

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Budget Estimates 2014 - 15, 25 February 2015

Ref No: SQ15-000039

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Recalls

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Senator: Moore, Claire

Question:

1. How many therapeutic products have been recalled to date in 2015, 2014 and 2013?
2. Explain the different types of recalls.
3. The number of class 1 product recalls that have occurred in 2015, 2014 and 2013.

Answer:

1. Please see below for the number of therapeutic goods recall actions managed by the Therapeutic Goods Administration (TGA) in 2015, 2014 and 2013:

Recall Actions by kind of therapeutic goods	2013	2014	2015 (as of 04 March 2015)
Medical Devices (inc. IVDs)	617	579	94
Medicines	45	43	6
Blood components	90	111	17
Biologicals	7	2	0
Total	759	735	117

2. Therapeutic goods which are found to be deficient in quality, safety, efficacy, performance or presentation may be subject to recall action in Australia. There are three key types of recall actions:
 - Recall – the permanent removal of deficient therapeutic goods from the market or from use.
 - Recall for Product Correction – repair, modification, adjustment or re-labelling of a therapeutic good undertaken at the user's premises or any other agreed location.
 - Hazard alert – Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

3. The number of class 1 product recall actions that have occurred in 2015, 2014 and 2013 are as follows:

	2013	2014	2015 (as of 04 March 2015)
Class I Recall Actions	223	216	37