Innovation in medicines reclassification

The Search for Switch Candidates - the Irish experience

Dr Lorraine Nolan, CE HPRA
19th Oct 2017
"Promote a ‘better regulation’ approach to effective legislation in areas such as mechanisms to facilitate reclassification of medicines"
HPRA Strategic Plan 2016-2020

Proactive approach
Adaptive response
Continued review
Developing our approach to reclassification

PROACTIVE

TIME TO ADAPT
Proactive Approach

The Independent Consultative Panel on Legal Classification of Medicines

- List of 12 active substances published by HPRA
  - > 30 medicines
  - Conditions covered: gastrointestinal disorders, dermatological conditions, pain management
  - Perception

Recommendations from panel

- Diclofenac 2% gel
- Triamcinolone nasal spray
- Product A - pending completion
List of 12 active substances published by HPRA

> 30 medicines

Conditions covered: gastrointestinal disorders, dermatological conditions, pain management

Perception
Diclofenac 2% gel
Triamcinolone nasal spray

*Product A - pending completion*
TIME TO ADAPT
Adaptive response

Case Study- Dovonex Psoriasis

Approval
- Product met required switching criteria
- Suitable for reclassification
- Amendments to SmPC, PIL, carton and label
- Approval April 2016

Changes
- Application constructed educational strategy with the Pharmaceutical Society of Ireland, the Irish Pharmacy Union, the Irish Skin Foundation and the Irish Pharmaceutical Healthcare Association
- Labelling clearly outlines where patients should seek medical advice and requires annual check-up
- Retention of original POM status (not marketed in EU)
- New look carton
- Never altered slightly

Assessment Process
- Assessment in line with principles detailed in EC "Guideline on changing the classification for the supply of a medicinal product for human use", and the HPA's "Guide to the reclassification (Switch) of legal supply status of human medicinal products"
- Two pre-submission meetings with applicant
  - Induction
  - TARGET population
  - Educational strategies

Salient Differences
List 2 Reclassification - Dovonex Psoriasis

Oct 2015 Company submission to HPRA

**Product:** Dovonex 50mcg/g ointment

**Reclassification:** POM (non-renewable) to OTC

**Active ingredient:** Calcipotriol

**Indication:** The topical treatment of plaque psoriasis and may also be used in combination with acitretin, ciclosporin or topical corticosteroids
Assessment Process

• Assessment in line with principles detailed in EC "Guideline on changing the classification for the supply of a medicinal product for human use" and the HPRA's "Guide to the reclassification (Switching) of legal supply status of human medicinal products"

• Two pre-submission meetings with applicant
  • Indication
  • Target population
  • Educational strategies
Approval

- Product met required switching criteria
- Suitable for reclassification
- Amendments to SmPC, PIL, carton and label
- Approval April 2016
### Salient Differences

<table>
<thead>
<tr>
<th>Prescription only product</th>
<th>OTC pharmacy product</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
<td>Dovonex 50 mcg/g Ointment</td>
</tr>
<tr>
<td></td>
<td><strong>Dovonex Psoriasis</strong> 50 mcg/g Ointment</td>
</tr>
<tr>
<td><strong>Indication</strong></td>
<td>Dovonex is indicated for the topical treatment of Plaque psoriasis.</td>
</tr>
<tr>
<td></td>
<td>Dovonex Psoriasis is indicated for topical treatment of adults with mild to moderate plaque psoriasis which has previously been diagnosed by a doctor.</td>
</tr>
<tr>
<td></td>
<td>Plaque psoriasis is mild to moderate when the area affected does not exceed 10% of body surface area (for guidance purposes, the body surface area of an arm is approximately 9%).</td>
</tr>
<tr>
<td><strong>Active substance</strong></td>
<td>Calcipotriol</td>
</tr>
<tr>
<td></td>
<td>Calcipotriol</td>
</tr>
<tr>
<td><strong>Posology</strong></td>
<td>Apply once to twice daily</td>
</tr>
<tr>
<td></td>
<td>Apply once daily</td>
</tr>
<tr>
<td><strong>Max weekly dose</strong></td>
<td>100 g in adults. (Lower in 6-18 year olds)</td>
</tr>
<tr>
<td></td>
<td>100 g</td>
</tr>
<tr>
<td><strong>Target population</strong></td>
<td>6 years of age and older</td>
</tr>
<tr>
<td></td>
<td>Adults only</td>
</tr>
<tr>
<td><strong>Method Of Sale and Supply</strong></td>
<td>Subject to medical prescription which may not be renewed</td>
</tr>
<tr>
<td></td>
<td>Not subject to medical prescription. Supply through pharmacies only</td>
</tr>
</tbody>
</table>
Each gram contains 0.05 mg of calcipotriene in a cream base of cetearyl alcohol, ceteth-20, diazolidinyl urea, dichlorobenzyl alcohol, dibasic sodium phosphate, edetate disodium, dl-alpha tocopherol, glycerin, mineral oil, petrolatum, and water.

Manufactured by: LEO Laboratories Ltd., Dublin, Ireland
Distributed by: LEO Pharma Inc., 1 Sylvan Way, Parsippany, NJ 07054, USA, 1-877-494-4536
U.S. Patent No. RE39,706 E
To report SUSPECTED ADVERSE REACTIONS, contact LEO Pharma Inc. at Phone 1-877-494-4536 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

WARNING: Keep Out of Reach of Children.

FOR TOPICAL DERMATOLOGIC USE ONLY.
Not for Ophthalmic, Oral or Intravaginal Use.
Usual Dosage: Apply twice daily, or as directed by physician.
See Insert for complete information.
Read all panels.
Lot no. and expiration date on carton end and crimp of tube.

NDC 50222-260-12
Rx only
Dovonex®
(calcipotriene) Cream, 0.005%%

Net Wt. 120 g

Store at controlled room temperature
15° C - 25° C (59° F - 77° F).
Do not freeze.
Dovonex®
PSORIASIS 50 microgram/g ointment
calcipotriol

- Topical treatment for adults previously diagnosed with mild to moderate plaque psoriasis
- Patients with psoriasis should see their doctor once a year for review
Changes

• Applicant coordinating educational strategy with the Pharmaceutical Society of Ireland, the Irish Pharmacy Union, the Irish Skin Foundation and the Irish Pharmaceutical Healthcare Association

• Labelling clearly outlines where patients should seek medical advice and recommends annual check-up

• Retention of original POM product (not marketed in IE)
  • New look carton
  • Name altered slightly
Key Lessons Learned

- Early engagement
- Legal basis defined early
- Organisational input
- Resource constraints (MAH)
- Value of relationships
- Buy in - HCPs, stakeholders
- Information dissemination
- European/Global awareness
Barriers

Time

Complexity in terms of small market

Commercial factors- global decisions; loss of reimbursement

No central patient medical record database

Differences across member states healthcare systems, product names differ, product -v- substance based reclassification
Future considerations

Combined proactive and adaptive response

Early engagement with applicant

Appropriate infrastructure- records and databases

Political appetite

Engagement with key stakeholders incl. educational strategy

Continued up-skilling of pharmacists/ Buy in from medical practitioners

Review reimbursement nationally and across Europe

Utilise resources available to us- Council of Europe (EDQM-melclass), EMA, ...

Expanded remit
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