Strategic plan for harmonization phaseout of Metered Dose Inhaler (MDI) using chlorofluorocarbon (CFC) as propellant in Thailand.

Presented by

Por Punyaratabandhu
PMU hired The Allergy and Immunology Society of Thailand as consultant.

The Allergy and Immunology Society of Thailand

• Society of specialists practicing in the treatment of allergy and COPD (Chronic Obstructive Pulmonary Diseases)
• Capable of coordinating with FDA and Essential Drug List Committee
• Capable of coordinating with other professional societies, pharmaceutical companies and patient clubs

Scope of Work

• Finding out present status of Thailand
• Identifying difficulties in phasing out of CFC MDI
• Proposing Strategic plan to phasing out CFC MDI
• Disseminating information to medical professionals, patients, and public.
Information of CFC MDI, non-CFC MDI, and DPI in Thailand

- All formulations are imported into Thailand.
- The first CFC MDI import into Thailand was in 1984.
- The first CFC-free inhaler launched in Thai market was DPI in 1990 while the first HFA MDI appeared in 1997.
- Prices of CFC MDI and HFA MDI are in the same level.

Total amounts (puff) and cost (Baht) of all forms of portable, hand-held, inhaled drugs imported for treating asthma and COPD in Thailand during 1996-2003.
Projections of consumption of all forms of portable, hand-held, inhaled drugs for treating asthma and COPD in Thailand for the next five and ten years (data are approximate)
Progress of transition from CFC MDIs to non-CFC MDIs and DPIs in Thailand.
Potential barriers to CFC MDI phaseout

- insufficient types and quantities
- price of CFC alternatives
- medical practice
- patient preferences
- regulatory factors

Retrospective survey and Clinical Study of patient preference and sensory comparison for three inhalers

- 280 questionnaires were filled by physicians
- 418 questionnaires were filled by patients
- 419 clinically tested in 9 clinics of 6 teaching hospitals

(A multicenter, comparative, double blind, crossover, randomized study)
Clinical Outcomes:

- CFC MDI was significantly less irritation but the least liking amongst the three inhalers.
- The most preferable inhaler was DPI.
- There was no significant different between CFC MDI and non-CFC MDI.

Conclusion of these studies

- The conversion from CFC MDI to non-CFC MDI was voluntarily occurred from 1999.
- The price of CFC MDI and non-CFC MDI was in the same level.
- The price of DPI was 3 to 5 times higher than CFC MDI and non-CFC MDI.
- There was one alternative product of bronchodilator non-CFC MDI in the market.
- There was no alternative product of anti-inflammatory non-CFC MDI in the market.
- There was no psychological nor preference effects in Thai patients.
- The most concerns over conversion of CFC MDI to non-CFC MDI were affordability of drug price and availability of alternative inhalers in the market.
“SWOT” analysis for CFC MDI transition strategic plan.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Weakness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Potential hazard to the environment and health.</td>
<td>1. Lack of awareness.</td>
</tr>
<tr>
<td>2. Availability of replacements by the initiation of the multinational pharmaceutical companies as a result of the international concern.</td>
<td>2. Adherence to CFC-form</td>
</tr>
<tr>
<td>3. the Ozone Secretariat encouraged the parties to formulate the national transition strategy by January 31, 2005. (Protocol Decision XII/2, 2000)</td>
<td>- Patient preference/experience</td>
</tr>
<tr>
<td></td>
<td>- Physician preference/experience</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunity</th>
<th>Threat</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Increased knowledge/awareness of</td>
<td>1. Insufficient types</td>
</tr>
<tr>
<td>- Physicians</td>
<td>quantities of replacement/alternatives</td>
</tr>
<tr>
<td>- Patients</td>
<td>compromise supply to the patients</td>
</tr>
<tr>
<td>- Pharmaceutical companies</td>
<td>2. Reduce treatment options</td>
</tr>
<tr>
<td>2. Increased CFC-free inhalers importation.</td>
<td>3. High cost</td>
</tr>
</tbody>
</table>
Substitution criteria:

1. Same route of administration.
2. Same indications.
3. Approx. same level of convenience.
4. Adequate production capacity.
5. Adequate post-marketing data.
6. Patients are adequately served.

1 – 6  Same as U.S.A.
7. Sufficient supply and affordable by all.

U.S.A.  Thailand
Phaseout strategic plan

1. Educational program
2. Phaseout decision with regulatory enforcement
Educational program

- **targets**: medical profession - physicians, pharmacists, healthcare providers, etc.
  - patients and public

- **procedures**: - promotional materials: brochures, posters, VDO/DVD
  - media e.g. TV/Radio, websites, publications.

- **timetables**: before - during - after phaseout.

- **responsible parties**: - FDA/MPH
  - AIST, other professional societies
  - patient associations, support groups
  - pharmaceutical companies
  - DIW
Phaseout decision with regulatory enforcement

- **targets:**
  - importation prohibition
  - sale and distribution prohibition
  - accelerated registration of new alternatives
  - comparable price of DPIs and other alternative

- **procedures:**
  - set reduction schedule
  - voluntary product withdrawal
  - manage stockpiling
  - encourage importation of new alternatives/fast tract registration
  - discontinuation of CFC MDI reimbursement
  - possible means to control the price

- **timetable:**
  - ???

- **responsible parties:**
  - FDA/MPH
  - Healthcare providers
  - Pharmaceutical companies
**Phaseout decision:**
- suitable alternatives = Non-CFC MDIs and DPIs
  - 2 alternatives from different producers in each category
  - reduction schedule
  - control price
  - constant awareness raising campaign
  - regulatory enforcement

**Procedure:**
FDA appoint “ad hoc working groups”
FDA has appointed this working group on March 10, 2005 and PMU is one of its committee.
On going-Awareness raising campaign by
Allergy and Immunology Society of Thailand

For Health Professionals

1. February 10, 2005  25 Nurses and technicians  Asthma Education
2. March 27, 2005  300 Pharmacists  Pharm. Care
3. May 4, 2005  300 General Practitioners  Family Physicians
4. May 10, 2005  300 Allergists and Immunologists  Asthma update

For Patients and Public

1. February 20, 2005  182 Patients and Families  Allergy Club, Bangkok
2.  150-200 “ “  Allergy Club, Chiang Mai
3.  150-200 “ “  Allergy Club, Khon Kaen
4.  150-200 “ “  Allergy Club, Hard Yai

For General Public

1. Brochures, Posters
2. VCD/DVD or VDO for OPD Education
3. Scientific/non-scientific Publications
4. Radio
5. Television
Thank You

Sawadee Krub