

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2015 - 2016, 10 February 2016

Ref No: SQ16-000067

OUTCOME: 1 - Population Health

Topic: Primates Testing

Type of Question: Written Question on Notice

Senator: Rhiannon, Lee

Question:

Evidence provided by Professor Anne Kelso in the recent inquiry hearing into the Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015) confirmed there is a high failure rate of drugs successfully tested in animal trials but which fail in human clinical trials, and that a large number of drugs failed during the pre-clinical animal trials:

Which drugs are known to have failed animal tests but have worked in humans – for example Tamoxifen is a widely used drug in the treatment of breast cancer despite having failed in animals?

Answer:

The statement Tamoxifen is a widely used drug in the treatment of breast cancer despite having failed in animals is not a correct statement on its own. Tamoxifen has been shown to be effective in at least four animal models. These include:

- Two rat models – a chemically-induced rat mammary tumour and in a rat ovariectomised bone density model
- Two mouse models – a nude (athymic) mouse model transplanted with human breast cancer cell line and a transplantable nude mouse model of acquired resistance to tamoxifen

Briefly, both the chemically-induced rat mammary tumour and the nude mouse models demonstrated that tamoxifen was effective against estrogen receptor (ER) positive mammary tumours. Clinical trials confirmed these findings that tamoxifen acted as an anti-estrogenic agent. Further animal studies using the nude mouse models elucidated the mechanism of resistance to tamoxifen – we now know that tamoxifen also has estrogenic activity.

The success of the tamoxifen studies in these animal models led to the development of a new class of drugs, selective estrogen receptor modulators; this was as a result of studies showing that tamoxifen possesses tissue specificity; that is, acts against ER receptors of which there are two: alpha and beta. Depending on the type of ER present, tamoxifen exerts either an agonist or antagonist effect.

In relation to tamoxifen, appropriate animal models significantly advanced the health for millions of women to live longer and healthier lives.

Prescription medicines may have unwanted adverse effects in some people. All medicines can have adverse effects; sometimes they are serious, but most of the time they are not.

Possible adverse effects of a medicine are described in the medicine's Product Information and Consumer Medicines Information.