

Innovation in medicines reclassification

The Search for Switch Candidates- the Irish experience

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HPRA

"Promote a 'better regulation' approach to effective legislation in areas such as mechanisms to facilitate reclassification of medicines"
HPRA Strategic Plan 2016-2020

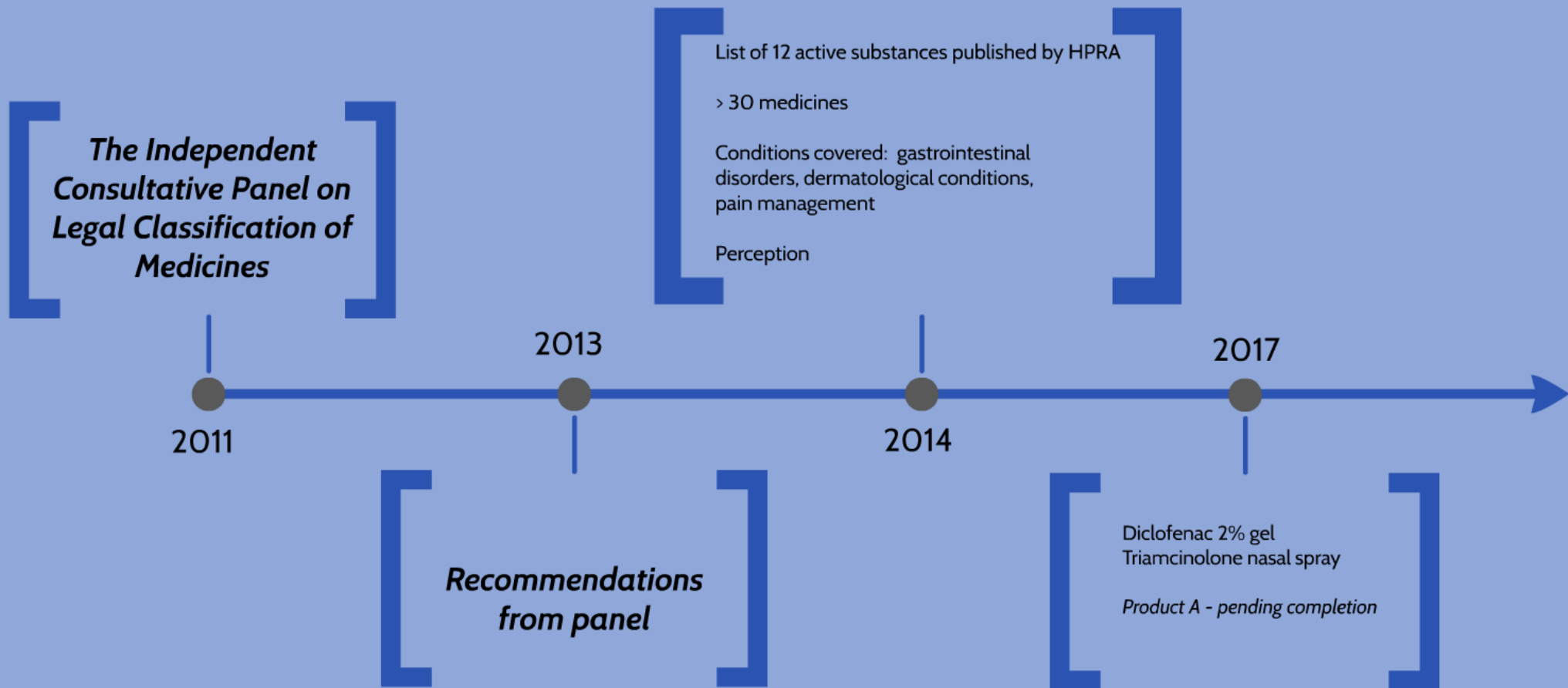
Proactive approach
Adaptive response
Continued review

Developing our approach to reclassification

PROACTIVE



Proactive Approach

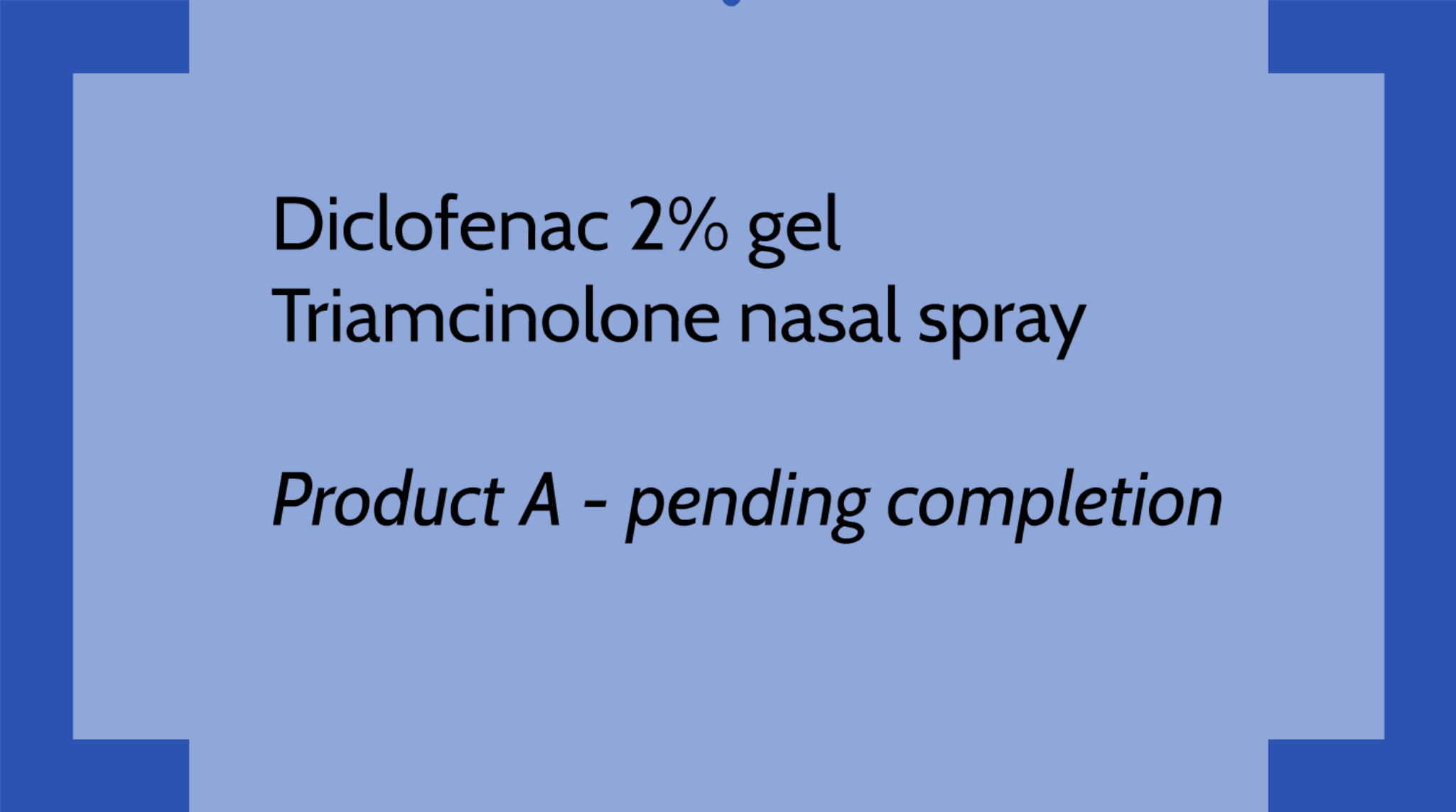


List of 12 active substances published by HPRA

> 30 medicines

Conditions covered: gastrointestinal disorders, dermatological conditions, pain management

Perception



Diclofenac 2% gel
Triamcinolone nasal spray

Product A - pending completion



Adaptive response

Case Study- Dovonex Psoriasis

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

Approval

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

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

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

Salient Differences

	Promethazine only product	OTC pharma product
Name	Promethazine only product	OTC pharma product
Indication	Promethazine only product	OTC pharma product
Contraindications	Promethazine only product	OTC pharma product
Warnings	Promethazine only product	OTC pharma product
Precautions	Promethazine only product	OTC pharma product
Interactions	Promethazine only product	OTC pharma product
Side effects	Promethazine only product	OTC pharma product
Pharmaceutical	Promethazine only product	OTC pharma product

Case Study- Dovonex

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Salient Differences

	Prescription only product	OTC pharmacy product
Name	Dovonex 50 mcg/g Ointment	Dovonex Psoriasis 50 mcg/g Ointment
Indication	Dovonex is indicated for the topical treatment of Plaque psoriasis. Dovonex may also be used in combination with acitretin, ciclosporin or topical corticosteroids.	Dovonex Psoriasis is indicated for topical treatment of adults with mild to moderate plaque psoriasis which has previously been diagnosed by a doctor. 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%).
Active substance	Calcipotriol	Calcipotriol
Posology	Apply once to twice daily	Apply once daily
Max weekly dose	100 g in adults. (Lower in 6-18 year olds)	100 g
Target population	6 years of age and older	Adults only
Method Of Sale and Supply	Subject to medical prescription which may not be renewed	Not subject to medical prescription. Supply through pharmacies only



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

LEO[®]

Store at controlled room temperature
15° C - 25° C (59° F - 77° F).
Do not freeze.



Dovonex[®]
(calcipotriene) Cream,
0.005%

Net Wt. 120 g

024607-XX



50 x 38 x 210

LOT
EXP.



Dovonex[®]

PSORIASIS 50 microgram/g ointment
calcipotriol

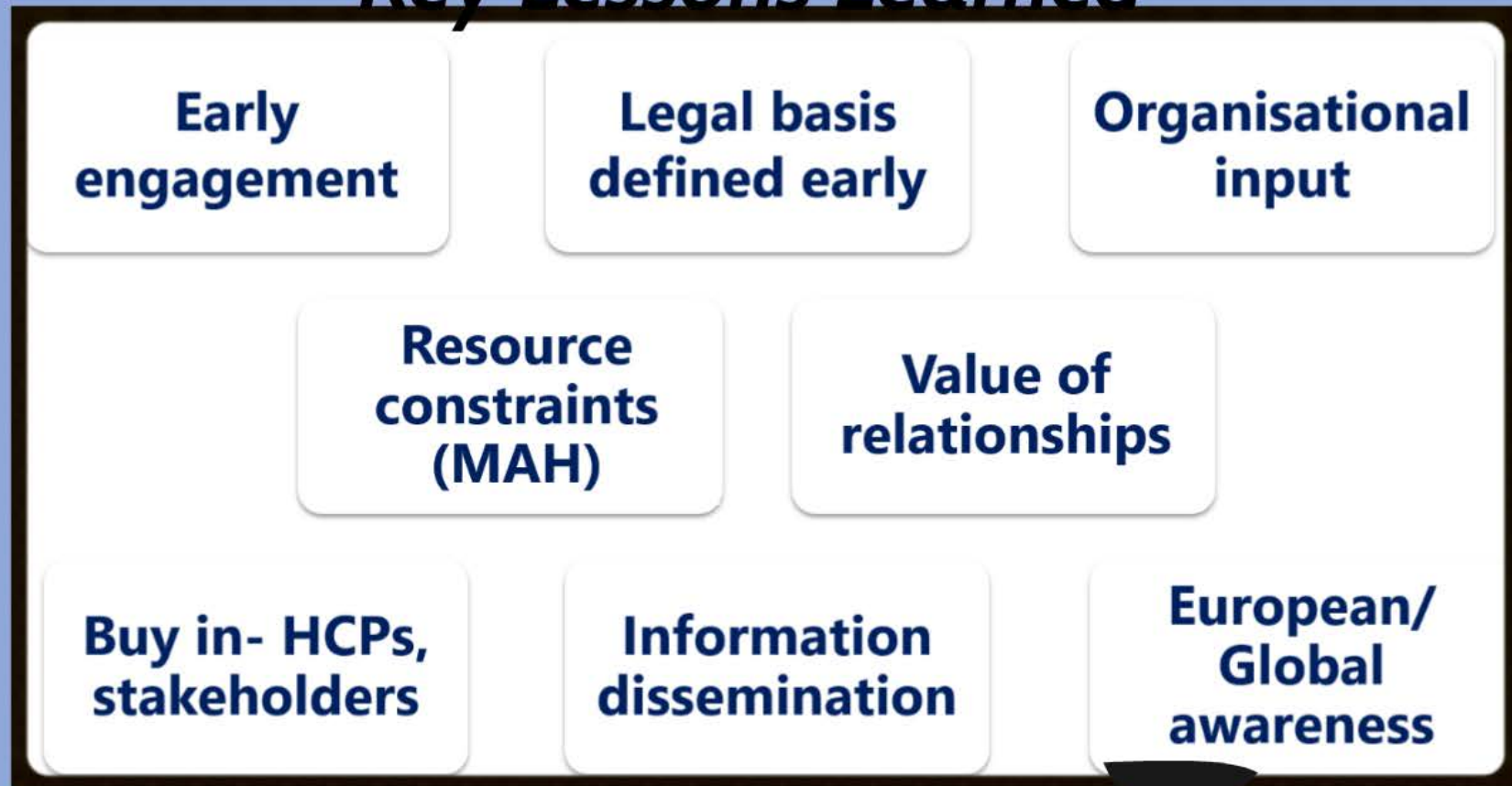
- ▶ Topical treatment for adults previously diagnosed with mild to moderate plaque psoriasis
- ▶ Patients with psoriasis should see their doctor once a year for review



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Key Lessons Learned



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, C

Expanded remit

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