

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH PORTFOLIO**

**Additional Estimates 2013 - 2014, 26 February 2014**

**Ref No: SQ14-000243**

**OUTCOME:** 1 - Population Health

**Topic:** Therapeutic Goods Administration Blueprint Reforms

**Type of Question:** Written Question on Notice

**Senator:** McLucas Jan

**Question:**

What monitoring is the TGA doing in relation to industry's compliance with the reform measures?

**Answer:**

Compliance with Therapeutic Goods Administration (TGA) reform measures is managed within the TGA's broader compliance program which includes a combination of monitoring strategies.

Underpinning all forms of monitoring is the legislated requirement for sponsors to monitor the performance of their products in the marketplace and, where higher risk products or serious health issues are involved, to report problems to the TGA in a timely manner.

The TGA uses its strategies to monitor the market for signals of potential non-compliance across the range of regulatory areas covered by the Therapeutic Goods Act.

The Australian Therapeutic Goods Advisory Council, established in response to Transparency Review Recommendation 1 also provides an oversight role in ongoing monitoring of the recommendations of the Blueprint recommendations.