

## Ozone Depletion and Metered-Dose Inhalers for Asthma

### The Issue

Metered Dose Inhalers (MDIs) are one of the main treatments for asthma and chronic obstructive pulmonary disease (COPD). For decades, chlorofluorocarbons (CFCs) were the most suitable propellant for use in MDIs but they were subsequently identified as contributing to ozone destruction and damage of the earth's ozone layer. The Montreal Protocol on Substances that Deplete the Ozone Layer entered into force in 1989 to manage the global elimination of CFCs and other ozone-depleting substances.

The Montreal Protocol originally called for a 50% reduction in the production and consumption of CFCs by 2000 for developed countries. On two occasions, the Protocol Parties have amended the Protocol to accelerate the phase out of CFCs, ultimately agreeing on 1996 as the phase-out date for all CFCs, except CFCs under a temporary "essential use" exemption. Recognising that MDIs play a critical role in the treatment of asthma and COPD, and that additional time would be needed to develop and obtain regulatory approval for CFC-free alternative treatments, the Parties have since 1996 granted "essential use" status for CFCs used in MDIs. Under the Protocol's "essential use" criteria, CFC-MDIs are required to be phased out when the Parties decide that adequate alternatives to CFC-containing medications are available.

In support of the principles of the Montreal Protocol, GlaxoSmithKline (GSK) embarked on a reformulation programme for all our MDIs and an expansion of our dry powder inhaler development programmes. Most GSK MDIs have now been reformulated to use a non-ozone-depleting delivery system; in 2007 just over 3% of GSK MDIs contained CFCs. Once regulatory approvals are obtained for the CFC-free formulation, the CFC-containing MDI is being actively withdrawn in line with local stakeholder timelines. Those few MDIs that are not being reformulated are being progressively withdrawn from sale by GSK. This has been a lengthy and costly process, with total costs estimated at \$1billion. The result of this work has been that in most countries GSK offers a selection of alternatives to CFC-containing MDIs.

The next step that the Parties need to take toward their goal of complete elimination of ozone depleting substances is the phase out of CFC-containing MDIs in developed countries where non-CFC alternatives are available.

### GSK's Position

- GSK supports the Montreal Protocol on Substances that Deplete the Ozone Layer and recognises that emissions of ozone-depleting substances can deplete the ozone layer in a manner that is likely to result in adverse effects on human health and the environment.
- GSK has invested in the elimination of ozone depleting substances by:
  - Developing new MDIs which no longer use CFCs as their propellant, but instead use hydrofluoroalkane (HFA) 134a, a non-ozone depleting replacement;
  - Agreeing to timeframes with relevant local authorities that ensure CFC-containing MDIs are replaced by equivalent CFC-free MDIs as soon as possible following launch;

# GLOBAL PUBLIC POLICY ISSUES

## GlaxoSmithKline's Position

- Launching and promoting, when approved, the use of dry powder inhaler products, which are propellant-free;
  - Continuing to invest in research and development of novel inhaler devices in an effort to further lower environmental impacts and;
  - Incinerating all waste CFC from the manufacture of CFC-containing MDIs.
- GSK has made the following commitments:
    1. We will make no further requests for “essential use” CFC volumes after 2005.
    2. We ceased manufacture in 2006 of all CFC-MDIs for sale in developed countries.
    3. We plan to eliminate the use of CFCs from GSK’s worldwide product portfolio by 2010.
  - CFC volumes used in MDIs are declining. GSK urges the Parties to the Montreal Protocol to now phase out the “essential use” exemption for CFC use in MDIs. Specifically, GSK believes that no more “essential use” CFC volumes should be granted by the Parties for the manufacture of salbutamol for sale in developed countries.
  - By doing this, the Parties would expedite the final phase-out of CFC’s, enhancing protection of the earth's ozone layer and the health of citizens. Patients would also benefit as healthcare professionals and stakeholders would be provided with a certain end-date for availability of CFC MDIs in order to manage a planned and controlled transition. Finally, companies would be rewarded that have abided by the principles of the Montreal Protocol and have invested in the research and development of CFC-free MDIs.

## BACKGROUND

GSK is a leading producer of MDIs; each year, the company manufactures over 140 million MDIs and markets them in over 150 countries. GSK HFC MDIs are manufactured at three facilities (France, Spain, and USA). This represents a significant consolidation compared to the manufacture of CFC-containing MDIs, that has been essential to balance demand with capacity, meet increasing regulatory standards and to ensure a cost effective manufacturing base.

The Montreal Protocol categorises countries into ‘Article 5’ (developing countries), which have until 2010 to phase out CFCs, and ‘non-Article 5’ (developed countries). The Parties (i.e., the signatory countries) set January 1, 1996 as the phase-out date for production and consumption for all CFCs, except CFCs for “essential uses”. The only “essential uses” currently allowed by the Protocol are for MDIs, laboratory and analytic uses, and the space shuttle. Companies needing CFCs for MDI manufacture submit an annual request for CFC volumes under this essential use exemption. These nominations are approved by the Protocol Parties.