Incentives for ‘Switching’ – the UK experience

Jan MacDonald
• UK OTC market
• Incentives
  – Legislative
  – Policy
  – Professional
• Future of the market
UK Over-the-Counter Market

- Across EU only 7 molecules are commonly available
- In UK ~ 75 molecules
- UK market worth £2.62bn (2016)
• Own-label products 18% market
• Four companies have 15 of the top 20 brands
• Increase of 2.3% over the year 2016
  – Analgesia 23%
  – Cough & cold 19%
  – Skin treatments 18%
Substance vs Product Based Reclassification

- Medicine Act 1968 – substance based
  - POM order
  - GSL order

- 2002 – product based
Legislative incentive

• Data exclusivity

Article 74a
Where a change of classification of a medicinal product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for one year after the initial change was authorised.
Policy Incentive

• When safe to do so HMG will widen access to medicines

• New procedure available to MAHs
  – Streamlined assessment
  – Predictable timeline
  – Involvement of stakeholders
UK Stakeholder Platform

UK Medicines Reclassification Platform

The UK Medicines Reclassification Platform for the recategorization of non-prescription medicines aims to increase stakeholder engagement in the recategorization process and to ensure the public receives maximum benefit from wider access to medicines when it is safe to do so.
Stakeholder Groups

- Commission on Human Medicines wants the patient perspective to be taken into account
- Stakeholder groups convened for innovative reclassification applications
- Practical implications of the ‘switch’ discussed and transmitted to CHM with assessment of application
- Can help deliver success
European interaction

- CMDh Taskforce on non-prescription medicines
  - provide recommendations to the CMDh and HMA to enable wider approval of products suitable for non-prescription use
  - to explore best practices at both NCAs and industry level
  - if appropriate, revise the BPG on DCP for non-prescription medicines
- 15 MS involved
- Joint EMA – CMDh initiative to involve stakeholders in the assessment process
Professional Incentive

• ‘P’ legal status in UK
• Pharmacy professionals able to help manage risk
• Right patient/right medicine/right time
• Can provide additional screening and health advice
• Supply in novel therapeutic areas
Future

• New molecules and disease areas
  – Applications are vibrant – we now have a booking system for new submissions
• Pharmacy – the first port of call for NHS
• Primary care prescribing