1. A report is considered as valid when it contains
2. Identifiable reporter
3. Identifiable consumer
4. Medicinal plant
5. Adverse event
6. All the above
7. A elderly age patient received Alendronate tablet for osteoporosis and he developed abdominal pain and she/he called the company to report the event.
8. Who is the reporter?
9. Elderly age patient
10. Pharmaceutical company
11. Abdominal pain is the adverse event.
12. True
13. False
14. Spontaneous case is a solicited report
15. True
16. False
17. Patient registries are considered as solicited reports
18. True
19. False
20. All are special situations except
21. Pregnancy
22. Drug use in elderly population
23. Both
24. None
25. There are specified timelines to submit the case for MAH to competent authority
26. True
27. False
28. Serious reports are to be submitted in how many calendar days?
29. 12 calendar days
30. 15 calendar days
31. 30 calendar days
32. 90 calendar days
33. Non-serious case is submitted in how many calendar days?
34. 12 calendar days
35. 90 calendar days
36. 15 calendar days
37. 30 calendar days
38. Consumer can report the case and considered valid & acceptable by the authorities in which country?
39. USA
40. Canada
41. Both
42. None
43. Is Lack of efficacy reportable usually?
44. True
45. False
46. The case Process contains the following flow of information:
47. Book-in—triage—Data entry-medical review
48. Triage---data entry—medical review
49. Book-in---triage—medical review—data entry
50. None of the above.
51. What is the reporting form called in USA?
52. Medwatch
53. ADR form
54. Both
55. None.