

Pharmacovigilance Inspection Metrics Report

July 2009 to March 2010

During the period 1st July 2009 to 31st March 2010 the pharmacovigilance inspectorate conducted 68 inspections of Marketing Authorisation Holders (MAHs). Of these, 42 inspections were conducted as part of the routine programme, 19 were re-inspections due to critical findings identified at previous inspections and 7 inspections were either triggered or carried out in response to a request from the CHMP.

The type of companies inspected during the period is presented in the table below.

	Innovative Pharma	Generics	Other
Number of MAHs inspected	30	34	4

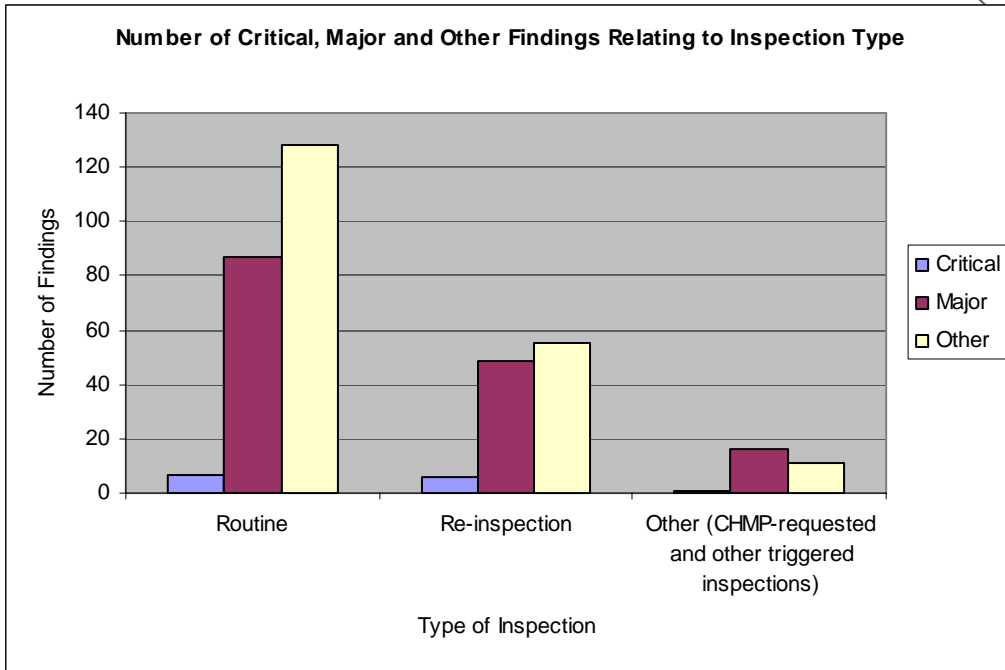
Findings identified during inspections are graded in one of three ways, the definitions for which are available on the MHRA website:

- Critical
- Major
- Other

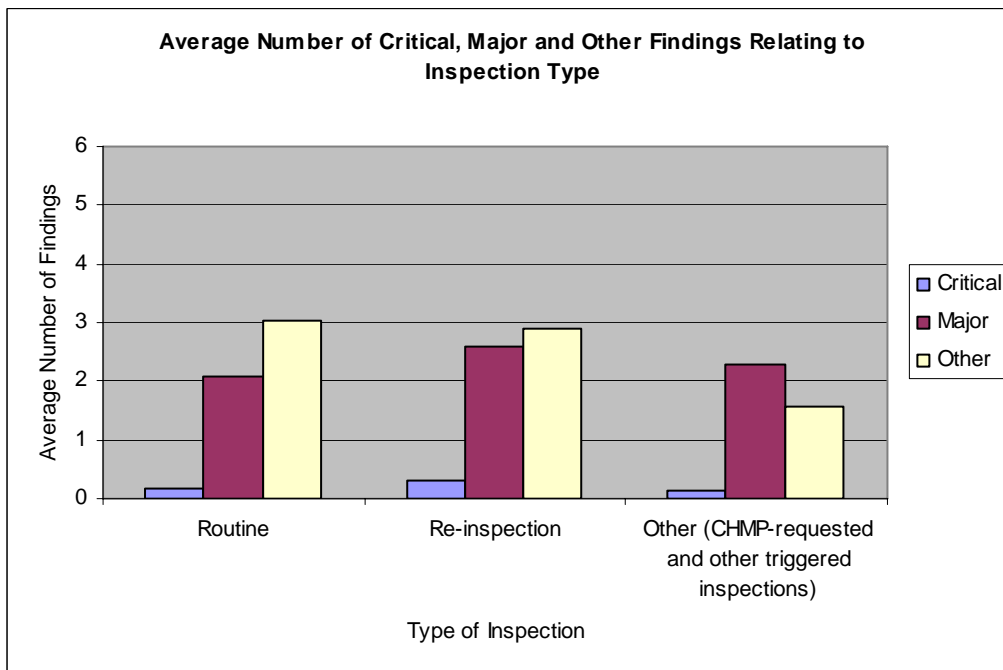
A total of 14 critical, 152 major and 194 other findings were identified during this period.

Type of inspection

A breakdown of the number of critical, major and other findings for each type of inspection (routine, re-inspection or other) is shown here:

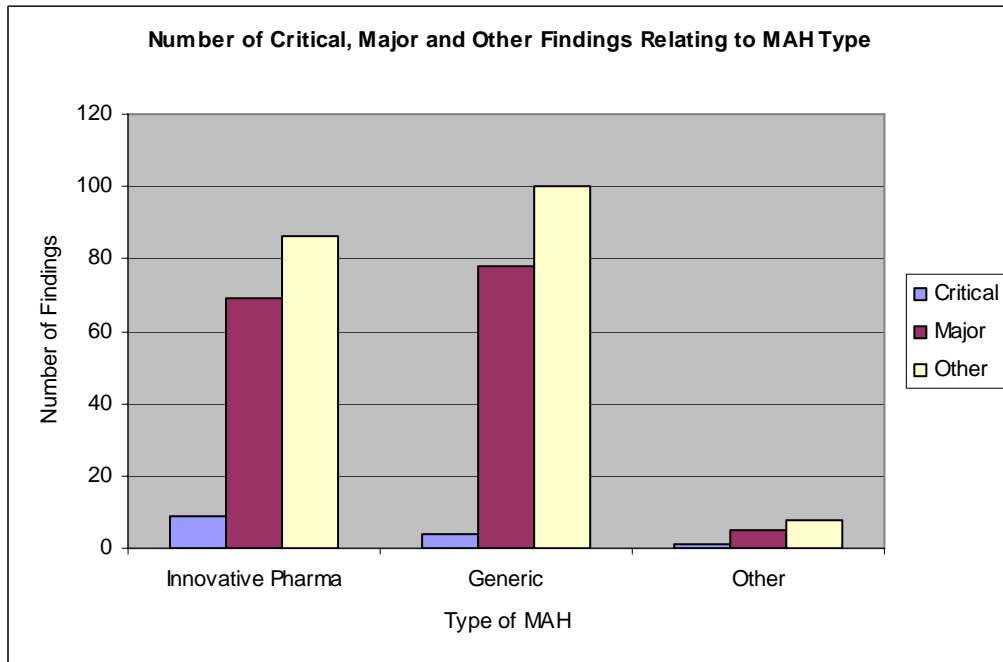


The information shown above can also be represented as the average number of findings for each type of inspection. It can be seen that the average number of critical, major and other findings is similar on routine versus re-inspections.

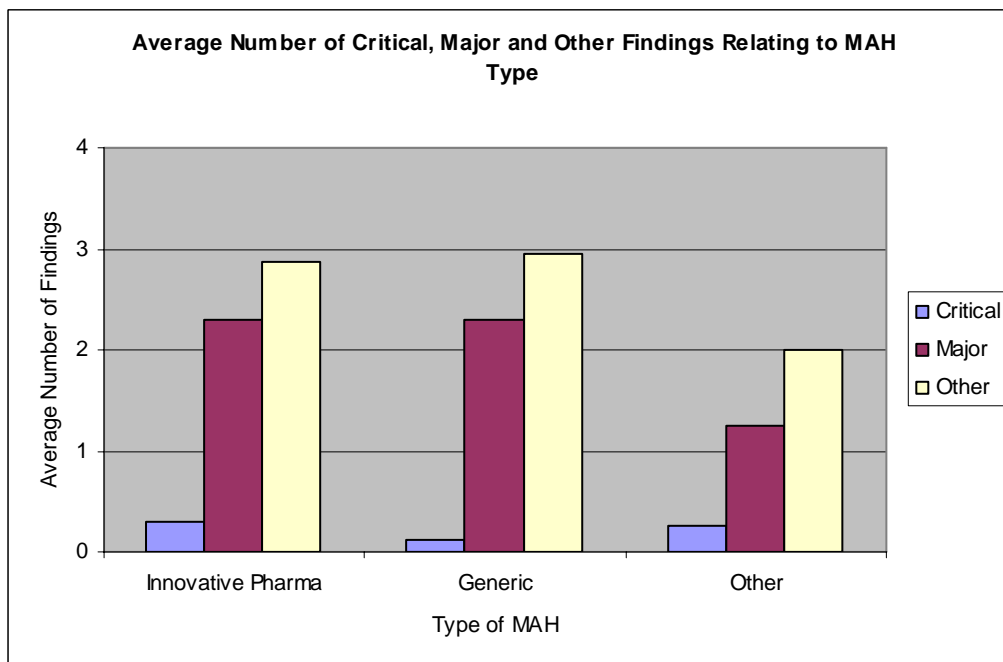


Type of MAH

A breakdown of the number of each grading of finding for each type of MAH is given below:



Similarly, this can be represented as the average number of findings for each type of MAH:



The average number of major and other findings is almost identical for Innovative and Generic companies during this period, but the average number of critical findings was slightly higher for Innovative Pharma companies.

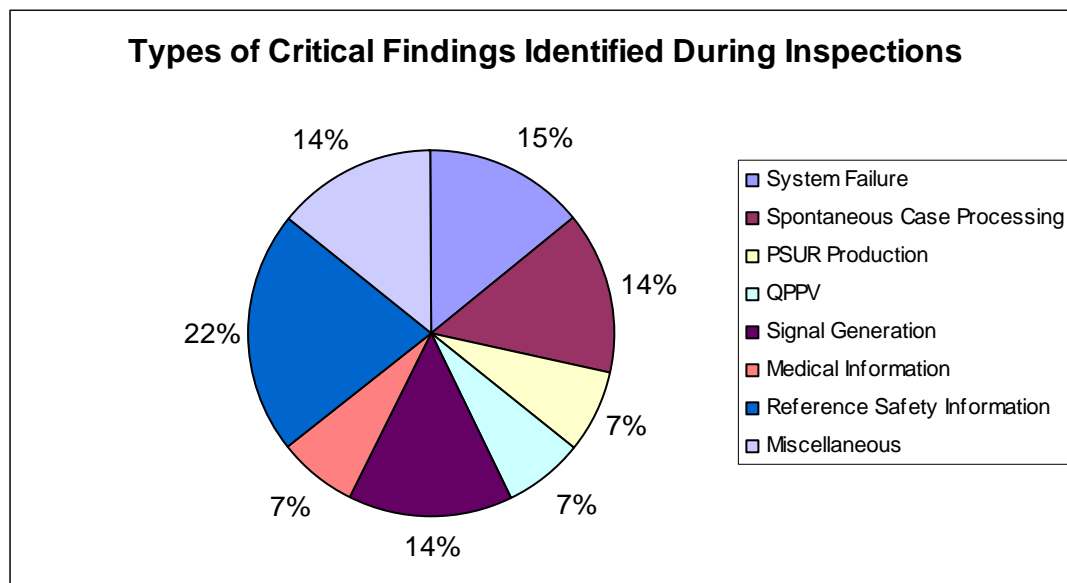
Critical findings

As stated previously, there were a total of 14 critical findings during this period, identified during 11 of the 68 total inspections that were performed.

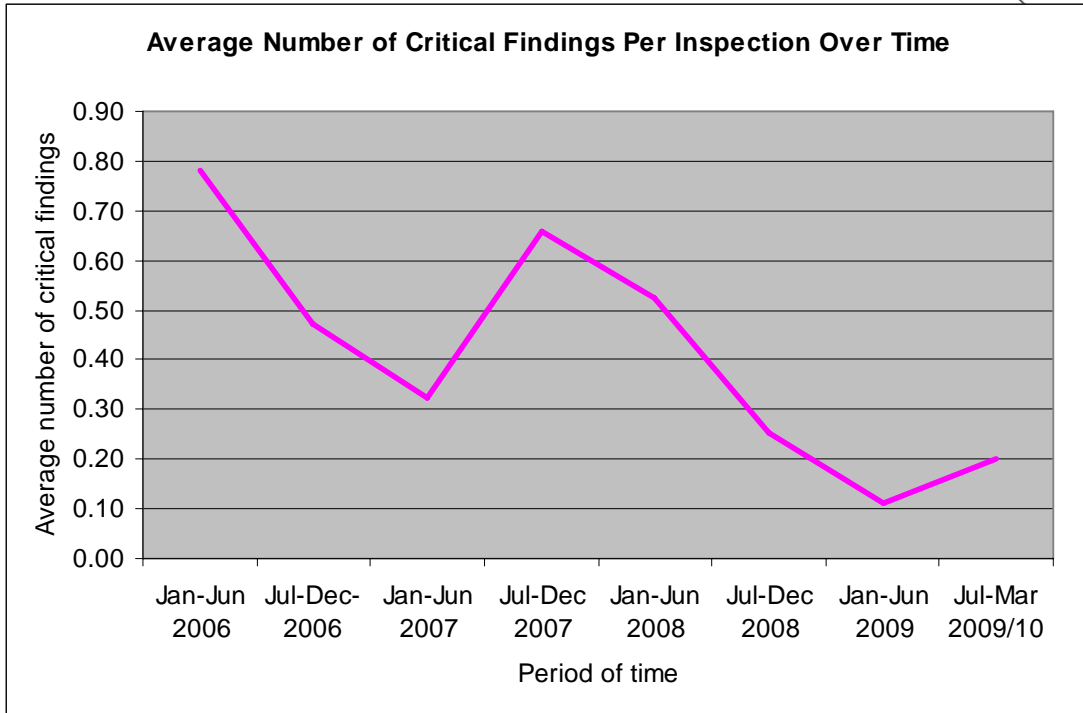
The breakdown of critical findings by type for the current period is given below.

This is the first metrics report period since 1st July 2007 – 31st December 2007 where critical system failures have been identified.

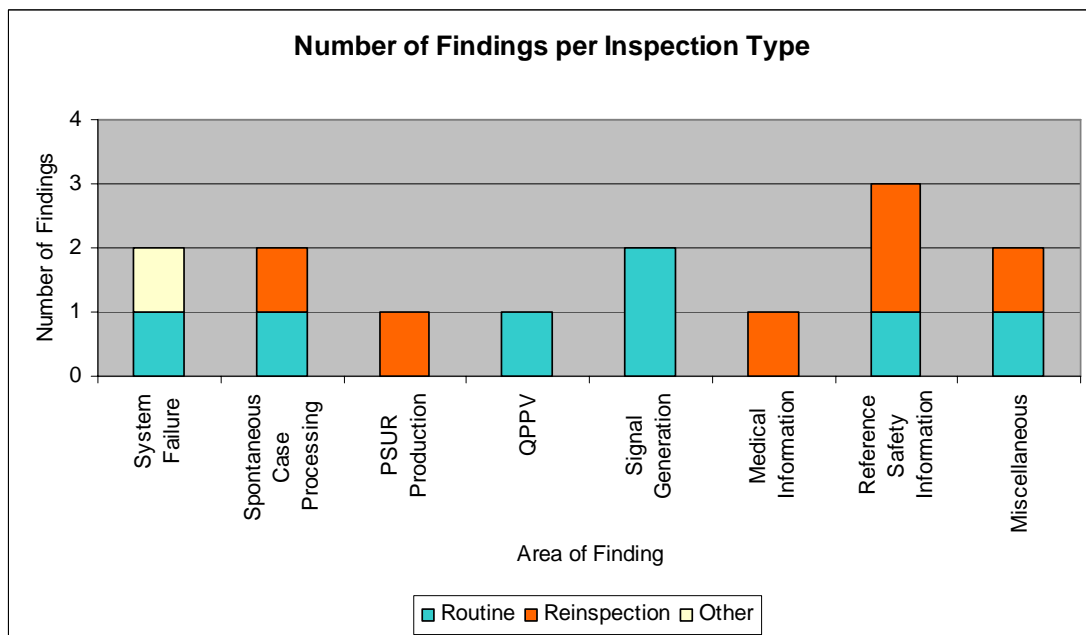
Miscellaneous critical findings included management of information on company websites and handling of data from Patient Support Programmes.



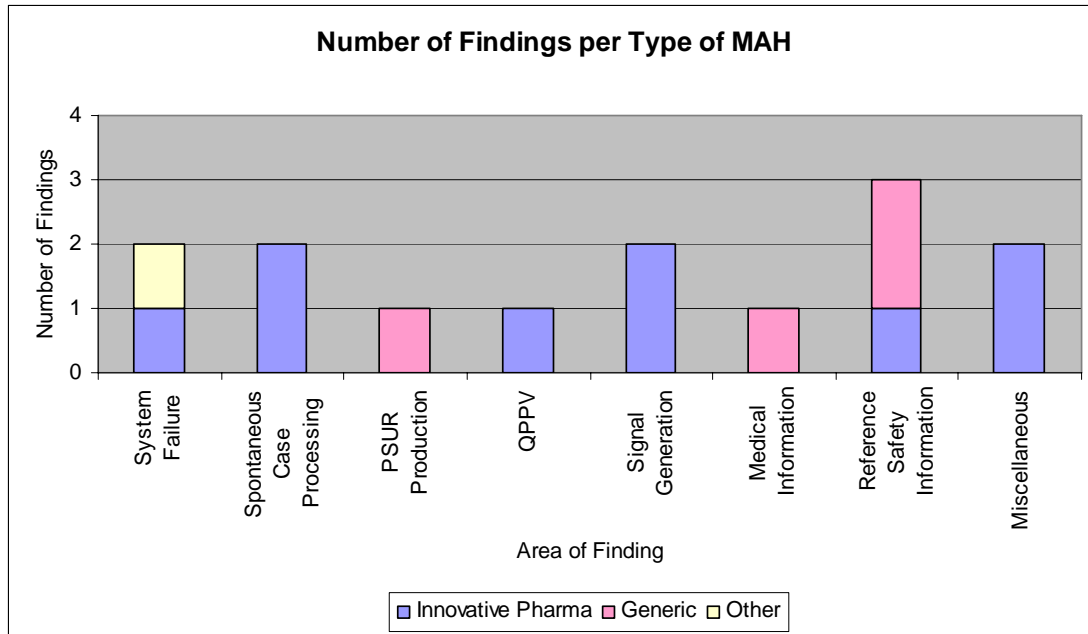
Looking at data relating to critical findings since metrics began, the graph below shows that over time, the average number of critical findings per inspection had been decreasing since 1st July – 31st December 2007. However, the average number of critical findings has increased during the period of this report when compared with the period covered by the previous metrics report.



The graph below illustrates the areas in which critical findings were identified versus the different types of inspection:



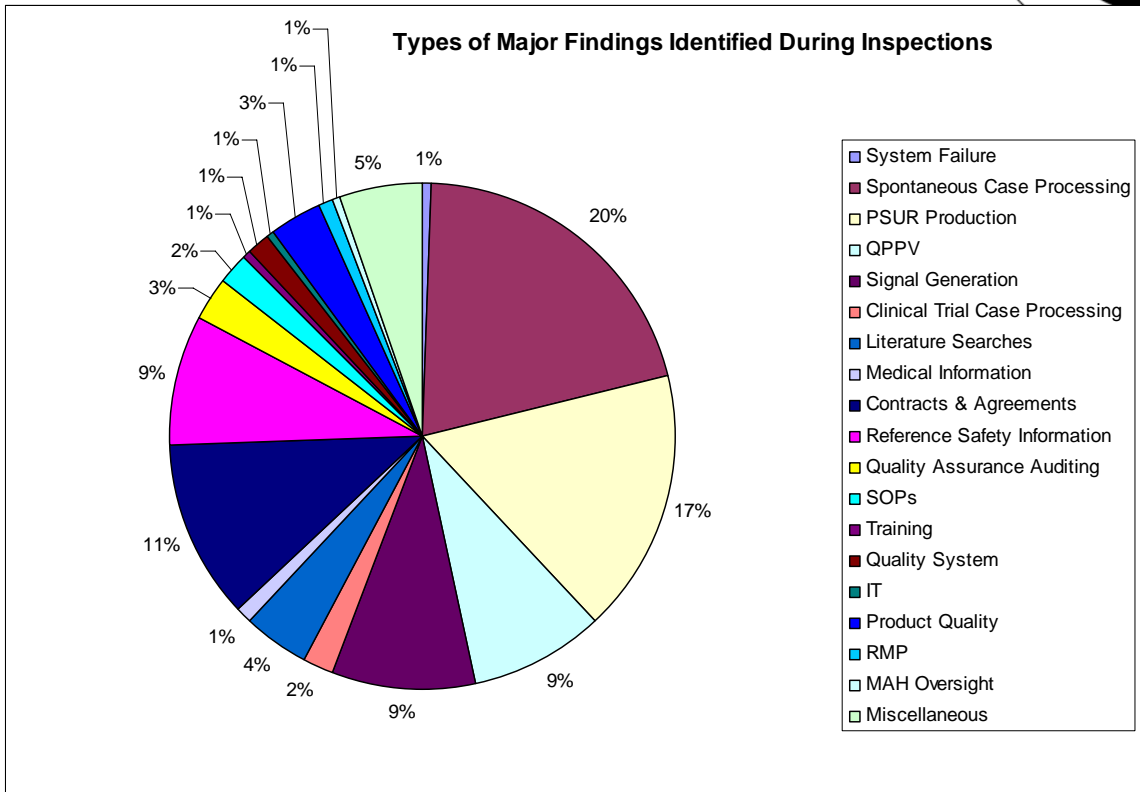
The graph below illustrates the areas in which critical findings were identified versus the different types of MAH:



Major Findings

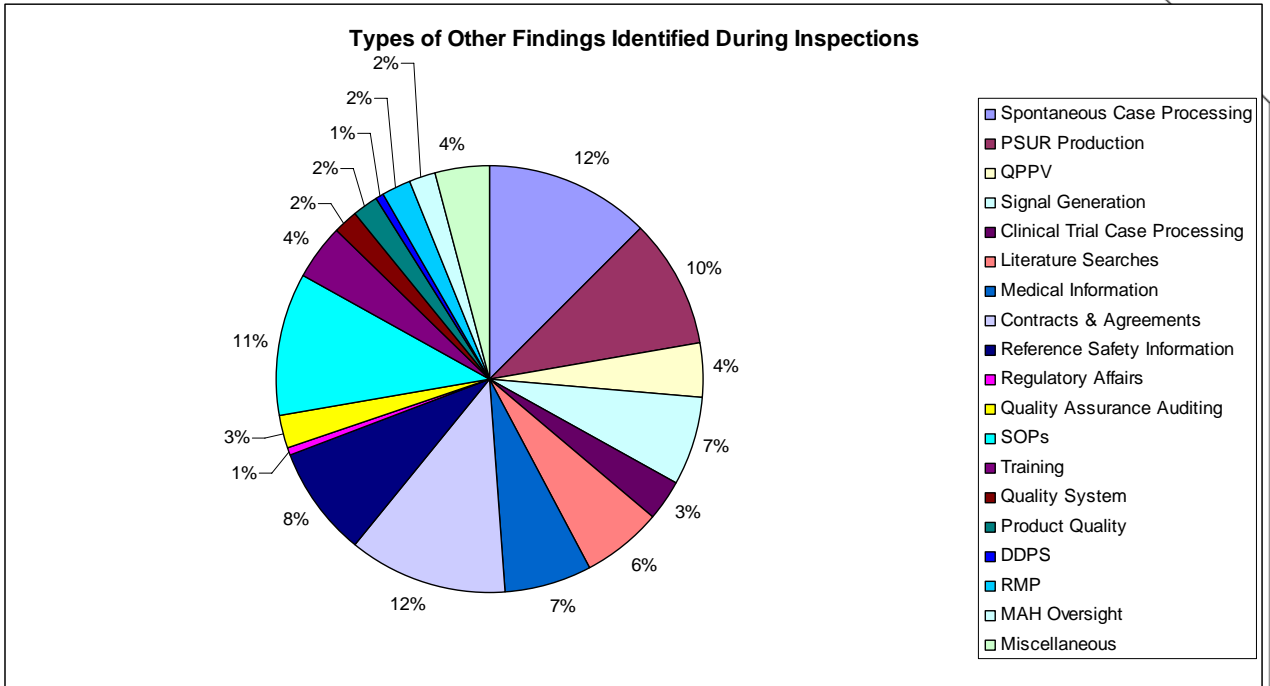
There were a total of 152 major findings identified during the period and a breakdown of the types of major findings is provided below. The chart shows that 55% of major findings were identified in the areas of spontaneous case processing, PSUR production, QPPV and signal generation. This is consistent with data from previous metrics reports.

Miscellaneous findings included issues in relation to patient support programmes, advertising and the management of corrective and preventive actions.

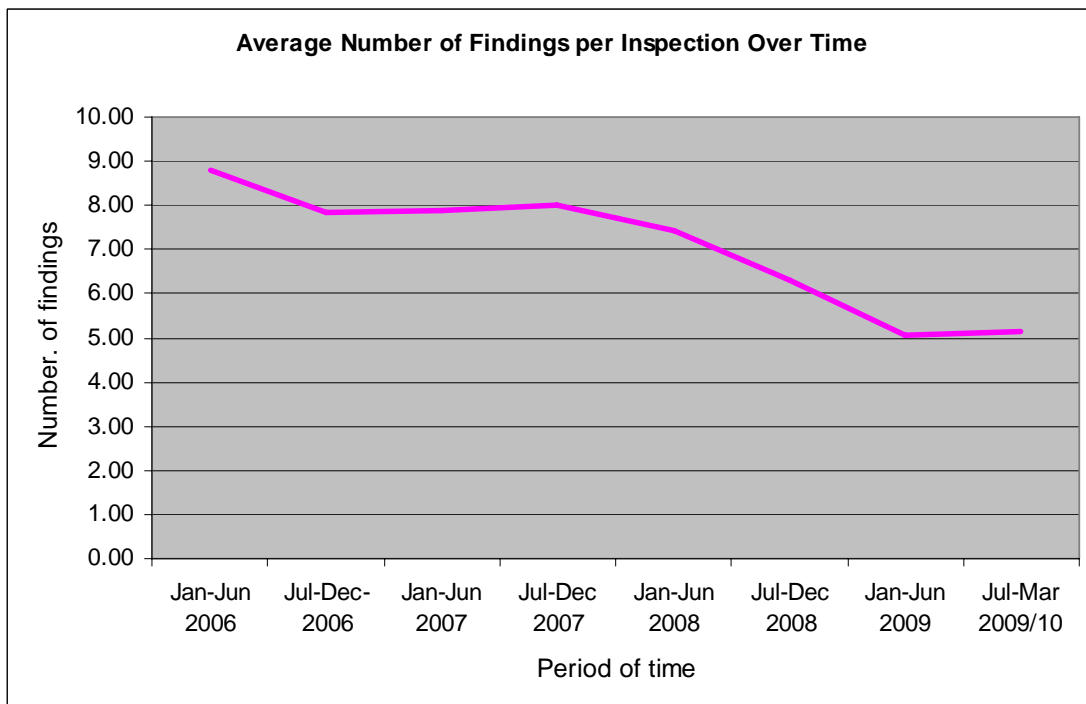


Other findings

194 findings were graded as other during this period and findings were identified in all areas of inspections. A breakdown of the types of other findings is presented below:



The average number of total findings (critical, major and other) per inspection had been decreasing over time, but did not decrease further during the period of this metrics report.



Conclusions

As per previous inspection reports, the majority of critical and major findings were identified in the areas of case processing, PSURs, QPPV, reference safety information and signal detection.

Issues in relation to reference safety information included:

- Failure to comply with MHRA requests to update SmPCs with new safety information
- Failure to update SmPCs with side effects identified through company signal detection processes

This metrics report has seen system failures identified for the first time since the 1st July – 31 December 2007 report. The average number of critical findings per inspection has increased during the period of this report.