Philippine Strategy for the Transition from CFC-containing MDIs to CFC-Free Alternatives

under the National CFC Phase-out Plan (NCPP)
Developing the Transition Strategy

- Findings of the study of the MDIs in the Philippines;
- Seminar/consultative meetings with concerned stakeholders;
- Regulatory framework in the Philippines as implemented by the Bureau of Food and Drugs (BFAD);
- Experiences of other developed countries; and
CFC CONSUMPTION PATTERN

- **50% reduction**
- **80% reduction**
- **Total phase out**

- **Total CFCs**
- **Montreal Protocol**
Background of the Strategy

- CFCs used in MDIs do not figure in the previous CFC consumption pattern chart since CFC-MDIs are finished products.

- Thus, CFCs used in MDIs are reported in the CFC consumption of the manufacturing country.

- Yet, the Philippines must formulate a transition strategy in order to prepare for the time when CFC-containing MDIs will no longer be available.

- It is necessary to ensure that patients will not be without essential drugs during the transition.
Strategy to Ensure Compliance with MP

- Determine the MDI use situation in the country;
- Some changes to the requirements and procedures for registration, and other policies;
- Setting the end-dates for the regulatory phase-out of CFCs from MDIs; and
- Assist the sectors that will be affected by the phase-out of controlled uses of MDIs.
HIGHLIGHTS OF THE PHILIPPINE MARKET SITUATIONER ON CFC CONTAINING MDIs AND CFC FREE ALTERNATIVES
## MDI PHILIPPINE MARKET SITUATIONER

### AVAILABILITY AND USAGE PER ACTIVE INGREDIENT-STRENGTH COMBINATION, CLASSIFIED BY PHARMACOLOGICAL CATEGORY

<table>
<thead>
<tr>
<th>Pharmacological Category</th>
<th>Number of Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenergic Bronchodilators</td>
<td>26</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>24</td>
</tr>
<tr>
<td>Anticholinergics</td>
<td>2</td>
</tr>
<tr>
<td>Combinations (A+B)</td>
<td>6</td>
</tr>
<tr>
<td>Combinations (A+C)</td>
<td>2</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>63</strong></td>
</tr>
</tbody>
</table>

**Note:** Of the 63 products in the list, there are 4 MDI products with same brand name & presentation/packaging but with different propellants that exist in the market as both CFC containing and CFC-Free MDIs.
## COMPANIES IMPORTING/DISTRIBUTING MDI PRODUCTS

<table>
<thead>
<tr>
<th>Manufacturer/Importer</th>
<th>Distributor</th>
</tr>
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<tbody>
<tr>
<td>3M</td>
<td>Metro Drug</td>
</tr>
<tr>
<td>Aldo-Union</td>
<td>Cathay Drug</td>
</tr>
<tr>
<td>Chiesi</td>
<td>Marketlink</td>
</tr>
<tr>
<td>Westmont</td>
<td>ULI</td>
</tr>
<tr>
<td>GlaxoSmithKline Phils. Inc.</td>
<td>Zuellig</td>
</tr>
<tr>
<td>IG-Spruhtechnik/Bole</td>
<td>JRalph Pharma</td>
</tr>
<tr>
<td>Pharmachemie</td>
<td>Marketlink</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Zuellig</td>
</tr>
<tr>
<td>Boehhringer Ingelheim</td>
<td>Metro Drug</td>
</tr>
<tr>
<td>Novartis Healthcare</td>
<td>Zuellig</td>
</tr>
<tr>
<td>Schwarz Pharma</td>
<td>Zuellig</td>
</tr>
<tr>
<td>Fisons</td>
<td>ULI</td>
</tr>
</tbody>
</table>
The 63 products in the market can be classified as follows:

- **As to preparation/form**
  - 36 MDIs, 29 propellants free, 2 undetermined/lacking data

- **As to CFC content**
  - 17 CFC-containing products, 41 CFC-free, 9 undetermined/lacking data

- **As to availability of CFC-free alternatives**
  - Upon preliminary analysis for availability of TEFA, it was found out that:
    - There are 4 unique active ingredient-strength combinations that are present only as CFC-containing MDIs;
    - There are 7 unique active ingredient-strength combinations that are present as both CFC-containing MDIs & CFC-free – 4 of which have at least 2 CFC-free alternatives
    - There are 24 products present only as CFC-free alternatives
SUMMARY CHART
Availability of CFC-containing MDIs and CFC-free Alternatives

Note:

a The 4 Active Ingredient-Strength combinations that are present only as CFC-containing are:
1. Terbutaline Sulfate 250 mcg
2. Samleterol 25 mcg
3. Ipratropium 20 mcg
4. Ipratropium + Salbutamol 21 mcg + 250 mcg

b The 7 Active Ingredient-Strength combinations that are present as CFC-containing and CFC-free are:
1. Salbutamol 100 mcg*
2. Fenoterol 100 mcg
3. Budesonide 100 mcg*

4. Budesonide 200 mcg*
5. Fluticasone 5o mcg*
6. Fluticasone 125 mcg
7. Fenoterol + Ipratropium 50 mcg + 20 mcg

* Has at least 2 CFC-free alternatives
TEFA Analysis for Salbutamol MDIs

• Out of the 720,240 units sold, sales of CFC-free Salbutamol MDI in year 2003 reached 710,659 units.

• Evidence that CFC-free Salbutamol MDI is already well established in the market and that the CFC-containing Salbutamol MDI maybe considered for phase-out.

• The early phase-out of CFC Salbutamol MDI is expected to result in the removal of a large percentage of CFC-containing MDIs in the Philippine market.
PHILIPPINE REGULATORY FRAMEWORK FOR DRUGS

• Republic Act (RA) 3720 or the *Food, Drugs, and Cosmetics Act*, as amended by Executive Order (EO) 175:
  - *An Act to ensure the safety and purity of foods and cosmetics, and the purity, safety, and efficacy of drugs devices, being made to the Public, to regulate importation, manufacture, distribution and sale of processed foods, drugs and medicines, medical devices, and household hazardous substances, to ensure the safety, efficacy and quality of these regulated products.*

• Products ordered banned by BFAD can be confiscated at any point in the supply line - at importation at the ports of entry, and distribution and sale at the retail outlets/drugstores is in cooperation with the BFAD’s partner government agencies.

• Necessary penalties are imposed by BFAD on companies that violate the conditions of the ban.
PHILIPPINE REGULATORY FRAMEWORK FOR DRUGS

• CFC-containing MDIs clearly fall under the Bureau of Food and Drugs (BFAD) jurisdiction and control.
• Drug products must first be determined by BFAD to be safe, effective and of good quality before they are registered and given marketing authority.
• Since MDIs contain potent pharmacologic drugs, MDIs are classified as prescription drugs wherein only licensed physicians prescribe MDIs.
• MDIs are used in the management of patients with bronchial asthma (BA), chronic obstructive pulmonary disease (COPD), and other respiratory conditions.
PHILIPPINE REGULATORY FRAMEWORK FOR DRUGS

- MDIs are dispensed by pharmacists at drugstores and health facilities only under a physician’s prescription to ensure that these medicines are:
  - used for the right therapeutic indications (e.g. BA & COPD)
  - given in the right doses
  - administered properly

- As prescription drugs, MDIs cannot be bought over-the-counter (OTC) by customers without a doctor’s prescription.

- Cannot be advertised directly to the public through mass media.

- Companies which sell MDI products can only advertise through medical journals, or promote them directly to medical professional.
PHILIPPINE REGULATORY FRAMEWORK FOR DRUGS

• To implement the regulatory phase-out of CFC-containing MDIs and phase-in of CFC-free alternatives, some changes to the requirements and procedures for registration, and other policies of BFAD may be necessary during the transition period.
PHILIPPINE TRANSITION STRATEGY
PHILIPPINE TRANSITION STRATEGY

- The firm end dates for the complete regulatory phase-out of CFC-containing MDIs, once TEFA become available and sustainable in the market, are set within the timeframe of the Montreal Protocol as follows:
  - EO year 2007: for CFC-containing Salbutamol MDIs
  - EO year 2010: for all other CFC-containing MDIs

- End dates will be subject to review and recommendation by an Expert Panel created by the BFAD composed of representatives from the affected and interested sectors to ensure that TEFAs are available and its supply is sustainable.
REGULATORY PHASE-OUT CRITERIA

1. Existence of at least 1 TEFA, but preferably 2 TEFAs – either in the form of CFC-free MDI using non-ozone depleting HFC 134a as propellant, or dry powder inhalers without propellant.

2. One (1) year post-marketing and/or post-marketing surveillance showing no adverse reaction and acceptability to patients and doctors.

3. Presence of acceptable TEFA or TEFAs including determination whether the needs of special sub-populations are served.

4. End-date for regulatory phase-out of CFC-containing MDIs must not be later than 1 year after declaration of existence of TEFAs by BFAD Expert Panel on the Transition, or by year 2010, whichever is earlier.
PHILIPPINE TRANSITION STRATEGY
Ten (10) Key Transition Strategies

1. Inform the stakeholders and the public of the impending shift through IEC activities.
   - Publication of the Department Administrative Order (DAO) 156
     - Signed and approved last 24 June 2004
     - Published last 12 September 2004
     - Control, regulate and eventually phase-out the importation of CFC-containing MDIs in the country.
   - Conduct of series of seminars/consultative conferences with affected and interested parties
   - Preparation/distribution of target-oriented information leaflets/posters and mass media
   - Development and management of a web page
   - Development of a communication plan for the MDI sector
## Communication Plan

**Sector: MDI**

<table>
<thead>
<tr>
<th>Target Audiences</th>
<th>Audience Analysis</th>
<th>Communication Objectives</th>
<th>Medium/ Media Mix</th>
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<tbody>
<tr>
<td>• MDI Importers – Pharmaceutical Industry</td>
<td>1. Demographic Characteristics</td>
<td></td>
<td>• Interpersonal Media</td>
</tr>
<tr>
<td>• Regulatory Agency</td>
<td>2. Psychosocial Characteristics</td>
<td></td>
<td>• Print</td>
</tr>
<tr>
<td>• Physicians (Pulmonary Specialists)</td>
<td>3. Level of Knowledge on ODS Phaseout</td>
<td>Knowledge Change Objective</td>
<td>• Broadcast</td>
</tr>
<tr>
<td>• Community Pharmacy</td>
<td>4. Attitude towards ODS Phaseout</td>
<td>Attitude Change Objective</td>
<td>• Film</td>
</tr>
<tr>
<td>• Patients</td>
<td>5. ODS Phaseout-related Behavior</td>
<td>Behavior Change Objective</td>
<td>• Special Media</td>
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</table>
PHILIPPINE TRANSITION STRATEGY
Ten (10) Key Transition Strategies

2. Advance signal to pharmaceutical companies concerned that CFC-containing MDIs will be phased-out.
   • Limiting the validity of new CFC-containing MDIs applying for registration or marketing authorization.
   • Renewal of current CPR for CFC-containing MDIs will also be limited to 1 year validity.

3. BFAD should have access to a laboratory that can detect CFC.
PHILIPPINE TRANSITION STRATEGY
Ten (10) Key Transition Strategies

4. Phase-in of CFC-free alternatives will be encouraged.
   • Application for registration of CFC-free MDIs will be given a special priority lane.
   • Registration will be good for 1 year initially, with a requirement for a mandatory post marketing surveillance.
   • Proof of quality, safety and efficacy of CFC-free MDIs when applying for initial registration will be subject to review and evaluation by an expert panel to be created by the BFAD.
   • Experience from other countries with good drug regulatory activities will be acceptable as a basis to support the new drug application.
5. Identification mark to distinguish “environment friendly” or “ozone layer-friendly” CFC-free products from the CFC-containing and Ozone-depleting counterpart.
   • CFC-free alternatives belonging to CFC-free MDIs and dry powder inhalers without propellants shall be required to bear the aforementioned green band.

6. Encourage companies with registered CFC-free MDIs to assist with the IEC campaign through:
   • Mass media
   • Release ads containing the following information:
     – CFC alternatives contains the same active ingredient, only the propellant has been substituted with a non-ozone depleting potential
     – Phase-out of CFCs from MDIs is made in compliance with the Philippine commitment to the Montreal Protocol
     – To help restore the ozone layer that protects human from the sun’s UV(B) radiation.
PHILIPPINE TRANSITION STRATEGY
Ten (10) Key Transition Strategies

   • Determine the availability of TEFA in the market per active ingredient
   • Approve the regulatory phase-out of CFC-containing MDIs
   • Update the MDI Philippine Market Situationer for use in TEFA analysis

8. Companies selling CFC containing MDIs will be given at least 1 year notice of regulatory phase-out.

9. Monitoring of the availability of CFC-free MDIs and the phase-out of CFC-containing MDIs.
   • BFAD will use its nationwide inspectorate

10. Cooperation of partner agencies in monitoring and stopping the entry of illegal or smuggled, unregistered or fake MDIs.
BFAD EXPERT PANEL ON THE TRANSITION

- Adult Pulmonary Medicine specialists
- Pediatric Pulmonary Medicine specialists
- Philippine Society of Experimental and Clinical Pharmacology (PSECP)
- Pharmaceutical Health Care Association of the Philippines (PHAP)
- Patients with Bronchial Asthma & COPD
- Interested NGOs
- BFAD & DENR representatives
CONCLUSION/RECOMMENDATIONS

- The CFC-free alternative is already well established in the Philippine market.
- The 2 CFC-free Salbutamol MDIs are products of big dependable pharmaceutical companies.
- The price differentials between the reference CFC-containing salbutamol MDI and the 2 CFC-free MDI alternative products are acceptable.
- Salbutamol MDI is the most widely used CFC-containing MDI and a phase-out would cut down the CFC-MDI usage significantly.
- The strategy employs active cooperation between government and industry to define firm end dates for the regulatory phase-out of CFC-containing MDIs once TEFA’s become available and sustainable in the market, as determined by BFAD Expert Panel on the transition.
Thank you