GSK Public policy positions

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 (ODSs).

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, GSK embarked on a reformulation programme for all our MDIs and an expansion of our dry powder inhaler development programmes. All GSK MDIs have now been reformulated to use a non-ozone-depleting delivery system and CFC-based manufacture ceased in 2009. This has been a lengthy and costly process, with total costs estimated at $1billion. The result of this work has been that GSK offers a selection of alternatives to CFC-containing MDIs.

GSK's Position

- GSK supports the Montreal Protocol on Substances that Deplete the Ozone Layer and recognises that emissions of ODSs 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 ODSs by:
  - Developing new MDIs which no longer use CFCs as their propellant, but instead use hydrofluoroalkane (HFA) 134a, a non-ozone depleting replacement
  - Launching and promoting, when appropriate, 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

- This investment has meant GSK has been able to meet the following milestones:
  - We have made no requests for temporary "essential use" exemptions for CFC volumes since 2005
  - We ceased manufacture of all CFC-MDIs for sale in developed countries in 2006
  - We have now eliminated the use of CFCs from GSK manufactured MDI's worldwide

- 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. By doing so, 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.

Background

GSK is a leading producer of MDIs; each year, the company manufactures over 200 million MDIs and markets them in over 150 countries. GSK HFA 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.

February 2014