

Group exercise 2.1: Review and create a few individual clinical and post-marketing PV case reports

Bakground

- Your company (Asiavac) is conducting interventional clinical trials in Belgium, Germany and Norway with the same active substance 'virusgone' for the prevention of yellow fever in healthy adult patients. The product is not yet marketed in any country.
- Your company also holds already a marketing authorisation for 3 other vaccines which are :
- Rotaway to protect against rotavirus infection in children under 2 years of age
- Hepaway for the prevention of hepatitis A in adults and elderly
- Fluaway in all age groups for the prevention of seasonal flu.
- These vaccines are marketed in India, China, Taiwan and in the EEA (centrally authorised products).

Your task

- Identify the reports which are valid
- Create a CIOMS report for at least 3 of these
- Identify follow-up questions
- Determine the reporting timelines for each report