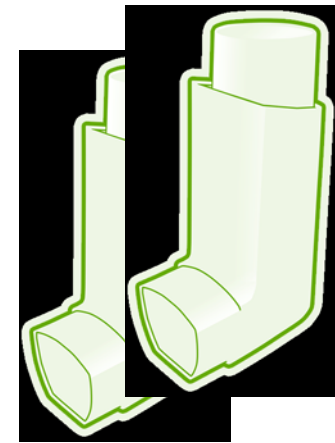


CFCs in inhalers for asthma and COPD



What's happening?



The Global Problem

- Hole in ozone layer (ozone depletion) is a problem
- Has serious consequences, such as
 - Increase in UV-B radiation-skin cancer
 - Crop damage
 - Decrease in marine phytoplankton
- Caused by ozone depleting substances that contain chlorine/bromine
 - E.g. chlorofluorocarbons (CFCs)



The Global Problem

- Most CFCs used for commercial and manufacturing purposes
 - E.g. aerosols, air-conditioning, refrigeration, foam manufacture
- CFCs also used as propellants of metered dose inhalers (MDIs) for asthma & COPD
 - MDI CFC use has always been small
 - Globally about 1–5% of total CFC use



The Global Solution

- Montreal Protocol on Substances that Deplete the Ozone Layer, 1987
 - International treaty, signed by 195 countries
- Aims to control ozone depleting substances
 - CFCs, halons, carbon tetrachloride
- Set phase-out schedule for CFC production and consumption worldwide
- Final phase-out date set: January 1, 2010



The Global Response

- Worldwide adoption and implementation
- Real international cooperation and progress
- One of the most successful international agreements

“I hope Governments will look at such results [from the Montreal Protocol] and feel empowered to act across a wide range of environmental challenges, and not only in prosperous times.”

Mr Ban Ki-Moon, UN Secretary-General



The Global Reality

- Even with successful implementation, ozone depletion will continue for some time
- CFCs charged and stored in equipment / products continue to rise to stratosphere
- CFCs remain in atmosphere for 50–100 years
- Ozone layer will return to normal about 2050



What are MDIs?



- Metered dose inhalers (MDIs) are aerosols that deliver medication into the airways by inhalation
- Until recently, the MDI propellant contained CFCs
 - Propellant evaporates, does not remain in patient's airways
- Dry powder inhalers (DPIs) are also available
 - Have been used for a long time
 - Contain no propellant
- MDIs and DPIs both need to be available
 - Not all patients can use DPIs
 - Patient preference is important



Global Needs

- MDIs and DPIs needed to treat asthma (300 million people) and COPD (210+ million people) worldwide
 - Available in developed and developing countries
 - Increasing use in developing and developed countries because the most effective treatment
- Necessary to develop efficacious, cost-effective and safe CFC-free alternatives
 - Pharmaceutical industry investment (US\$2 billion) to develop CFC-free propellant over past 20 years
 - CFC-free MDIs contain hydrofluoroalkanes (HFAs)



Patient Health

- Patients need ongoing access to safe, efficacious and affordable inhalers
 - Absolute goal of phase-out
- DPIs are available in most countries
 - Cost may be an issue
- Supply must be ensured at affordable price
- Patients must remain confident about their treatment
- Doctors and patients must understand the reason for CFC-free transition



Transition

- Transition to CFC-free MDIs varies between
 - Developed and developing countries
 - MDI manufacturing and MDI importing countries
- Transition from CFC-containing MDIs to CFC-free MDIs must be seamless
 - Supply must be ensured
 - Patient health considerations



Manufacturing Countries

- Developed countries likely to cease manufacture of CFC-containing MDIs by January 1, 2010
- About 12 developing countries will need CFCs after that for local MDI manufacture
 - Local manufacturers don't yet have new technology
 - Local manufacturers can supply affordable MDIs locally
- Challenges to be faced
 - Technology transfer
 - Ongoing supply of pharmaceutical grade CFCs



Importing Countries

- Depend on importers to start supply of CFC-free MDIs
- Need to restrict approvals to CFC-free MDIs only
- Need to control costs of CFC-free MDIs and DPIs
- Open borders may create control problems
- Drug regulatory authorities need to negotiate with importers and manufacturers



Alternatives and Approaches

- Possible approaches in manufacturing
 - A final large production of suitable CFCs
 - Industrial conversion
 - Support for local CFC-free MDI manufacture
- Increased use of affordable DPIs
- Supportive regulations to phase-out use of CFC-containing MDIs and adopt alternatives
- Conduct health professional and patient awareness campaigns



Who's Involved?

- Government (National Ozone Units)
 - Coordinates national strategies and projects
- United Nations Environment Programme (UNEP)
 - Coordinates development of environment policy & practices
- Montreal Protocol Technical Panels
 - Technology and Economic Assessment Panel
 - Medical Technical Options Committee
- UN Industrial Development Organisation (UNIDO), UN Development Programme (UNDP), World Bank
 - Support conversion projects and aid technology transfer



Stakeholders

- Pharmaceutical industry (including manufacturers and importers)
- Government health & environment departments
- Regulatory and/or pricing bodies
- Health promotion organisations for asthma & COPD
- Health professionals, and medical associations
- Patients, and patient groups
- Environmental groups
- Media



Transition Process

- Involves all stakeholders
- Collaborate through implementation taskforce
- Needs multiple strategies
 - Includes workshops, educational materials, stakeholder liaison, media briefings
- Complicated process especially in CFC manufacturing countries
 - Technology transfer issues



Transition Support

- Multilateral Fund established to help developing countries meet compliance obligations
- Technical and financial assistance for projects and activities to implement Montreal Protocol, such as:
 - Conversion of manufacturing processes
 - Implementation of new technologies
 - National ozone units
 - Educational strategies
- Includes regional awareness packages adapted and translated for local needs



Transition Opportunities

- Reinforce asthma & COPD management messages to doctors and patients
- Changeover is good reason for medical review & inhaler technique check
- Specific messages:
 - Environmental reason for changeover
 - CFC-free inhalers may taste, feel or look different
 - CFC-free inhalers are just as effective
 - Don't change or stop using your inhaler without consulting your doctor



Successful Transition Planning

- Involve stakeholders in implementation taskforce
- Link to national or international treatment guidelines
- Develop patient education campaigns (use media)
- Ensure doctors understand issue and its potential
 - Review patient treatment
 - Explain CFC-free MDIs
 - Improve patient health outcomes



Case Study Australia: Planning

- Implementation taskforce of all relevant stakeholders established as first step
- Taskforce included:
 - UNEP Medical Technical Options Committee
 - National Asthma Council Australia – NGO (Co-Chair)
 - Department of Environment – government (Co-Chair)
- Taskforce developed transition plan in 1998
- First CFC-free MDIs introduced in 1999



Case Study Australia: Strategy

- Commitment to education program for patients and health professionals
 - Letters to all general practitioners, pulmonologists, allergists, pharmacists and asthma nurses in Australia
 - Used medical and pharmacy media
 - Also national consumer media
 - National patient brochures, websites etc
- Activities repeated as more CFC-free MDIs released
- Funded by pharmaceutical companies and Department of Environment



Case Study Australia: Outcomes

- Collaborative planning led to smooth transition
- Strong regulatory & pricing processes important
- Few health professional complaints or inquiries
- Few patient complaints
 - Related to under-managed disease not CFC-free MDI
- Problem with stickiness in two CFC-free MDIs
 - Resolved with experts and National Asthma Council
 - Now 2 actuators supplied (one for use, one for cleaning)



Global Progress

- Most countries have or are about to phase-out CFC MDIs
- Deadline of January 1, 2010 will be achieved by most
- Countries that take longer will be monitored
- Patient needs are the most important aspect



More Information

- United Nations Environment Programme
<http://www.unep.fr/ozonAction>
- United Nations Industrial Development Organisation
<http://www.unido.org/index.php?id=o18265>
- United Nations Development Programme
<http://www.undp.org/chemicals/montrealprotocol.htm>
- National Asthma Council Australia
<http://www.NationalAsthma.org.au>
- International Pharmaceutical Aerosol Consortium
<http://www.ipacmdi.com>
- The World Bank
<http://go.worldbank.org/KXM814CLA0>

