Assignment Single ADR case

Aim
The aim of this exercise is to familiarize the students with the concepts of causality assessment. This assignments can be used for training PV Key aspect 2 (Preventing ADR), 3 (Recognizing ADR), 4 (Managing ADR).

Source
The Netherlands Pharmacovigilance Centre Lareb, WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting

Learning outcomes
The student, …

- … has knowledge about ADR classification, risk factors, confounding factors, and epidemiology.
- … knows how to apply clinical reasoning and causality reasoning when encountering a patient case with a potential ADR.
- … develops an open mind of adverse outcomes of drug use in pharmacotherapy.

Description
This Single ADR case assignment can be used to assess and discuss ADRs of special interest. Any well documented ADR report of case-report from literature can be used for discussion. Below, an example has been given from a pharmacovigilance database. But you are free to choose any drug-ADR association for yourself, that is applicable for your audience.
General questions to the discussion are:

- Is the reported ADR known with the suspected drug?
- Are there any other causes (reported or not reported) that could have caused the event?
- What is the background incidence of the event in general or in this patient group?
- What are contributing factors or risk factors for this ADR?
- Is there a plausible time relationship of the ADR? (e.g. latency, outcome)
- Can the ADR pharmacologically be explained by use of the drug?
- If you were a healthcare professional, would you consider to report this ADR to a pharmacovigilance centre?

Example
You received a report of a patient that developed skin carcinoma during the use of tioguanine.

Summary of report:
This moderately documented serious spontaneous report from a consumer concerns a female aged 66 years, with skin carcinoma following administration of tioguanine for Crohn's disease with a latency of 4 months after start. The drug tioguanine was withdrawn after 6 months of use. The skin cancer was surgically removed. At the time of reporting, 2 months after onset of the reaction, the patient is recovering. Concomitant medication was not reported. The reporter mentioned that exposure to sunlight in combination with the use of the tioguanine also could have caused or aggravated the reaction. The patient has no known medical history. The patient has no known past drug therapy. Additional information from the reporter: When I started tioguanine about 6 months ago, I received an information leaflet from my specialist doctor about this drug. Among others, it was described that this drug could cause skin carcinoma. Some time ago, I asked me specialist doctor how many of his

patients using this drug developed skin carcinoma. He told me that there were 2 other patients with skin carcinoma, using this drug. I provide you this information because I know that not all patients would report their adverse drug reaction to the pharmacovigilance centre.

Questions:

- Is skin carcinoma a known ADR with tioguanine?
- Are there any other causes for skin carcinoma in this patient?
- Can the indication, Crohn's disease, be of influence of the development of skin carcinoma?
- Can skin carcinoma pharmacologically be explained by the use of tioguanine? How?
- Is this a dose-related ADR?
- What would you advice about the use of this drug in this patient, and in general?

Extra: Students can write a report or prepare an oral presentation, or a poster presentation to present their findings.