

IIHMR UNIVERSITY
School of Pharmaceutical Management
MBA Pharmaceutical Management
Batch-09th (2017-2019)
First Year
Essentials of Pharmaco-epidemiology



Term Examination

Time - 3 Hour

MM-70

The question paper contains two printed pages. Question one is compulsory and from remaining five questions do any three questions.

Q. 1. Follow the case study and answer following questions:

(28)

In May 1999, Vioxx (Rofecoxib) by parent company Merck Ltd. was approved by FDA in USA with major role to relieve pain and inflammation. The clinical trial produces no significant increase in myocardial infarction (MI) by use of its drug. The serious adverse event was seen in 2% of population out of 1400 when treated for 6 months or more. They either ignored or dismissed several early indications of increased risk of heart attacks both in its own studies and other published articles, in an attempt to get to the market faster.

Merck voluntarily withdrew Vioxx from the market in 2004. Research published in the medical journal Lancet estimates that 88,000 Americans had heart attacks from taking Vioxx, and 38,000 of them died. Merck announces it will pay \$4.85 billion to end thousands of lawsuits over its painkiller Vioxx.

- a) Narrate the situation with your description.
- b) Suggest the possibility of missing the event of MI in the clinical trial and suggest possible studies which could be done by stakeholders to avoid such issues.

Q.2. Describe following terms (any seven, two marks each):

(14)

- | | | | |
|------------------|---------------------------|--------|-------------------|
| a) Type II error | b) Drug utilization study | c) DDD | d) PEM |
| e) Randomization | f) Sources of PE Data | g) SAE | h) Rate and ratio |
| i) ICER | | | |

Q.2. a) Solve the problem and find: Incidence Rate, Relative Risk, and Attributable Risk (per 100 persons) (use round figure)

In a cohort study with a population of 1050, the no. of person consumed paracetamol daily are 150. Of 150 patients, 82 were found to be having peptic ulcer. While 23 peptic ulcer cases found in the cohort study did not consume paracetamol.

(7)

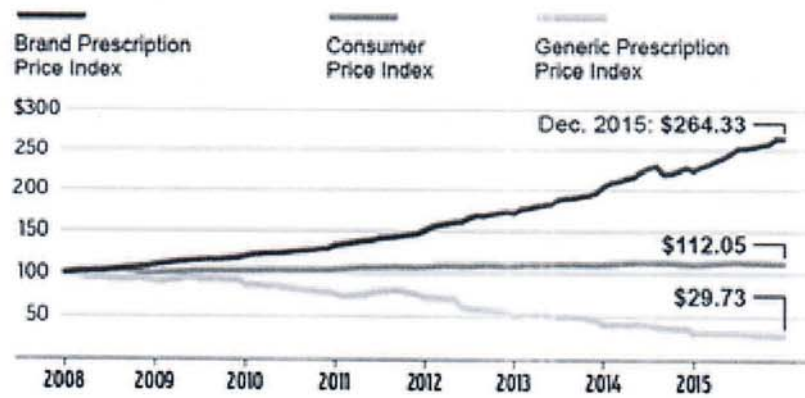
- b) After a dinner attended by 100 people, 12 individuals become ill. All 100 people are interviewed about their food consumption at the dinner. The interviews showed that 8 of the 12 people who are

ill; and 25 of the 88, who are healthy, ate fish. Calculate incidence rate, attack rate, and relative risk. (Per 100 persons) (7)

Q.5. Solve the problem: (14)

In a cohort study, 600 adults with TB were recruited. 210 had bed rest alone, 390 had bed rest + streptomycin. There were 14 deaths in the non-exposed group and 4 in the exposed group. Calculate event rates in exposed and non-exposed group, Attributable Risk, Attributable Fraction, Odds ratio, and Risk ratio.

Q.6. Describe the graph below for correct labels of title, x-axis, y-axis and variables: (14)



Q.7. a) Describe the ADR and its types. (7)

b) Define Pharmacoeconomics and its study designs (7)

