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
- International Pharmaceutical Aerosol Consortium
  http://www.ipacmdi.com
- The World Bank
  http://go.worldbank.org/KXM814CLA0