### 6. Anti-infective medicines

#### 6.4. Antiviral medicines

##### 6.4.3. Other antivirals

- **Oseltamivir**

  **Essential medicine status**

  **Expert Committee recommendation**

  The Expert Committee recommended the deletion of oseltamivir powder for oral liquid 12 mg/mL from the complementary list of the EML and EMLc noting that this formulation has been discontinued by the manufacturer and is no longer marketed. The Committee noted that the capsule formulations of oseltamivir can be manipulated for the preparation of an oral suspension, providing an alternative for patients, particularly young children, who are unable to take a solid dosage form. However, the Committee also recognized the importance of having age-appropriate formulations for children that do not need to be compounded or manipulated. The Committee noted the market availability of a 6 mg/mL oseltamivir powder for oral liquid formulation, and requested that the manufacturer be asked to clarify the status of this particular product.

### Background

Oseltamivir (capsules 30 mg, 45 mg and 75 mg; oral powder 12 mg/mL) was added to the core list of the EML and EMLc in 2011 for treatment of influenza following the 2009 H1N1 influenza outbreak which was classified at the time as a public health emergency (1). In 2017, the Expert Committee reviewed additional evidence for oseltamivir in seasonal and pandemic influenza which indicated that the beneficial effect of oseltamivir on relevant outcomes of hospital admissions and mortality was lower than previously estimated. The Expert Committee therefore recommended oseltamivir be transferred from the core to the complementary list, and its use be limited to patients with severe illness due to confirmed or suspected influenza virus infection in critically ill hospitalized patients (2).
Influenza serotypes A and B infect humans and are responsible for an acute febrile infection of the respiratory tract characterized by the sudden onset of cough, fever, headache, malaise and myalgia. Illnesses range from mild to severe and even death. Hospitalization and death occur mainly among high-risk groups. Influenza is a seasonal illness, with epidemic infections occurring annually during cooler months. Annual influenza epidemics are thought to result in between 3 and 5 million cases of severe illness and between 290,000 and 650,000 respiratory deaths worldwide (3). In industrialized countries, most deaths associated with influenza occur among people aged 65 years or older (4). It is estimated that 99% of deaths in children under 5 years with influenza-related lower respiratory tract infections occur in developing countries (5).

Benefits

Evidence of the clinical efficacy of oseltamivir was previously reviewed by the Expert Committee in 2011 (1), 2013 (6) and 2017 (2).

Harms

Evidence for the safety of oseltamivir was previously reviewed by the Expert Committee in 2011 (1), 2013 (6) and 2017 (2).

Availability

Roche ceased to manufacture and supply its brand of this formulation (Tamiflu®) in August 2016, with the last commercial supply in February 2017. Global deregistration for Tamiflu 12 mg/mL oral powder is ongoing. The approved labelling for Tamiflu® capsules includes instructions for pharmacists on compounding a 6 mg/mL oral suspension of oseltamivir using the contents of the 30 mg, 45 mg or 75 mg capsule formulations (7). The application stated that generic brands of oseltamivir capsule formulations are widely available in many countries from which oral suspension formulation may be compounded.

Other considerations

Oseltamivir capsules 30 mg, 45 mg and 75 mg are still included on the Model Lists.