UK strategy for reclassification of medicines

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MHRA commitment to reclassification

- Reclassification of medicines to non-prescription when safe to do so and clear benefit to public health

- Government policy to widen access to medicines
  - best use of healthcare professional resources
  - supports patient empowerment through self-care

- Leading role in non-traditional indications currently unique to UK or available in only a few other countries worldwide
Two legal categories for UK non-prescription medicines

Do the criteria for prescription-only apply?
NO = Pharmacy medicine (P)

Is sale without pharmacy supervision reasonably safe and would it be convenient?
YES = general sale list (GSL)
Pharmacy only - P

• Pharmacy supervision allows innovative reclassifications, supported by protocols and training materials as needed

• Support from UK pharmacy professional bodies
General Sale List (GSL)

- Supermarkets and other retail outlets
- Convenience and increased choice of medicines where safe for sale without pharmacy supervision
MHRA reclassification programme

• New streamlined UK reclassification guideline

• Engaging in the European Commission project on ‘promoting good governance for non-prescription’ drugs

• National stakeholder platform on reclassification of non-prescription medicines
Streamlining Reclassification

- Focus on all OTC supply – POM to P & P to GSL
- More (collaborative) work before submission
- Evidence of safe OTC use in other countries
- Stakeholder group only for some innovative applications
- Analysis of the benefits as well as the risks of wider access
• The new guidance has a specific section on benefit-risk assessment based on the Brass model.

• This is intended to help applicants evaluate a candidate product prior to submission, to provide a rationale for their justification that the balance of benefits and risks are in favour of the product as a non-prescription medicine.

• Benefit-Risk assessment looks beyond the product itself and considers wider issues such as:
  – Public health
  – The roles of healthcare professionals – pharmacists and doctors
  – The importance of consumer information to manage risks and ensure greatest benefit is gained from use of the medicine
  – Timeliness and speed of access
• OTC medicines have different types of benefits…..
Evolving safety issues

• New information needs to be evaluated in OTC setting as well as for prescription medicines

• Safety reviews Europe-wide but legal classification is a competent authority matter

• No systematic review of older medicines – but is information up-to-date?
Within the current regulatory framework, measures that could increase accessibility to non-prescription medicines for patients/consumers in the EU.
Stakeholder Perspectives

- **Safety** is main priority for all stakeholders but should be seen in context of benefit.
- People need **information and support** to help them make informed decisions.
- Doctors and pharmacists have **important role** to play in supporting people in self-care - providing information and advice proactively.
Ten Recommendations

1. Consider successful switch elements
2. Industry innovation
3. Early involvement of all stakeholders
4. Collaboration within MSs
5. Stakeholder cooperation on list of EU OTCs
6. National platforms for OTC
7. Pharmacovigilance for OTCs - collaboration
8. Health professional training on self-care
9. Knowledge & skills of citizens on self-care
10. Information on reclassifications to all stakeholders
UK Stakeholder Platform for Reclassification of Non-prescription medicines

- To increase stakeholder engagement and to ensure the public receives maximum benefit from wider access to medicines when it is safe to do so
- To advise on strategies and processes to ensure the public has the support needed, including from healthcare professionals, to benefit from increased access to medicines after reclassification.
Areas covered

• Increasing transparency and visibility on assessment and the outcome, including refusal

• Making pharmacists and doctors more aware of new reclassifications through methods independent of the manufacturer

• Further analysis of risk management plans to meet the needs of pharmacists and doctors as well as effectively manage the risks associated with reclassification

• A fundamental review of the reclassification public consultation process to ensure that it is fit for purpose
Emerging issues

- Supervision of pharmacy medicines
- National Health Service availability after reclassification
- Public perceptions of the effectiveness of OTCs
- Confusion about pack sizes, and limitations on indications, dose and length of treatment
- Ensuring consistent messages from HCPs and in patient leaflets
- Evidence of safety and effectiveness in use post-reclassification
- Need for increased awareness within the medical profession of reclassified products
Next Steps

Regular meetings to continue the work of increasing stakeholder engagement …

… with a view to achieving successful reclassification applications which contribute positively to public health.