



Medicines & Healthcare products
Regulatory Agency



Incentives for 'Switching' – the UK experience

Jan MacDonald



- UK OTC market
- Incentives
 - Legislative
 - Policy
 - Professional
- Future of the market

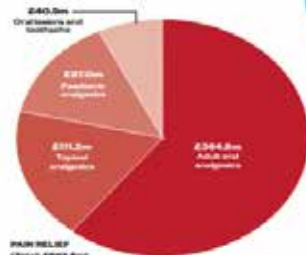
UK Over-the-Counter Market

- Across EU only 7 molecules are commonly available
- In UK ~ 75 molecules
- UK market worth £2.62bn (2016)

A BREAKDOWN OF THE OTC MARKET IN BRITAIN IN 2016

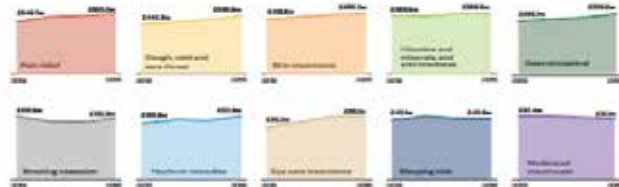
The over-the-counter medicines market grew by 2.7% during 2016 to reach £2.62bn.

DAWN CUNNEILL



Trends in OTC products by category

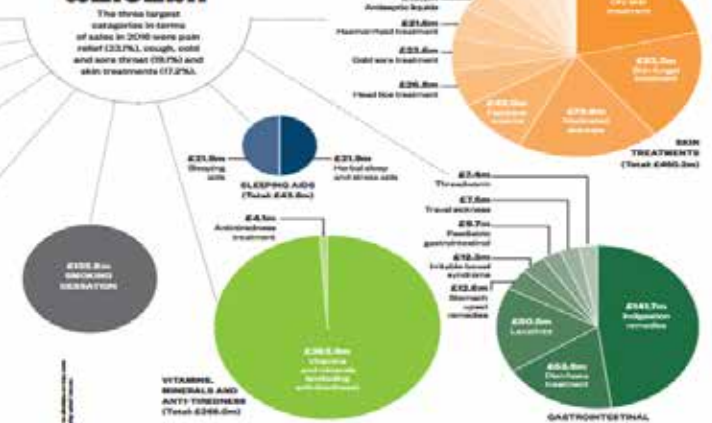
Sales in most categories have increased over the past four years, with the exception of smoking cessation and medicinal mouthwash, where sales have slightly decreased overall.



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£2.62bn

The three largest categories in terms of sales in 2016 were pain relief (30.7%), cough, cold and sore throat (29.7%) and skin treatments (17.2%).



Top 20 brands by sales
 NDI continued to dominate the branded OTC medicines market in 2016, with 6 products in the top 20 brands. Retailers' own label products had an 18.7% share of the market.

Rank	Brand	Company	Value	Share
1	11111	11111	111.1	4.2%
2	11111	11111	111.1	4.2%
3	11111	11111	111.1	4.2%
4	11111	11111	111.1	4.2%
5	11111	11111	111.1	4.2%
6	11111	11111	111.1	4.2%
7	11111	11111	111.1	4.2%
8	11111	11111	111.1	4.2%
9	11111	11111	111.1	4.2%
10	11111	11111	111.1	4.2%
11	11111	11111	111.1	4.2%
12	11111	11111	111.1	4.2%
13	11111	11111	111.1	4.2%
14	11111	11111	111.1	4.2%
15	11111	11111	111.1	4.2%
16	11111	11111	111.1	4.2%
17	11111	11111	111.1	4.2%
18	11111	11111	111.1	4.2%
19	11111	11111	111.1	4.2%
20	11111	11111	111.1	4.2%

- 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

HOW TO CHANGE THE LEGAL CLASSIFICATION
OF A MEDICINE IN THE U.K.

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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.



London, 26 July 2006
Doc. Ref. EMEA/106278/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
(CHMP)

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

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

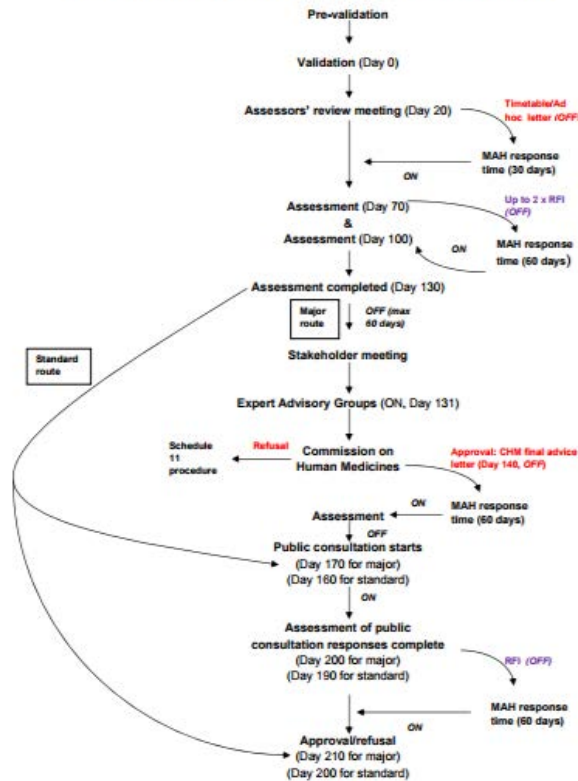
UK Stakeholder Platform



UK Medicines Reclassification Platform

The UK Medicines Reclassification Platform for the 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.

Flowchart for national major or standard reclassification applications



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 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

