FOR IMMEDIATE RELEASE
BY THE DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA

NEW SAFETY CONCERNS RELATING TO USE OF ZELMAC (TEGASEROD)

The Drug Control Authority (DCA) is issuing this public statement to inform patients and health care professionals about new safety concerns relating to Zelmac (tegaserod maleate). A new safety analysis conducted by the United States Food and Drug Administration (US FDA) on Zelnorm (the brand name under which tegaserod is marketed in the US) found a higher incidence of serious adverse cardiovascular events (e.g. angina, heart attack and strokes) in patients treated with Zelnorm compared to those treated with placebo (sugar pill). Zelnorm is being taken off the US market.

In Malaysia, Zelmac is approved for the symptomatic treatment of female patients with abdominal pain and constipation associated with irritable bowel syndrome (IBS)

DCA announces the following:

- Novartis Corporation (M) Sdn. Bhd. has suspended importation and sale of Zelmac with immediate effect
- New patients should not be started on Zelmac
- Patients being treated with Zelmac should contact their doctor to discuss if alternative treatment is needed for their condition

In the meantime the DCA will monitor the decisions taken by other health authorities and further assess the situation before taking a final position on Zelmac's product registration status.