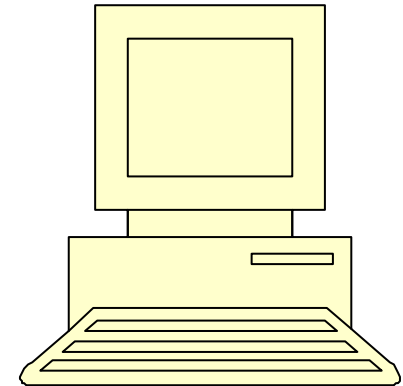
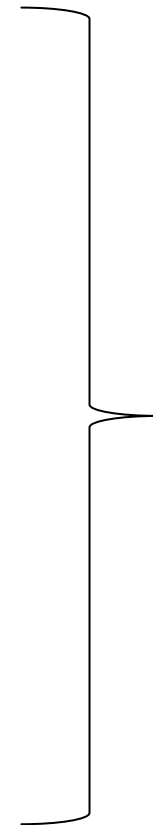
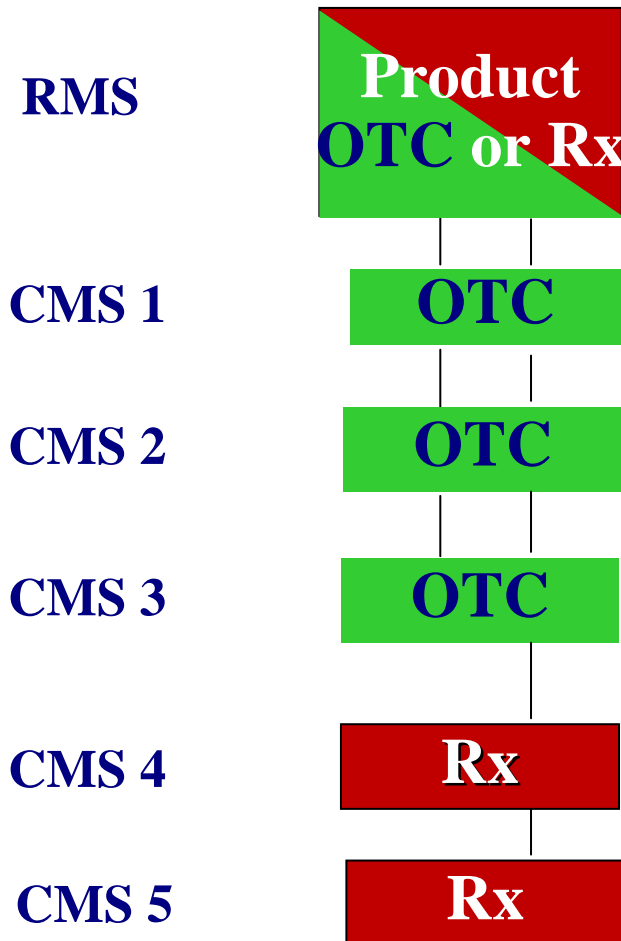
Step 2: Subset of product information as outcome of the MRP/DCP



Step 3: Record of legal status in RMS and CMSs at the end of MRP/DCP and subsequent tracking

- Final outcome of legal status could be sent by the MAH at end of procedure
- Should appear in the MRI Product Index
- Information update on changes in prescription status could be provided by the MAH to RMS
- Reasons as to why a Member State opted for Rx status should also be known by MAH and recorded

Step 3: Record of legal status in RMS and CMSs at the end of MRP/DCP and subsequent tracking



Legal status given per RMS and CMSs recorded (possibly in MRI system)

‘Automatic recognition’ of non-prescription status

- **At the latest, after five years, an ‘automatic switch’ may be triggered by the MAH in any/all of the ‘prescription countries’ via a simple notification.**
- This would occur ‘automatically’ in the absence of new safety information of concerns.
- The non-prescription version of the package leaflet (agreed as part of the outcome of the MRP/DCP) would be used as such for the newly switched countries.

Step 4: 'automatic switch' to the OTC PI sub-set at the latest after five years

