MaHTAS
Malaysian Health Technology Assessment Section

ANTIVIRAL [redacted]MASK™
Executive Summary

[Adapted from the report by MAHARITA AB RAHMAN]

Review Group Membership

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http://www.moh.gov.my

2010

Introduction

Medical face mask is defined as a mask used for medical purposes especially to protect airway from any contamination.

Today, the used of face mask is crucial after the outbreak of air borne diseases such as influenza H1N1. For this reason, various types of face mask are introduced in Malaysia. Following the outbreak of H1N1, the shape and type of face mask is changed accordingly. Based on this, a new generation of face mask is introduced by [redacted] Limited Company known as Antiviral [redacted]mask™.

This technology review was requested by Senior Principle Assistant Director of Medical Resource Unit following the proposal from [redacted] Sdn. Bhd. to introduce the usage of Antiviral [redacted]maskTM in Ministry of Health facilities.

Objective/Aim

The objective of this technology review was to assess the safety, efficacy or effectiveness and cost-effectiveness of Antiviral [redacted]mask™.

Results and Conclusions

The search strategies did not yield any article regarding the safety, efficacy or effectiveness and cost-effectiveness of Antiviral [redacted]mask™. The only source of the studies was from the company itself. However, evidence on its efficacy and safety were laboratory studies. Clinical researches on human beings and in clinical setting are warranted.

Methods

Electronic databases were searched, which included PubMed, Ovid Medline (R) from 1990-2006 (EBM Reviews – Cochcrane Databases of Systematic Reviews), National Horizon Scanning, INAHTA and FDA website, for published reports. There was no limit in the search. Additional articles were identified from reviewing the bibliographies of retrieved articles.

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UPDATE

Addendum 24th AUGUST 2011

Malaysia Health Technology Assessment (MaHTAS) Unit received new information on the Antiviral [redacted]mask™ from the manufacturer / distributor. Herewith is the updated information about this medical device.

SAFETY

Through the search in the United State Food and Drug Administration (USFDA) website, it was found that, on 26 Mei 2011, USFDA gave 510(K) clearance to the Biofriend [redacted]mask™ Surgical Facemask, Models Universal [redacted] and Premium [redacted] [redacted] Limited with 510(K) number K101128.

EFFICACY/EFFECTIVENESS

No new evidence was found from the evidence search in the available scientific databases in MaHTAS.

CONCLUSION

There was no new clinical evidence on the efficacy/effectiveness, and cost-effectiveness of Antiviral [redacted]mask™. However, it has received the 510(k) clearance from the USFDA.