**Background:**
On September 23, 2010, the US Food and Drug Administration (FDA) announced that it will require a restricted access program for the elevated cardiovascular risk associated with rosiglitazone. The same day, the European Medicines Agency (EMA) recommended marketing suspension for medicines containing rosiglitazone. Before these regulatory actions, safety concerns had sent global sales of Avandia® sliding dramatically from $2.2b in 2006 to $1.2b in 2009. We monitored the actions of national regulatory authorities (NRA) from developing countries in relation to rosiglitazone using a metric from the indicator-based pharmacovigilance assessment tool (IPAT) developed by the USAID-funded Strengthening Pharmaceutical Systems program. One of the core indicators of the IPAT is the average time lag from safety signal to communication.

**Objectives:**
Identify time lag between the announcements on rosiglitazone by stringent regulatory authorities (SRAs) as represented by FDA and EMA, and actions by national regulatory authorities (NRA) from selected developing countries.

**Methods:**
We reviewed the Drug Information Association’s global regulatory activity digest that provides global regulatory updates, searched websites of 12 NRAs that registered rosiglitazone, and interviewed selected regulatory professionals to validate findings. We used the relevant IPAT indicator to monitor the actions of the NRAs. The IPAT evaluates current state of collection, analysis, and interpretation of data on the safety aspects of medicine regulation. We calculated average lag time in days from date of first announcement by SRAs (index date) to date of regulatory action (defined as any regulatory communication) by NRAs.

**Results:**
We studied the FDA, EMA, and 12 NRAs; 3 NRAs from outside Africa; and 9 NRAs outside Africa. The NRAs outside Africa took regulatory actions related to safety of Rosiglitazone either before the SRA or within 2 weeks of SRA action. Of particular interest, Saudi Arabia suspended rosiglitazone on March 17th, 2010, 190 days before the SRAs. Indonesia took regulatory action a day after the SRAs and India 14 days after. For the nine African NRAs that registered rosiglitazone, the average time lag before regulatory action was 55 days. From the index date until August 5, 2011, 316 days—nearly 10 months—the other African NRAs that have also registered rosiglitazone has not taken any regulatory action or reacted to that of the SRAs.

**Conclusions:**
Average time lag for safety communication is shorter for NRAs outside Africa. Even after 10 months from the index date, many African NRAs had not communicated anything regarding the safety of rosiglitazone to consumers or health providers. This IPAT indicator provides a way for assessing timely communication of safety information. Developing countries should create systems for timely management of new safety issues, particularly for products they have registered and that are being used by their citizens.