The Ministry of Health and Family Welfare has issued draft rules under GSR 686(E) dated 25.9.2023 and it is proposed to include the drugs namely Oseltamivir and Zanamivir at serial no. 49 and 50 in Schedule H1 to the Drug Rules, 1945. Oseltamivir formulations have been approved as new drug on 25.10.2005, 24.04.2006, 28.01.2008 and 19.06.2010 for treatment of Influenzae. Zanamivir is approved as new drug as Inhalation powder for treatment of Influenzae and also for Prophylaxis and treatment of both Influenzae A and B for adults and children on 13.02.2006 and 22.01.2008 respectively. Both drugs have ceased to be new drugs in view of elapse of four years period.

In fact, in view of the GSR 144(E) dated 17.2.2017, these drugs are already regulated as Schedule H1 drugs and they are already subject to additional restrictions as under:-

In view of Rule 65(3)(1)(h) for supply Schedule H1 drugs by retail, the pharmacist /chemist is required to maintain a separate register. It is also necessary to record the details such as name and address of the prescriber, name of the patient, name of the drug and quantity supplied. Such records are required to be maintained for three years.

In view of Rule 97, the drugs specified in Schedule H1 are required to be labelled with the words “Schedule H1 prescription drug – It is dangerous to take this prescription except in accordance with the medical advice. Not to be sold by retail without a prescription of a Registered Medical Practitioner.” These words are required to be in legible black coloured font size in a completely red rectangular box.

It may however be noted that both drugs will continue to be governed by the restrictions contained in GSR 144(E) dated 17.2.2017.

As these drugs are already regulated as H1 drugs, the proposed draft rules will not make any difference even after final notification.