Medicines & Healthcare products Regulatory Agency

MHRA

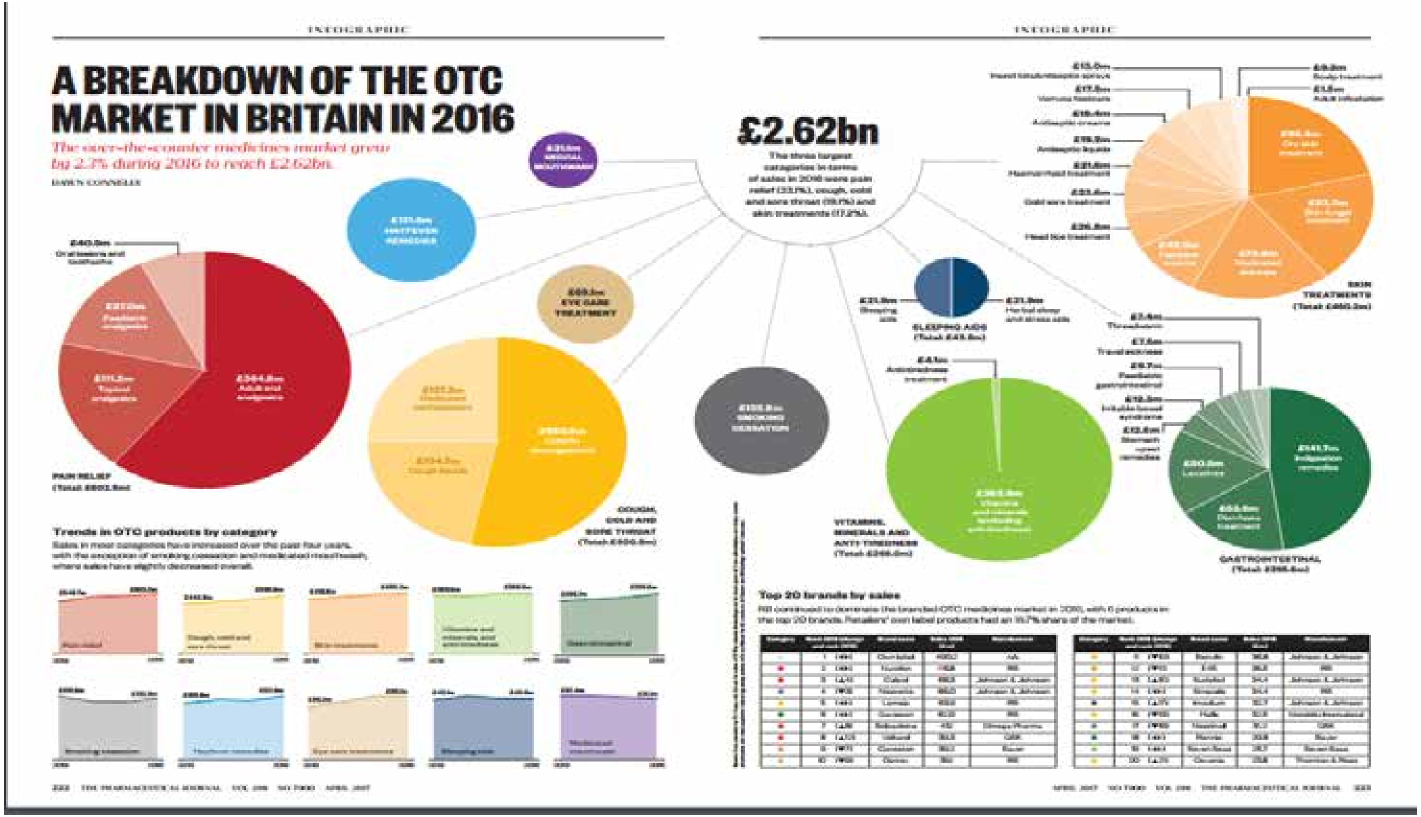
Incentives for 'Switching' – the UK experience

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)



APRIL 2017 NO 7900 VOL 298 THE PHARMACEUTICAL JOURNAL 223

- 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%

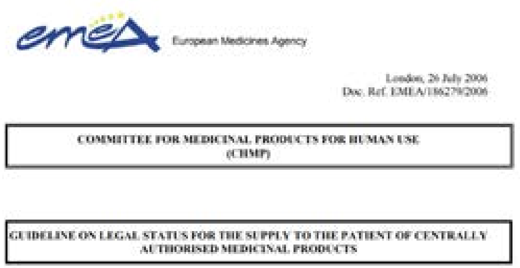
Substance vs Product Based Reclassification

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

- 2002 – product based

Legislative incentive

- Data exclusivity



European Medicines Agency

London, 26 July 2006
Doc. Ref. EMEA/186279/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
(CHMP)

GUIDELINE ON LEGAL STATUS FOR THE SUPPLY TO THE PATIENT OF CENTRALLY AUTHORISED MEDICINAL PRODUCTS

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

GOV.UK

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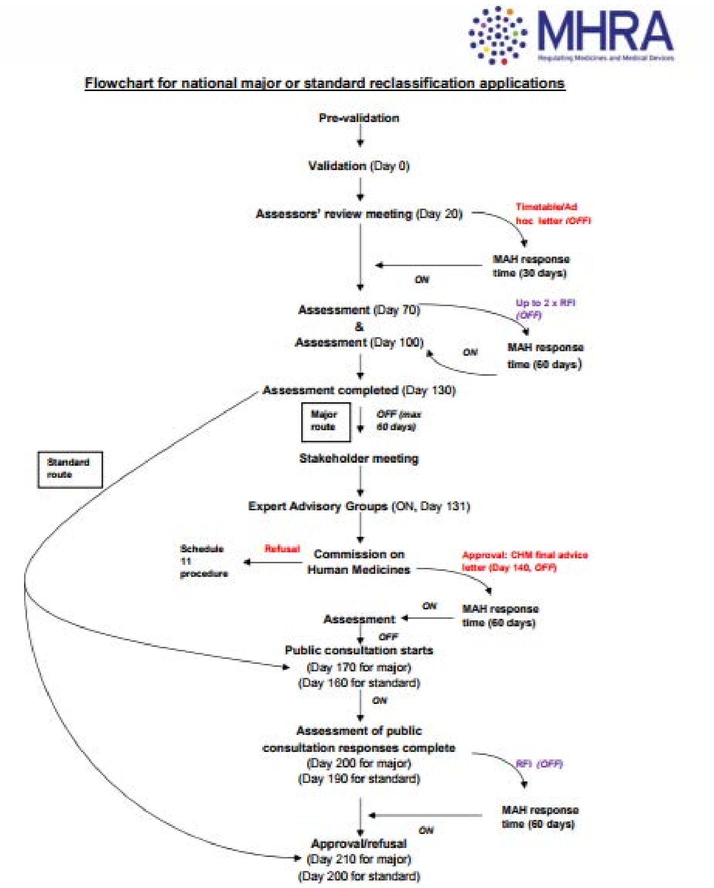
UK Medicines Reclassification Platform

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



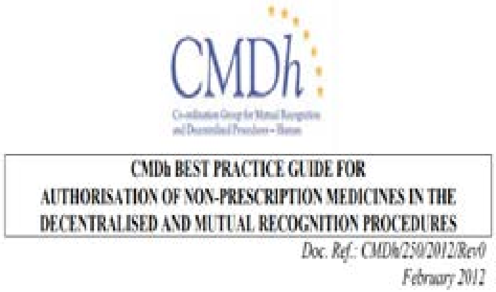
MHRA
Flowchart for national major or standard reclassification applications
Pre-validation
Validation (Day 0)
Assessors' review meeting (Day 20)
Timetable/Ad hoc letter (OFF)
MAH response time (30 days)
ON
Assessment (Day 70)
&
Assessment (Day 100)
Up to 2 x RFI (OFF)
ON
MAH response time (60 days)
Assessment completed (Day 130)
Major route
OFF (max 60 days)
Standard route
Stakeholder meeting
Expert Advisory Groups (ON, Day 131)
Schedule 11 procedure
Refusal
Commission on Human Medicines
Approval: CHM final advice letter (Day 140, OFF)
ON
MAH response time (60 days)
Assessment
OFF
Public consultation starts
(Day 170 for major)
(Day 160 for standard)
ON
Assessment of public consultation responses complete
(Day 200 for major)
(Day 190 for standard)
RFI (OFF)
MAH response time (60 days)
ON
Approval/refusal
(Day 210 for major)
(Day 200 for standard)

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


CMDh

CMDh BEST PRACTICE GUIDE FOR AUTHORISATION OF NON-PRESCRIPTION MEDICINES IN THE DECENTRALISED AND MUTUAL RECOGNITION PROCEDURES

Doc. Ref.: CMDh/250/2012/Rev0

February 2012

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