Health Canada Santé Canada

Clarification from Health Canada Regarding the Status of Iressa® (gefitinib) in Canada

Issue

This advisory has been prepared to inform the healthcare providers and patients of Health Canada's decision to maintain market authorization of Iressa®, despite a recent report of its ineffectiveness in prolonging survival in a major efficacy outcome study.

Background

Iressa® (gefitinib) is a drug of AstraZeneca Inc. It is an epidermal growth factor inhibitor, that received a Notice of Compliance with conditions (NOC/c) on December 17, 2003 for third line therapy of locally advanced or metastatic non-small cell lung cancer (NSCLC). The approval was based on data from two clinical trials demonstrating that Iressa® shrinks tumours in lung cancer patients whose cancer recurred or progressed following two subsequent chemotherapy regimens.

Conditions to be Fullfilled Following Market Authorization

The conditions of the NOC/c

1. Iressa® prolongs survival;
2. Iressa® alleviates disease related symptoms
3. Iressa® is a efficacious in prolonging life as the approved standard for second line therapy of NSCLC i.e. Taxotere;
4. Iressa® is safe from a cardiovascular point of view
5. Iressa® continues to show a stable and acceptable post market safety profile.

Canada

Evidence Regarding the Efficacy of Iressa® and its Current Regulatory Status in Canada

The manufacturer, AstraZeneca, notified Health Canada in December 2004 that a large clinical trial comparing Iressa® with placebo in patients with NSCLC, who had failed other courses of chemotherapy, showed no survival advantage from taking Iressa®. This failure to meet commitment #1 could have resulted in revoking the market authorization even though final data were not available to review by Health Canada.

Health Canada carefully reviewed the available interim data, other available information and took the following points into consideration when deciding not to revoke the market authorization at this time:

1. There is no alternative therapy available for treatment of Canadian NSCLC patients who failed two lines of therapy;
2. Iressa® shrinks tumours, which may lead to less shortness of breath, less pain and less cough;
3. The safety profile of Iressa® is more acceptable than that of any other chemotherapy which may be considered in this situation;
4. The data set, as of the December 2004 clinical trial update, has not yet been submitted by AstraZeneca for full review by Health Canada.

This recommendation will be reconsidered following the provision of more detailed evidence by the manufacturer, if new safety concerns arise, or other therapeutic options become available.

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Therapeutic Products Directorate Direction des produits thérapeutiques	Health Products and Food Branch Direction générale des produits de santé et des aliments