



MHRA annual statistics 2011/12

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Inspection and Standards 2011/12

Good Manufacturing Practice (GMP)

In summary, GMP performed a total of 550 inspections, of which 149 were overseas, of which 37 were EMA inspections.

Defective Medicines Reporting Centre

Reports received: 902
Drug alerts issued: 35

Good Distribution Practice (GDP)

GDP performed 703 inspections.

Good Clinical Practice (GCP)

Organisations inspected: 101
Investigator sites done: 28

Good Pharmacovigilance Practice (GPvP)

81 inspections performed. Of these, 10 were performed to fulfil the EMA Routine Pharmacovigilance Inspection Programme.

Total number of inspections conducted by GLPMA team (GLP, GMP and GCP) = 111

Good Laboratory Practice (GLP) breakdown:

65 routine biennial
6 for cause

Total GLP Inspections = 71

Total GMP QC Lab inspections = 23

Total GCP Lab inspections = 13

Manufacturers and wholesale dealer's licences plus export certificates

Licences issued

Manufacturer's licences	27
Wholesale Dealer's licences	289
Manufacturer's licence variations	723
Wholesale dealer's licence variations	994

Export certificates

Certificates issued: 6582

Unlicensed import notifications

Total number of notifications 109402

Objections to importation 1259

Clinical emergencies 4607

The number of Clinical Emergencies processed was greater than in previous years as a result of an increased number of critical product shortages

Medicines Testing Scheme

Reports Received

Source of Samples	2008/09	2009/10	2010/11	2011/12
Defect Samples DMRC Inc Comparators	48	56	40	42
Medicines Inspectorate	16	64	88	49
Enforcement/Borderline	341	446	578	505
Pre-Approval (internal MHRA) inc Comparators	229	326	327	249
Market Surveillance Studies	1448	1159	754	237
EMEA (Centrally Authorised Products)	6	10	9	6
Counterfeit surveillance samples; authentication	Not recorded	608	493	567
Other (Includes Public, NHS, Contract Analysis and European Collaboration)	374	186	152	98

Commentary

Surveillance sampling this year has continued to be more focussed on “high risk” products and sites. In particular a large amount of work has been done providing analytical support to the cross-Agency Levothyroxine working party.

MHRA laboratory staff assisted MHRA Enforcement and UK Border Agency staff during Operation Pangea IV. Two analysts took our portable spectroscopy equipment to the Coventry mail hub, where it was used to identify counterfeit products entering the country through the postal service. The instruments even made an appearance on the BBC programme “Fake Britain”.

Proactive continuous surveillance of selected high risk products has continued throughout the year. Samples are collected on behalf of MTS by the General Pharmaceutical Council inspectors and from wholesalers collected by the GDP Inspectorate. This programme provides reassurance that products reaching patients are genuine.

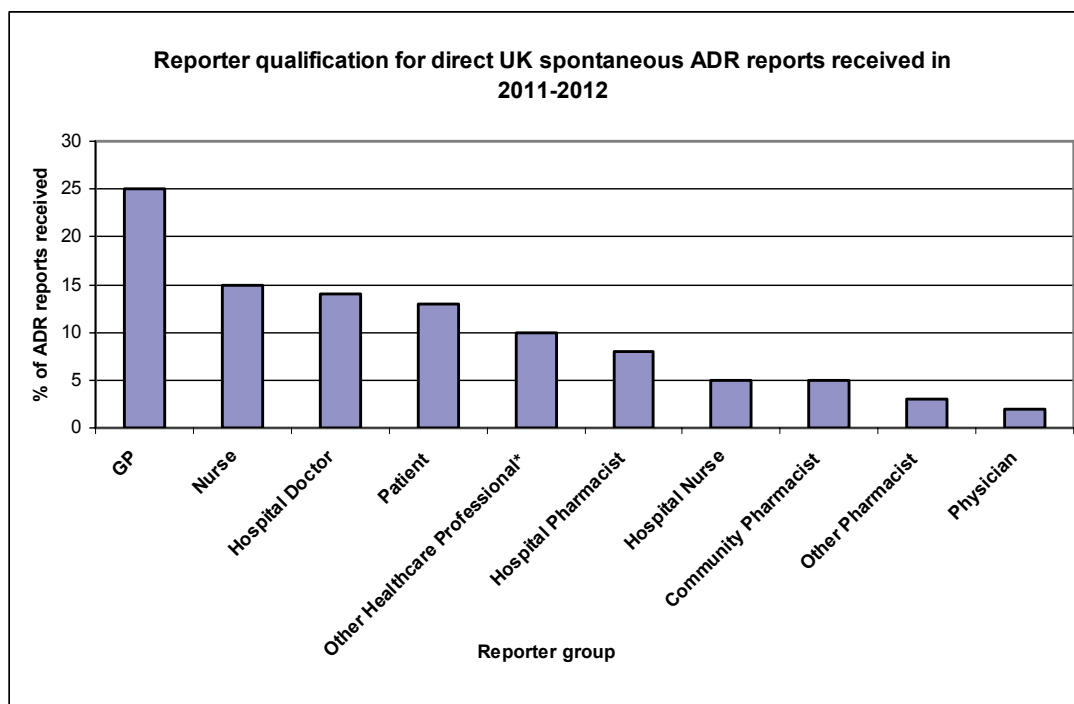
MTS collaborated with EDQM in the sampling of 3 Centrally Authorised Products (CAP) (Angiox, Atripla and Revalimid) and analysis of 3 CAP products (Myocet, Retacript and

Silapo). We also analysis Clopidogrel products (Plavix and generic equivalents) as part of a European market surveillance study.

MTS has continued to provide “Contract Analysis” support to other European Agencies lacking laboratory facilities (Malta and Ireland) and has worked with colleagues in the Official Medicines Control Laboratory network such as Infarmed and Swissmedic.

Pharmacovigilance 2011/12

Reporting source of suspected ADRs in the UK received



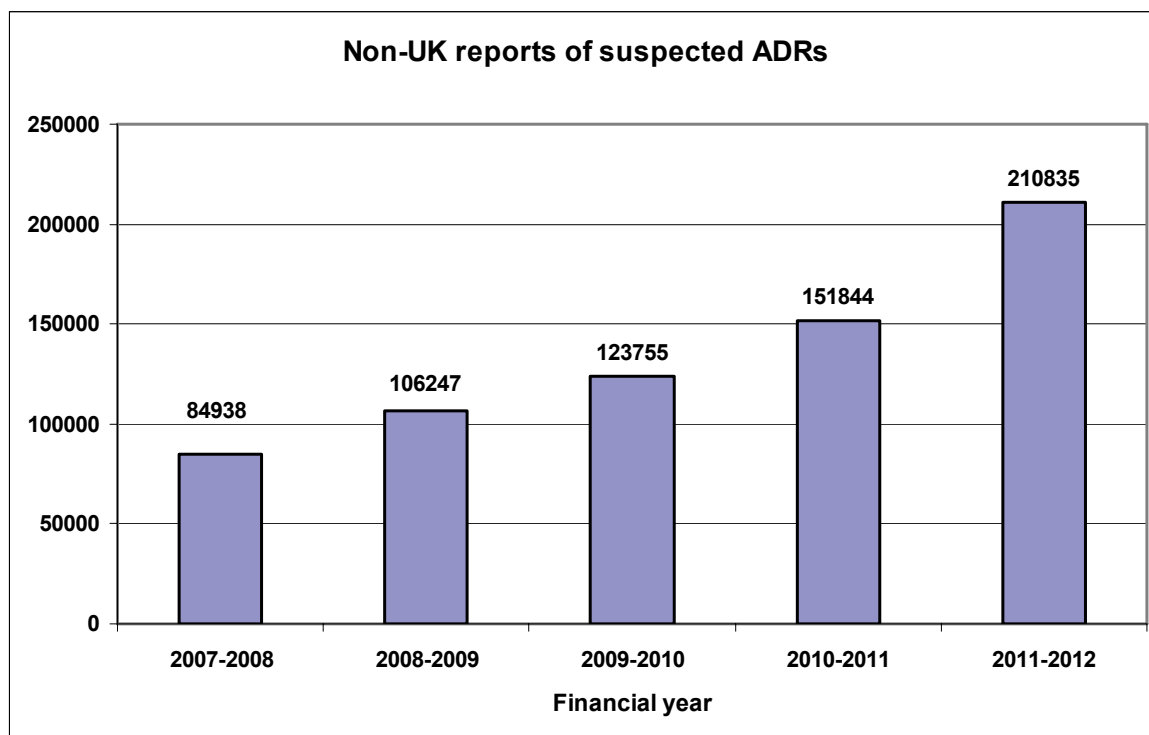
Reporter Group	Percentage
Community Pharmacist	5%
GP	25%
Hospital Doctor	14%
Hospital Nurse	5%
Hospital Pharmacist	8%
Nurse	15%
Other HCP*	10%
Other Pharmacist	3%
Patient	13%
Physician	2%

* Other Healthcare Professionals (HCPs) include: chiropodist, coroner, dentist, healthcare assistant, medical student, midwife, optometrist, paramedic, radiographer, unspecified healthcare professionals.

UK spontaneous suspected ADR reports

	Total Reports	Fatal (%)	Serious (%)
2011-2012	25846	7	87
2010-2011	23411	7	87
2009-2010	26173	4	81
2008-2009	24369	5	84
2007-2008	22201	5	86

Non-UK spontaneous suspected ADR reports



Devices

Adverse incident reports, numbers received, sources and outcomes

Incidents reported 2011/12	11970
Investigated by MHRA	2459

Source	Number	Percentage
Manufacturer	5959	49.8
NHS	3158	26.4
Non-govt organisation	127	1.1
Other govt. dept.	1064	8.9
Overseas reporting organisation	586	4.9
Private healthcare	740	6.2
Patient / MOP	336	2.8
Total	11970	100.0

Outcome	Number	Percentage
No further action yet - trend only	8872	71.6
Single faulty device	976	7.9
Design change of device, label or packaging	895	7.2
Manufacturer changed /Improved QA	754	6.1
Device recall / Field Correction	1719	13.9
Improved maintenance	100	0.8
Revised/additional user training/publicity	238	1.9
MHRA safety warning / Manufacturer notice or letter	343	2.8
Production ceased	61	0.5

Safety warning notices issued

Medical Device Alerts - Immediate Action - 2
 Medical Device Alerts - Immediate Update - 1
 Medical Device Alerts - Action - 101

Total MDAs issued: 104

Enforcement

Medicines

Referrals

New investigations	253
New intelligence files	335
Referral dealt with by CRC	2408
TOTAL	3000
Number of these referrals relating to counterfeit allegations	
Received through dedicated hotline	131
Received through other channels	135
TOTAL	266

Investigation outcomes

Visits conducted	199
Value of medicines seized	£8,230,830
Compliance advice given	139
Formal cautions	32
Prosecutions completed	16
Prosecutions pending	27
Confiscation orders	£111,088
Conviction rate	82%

Intelligence Unit outcomes

Covert test purchases	109
Intelligence shared with UK agencies	163
Intelligence shared overseas	110

Enforcement Policy Unit outcomes

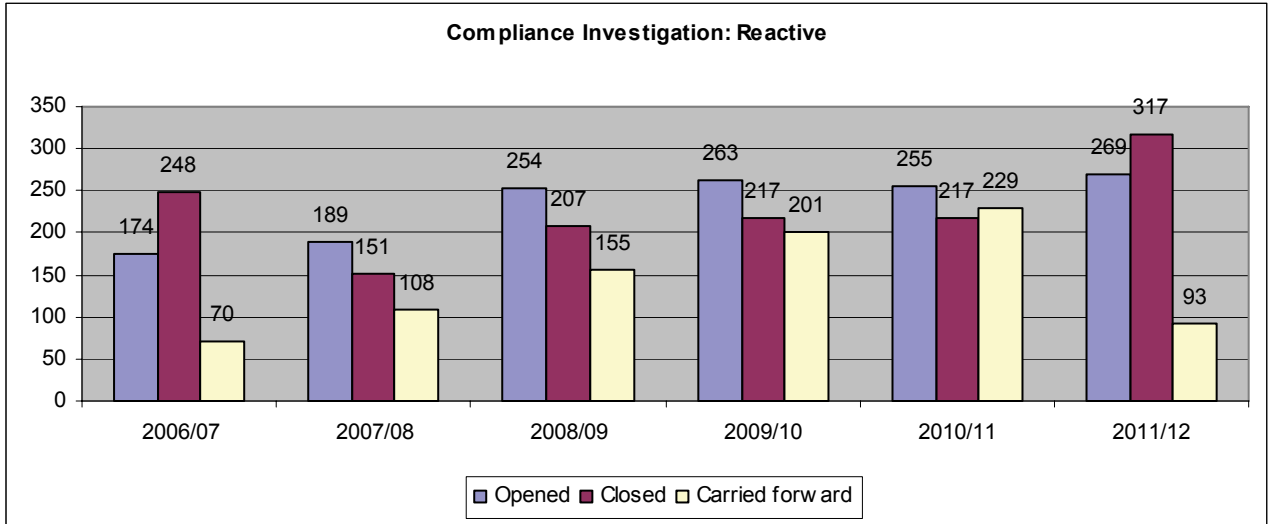
Parliamentary Questions answered (includes POs, TOs and DEs)	16 (+7 contributions)
FOI requests answered	16 (+3 contributions)
Ministerial briefings provided	9 (+3 contributions)
Other government briefings provided	17

Devices

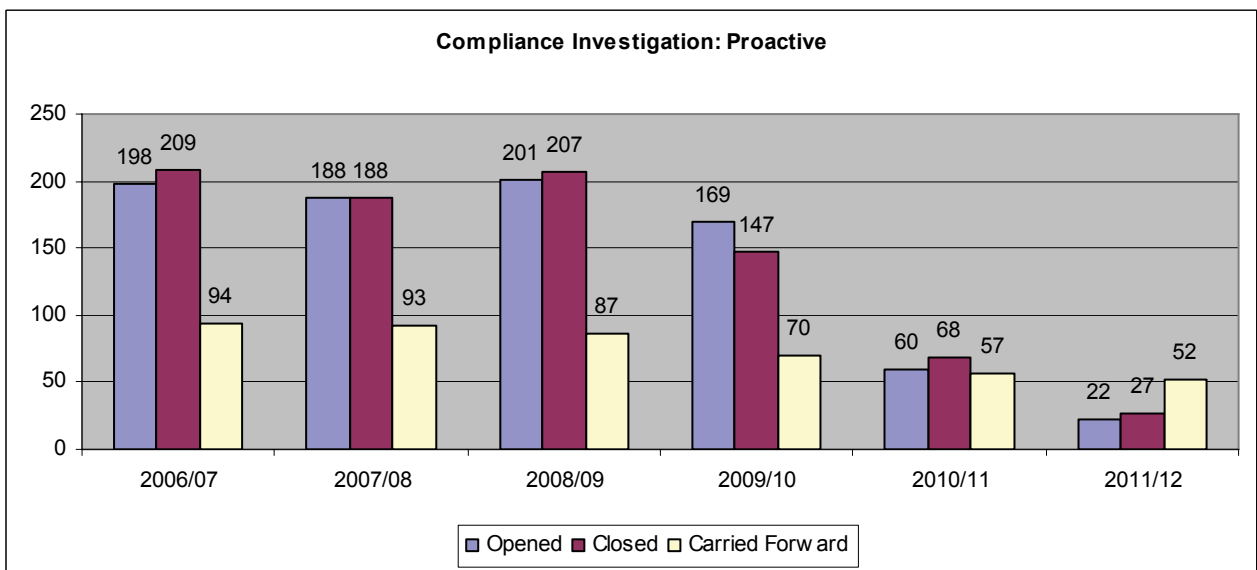
The agency changed its focus in relation to proactive investigations where they now focus on a risk based proactive investigations regime, where they select devices, manufacturers and specific areas identified through complaints, incidents and completed reactive cases meeting a specific criteria . As a result of this the agency started 22 proactive cases and completed 27. It opened 269 reactive cases and completed 317. There are currently 93 under investigation. There were 23 inspections where the agency obtained search warrants to gain entry to premises. The Agency issued 4 compliance notices and in addition 6 devices were removed from the market as a result of compliance action and another 14 cases referred to

other Member States for Investigation. All other cases were resolved satisfactory by working co-operatively with the manufacturers concerned.

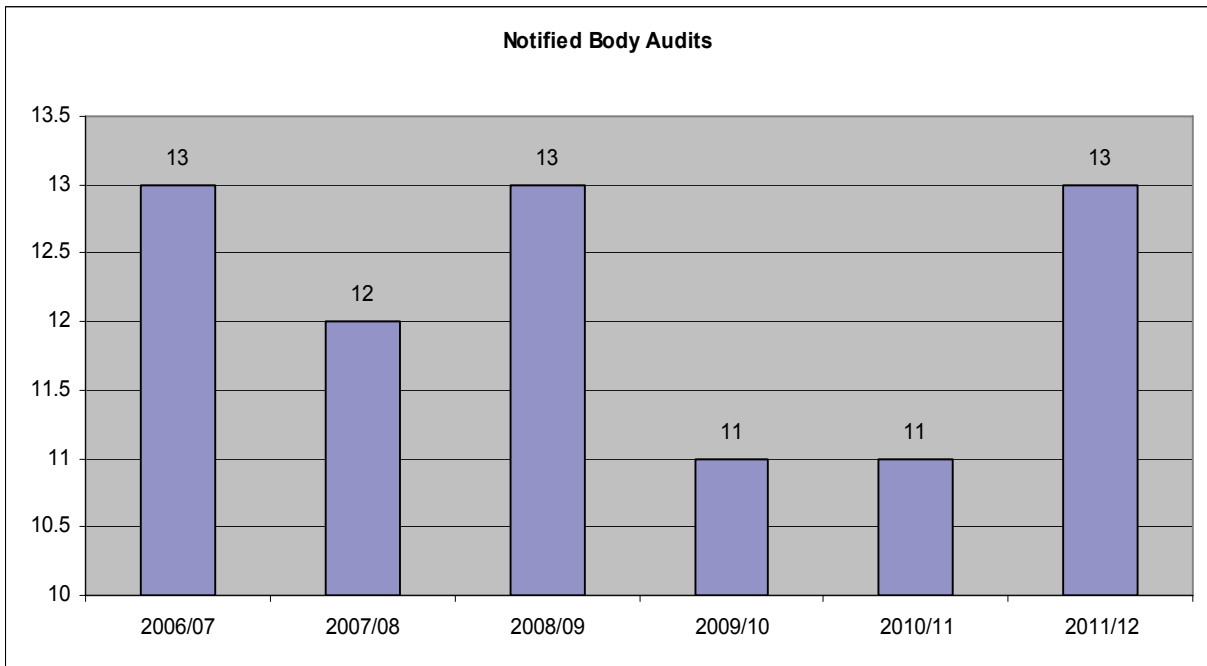
Compliance Investigations: Reactive



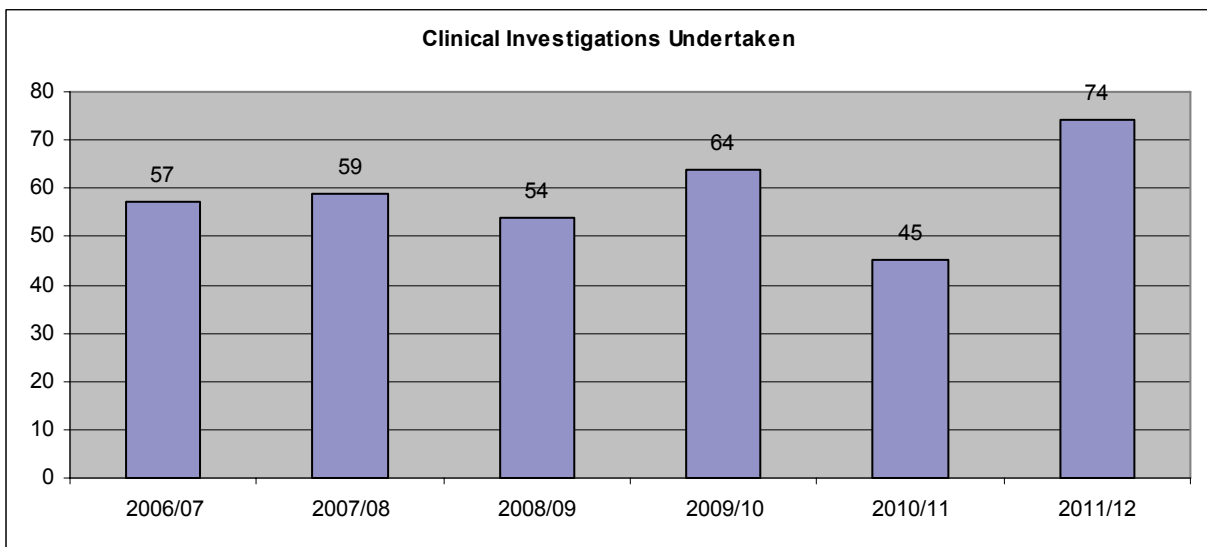
Compliance Investigations: Proactive



Notified Body Audits



Clinical Investigations Undertaken



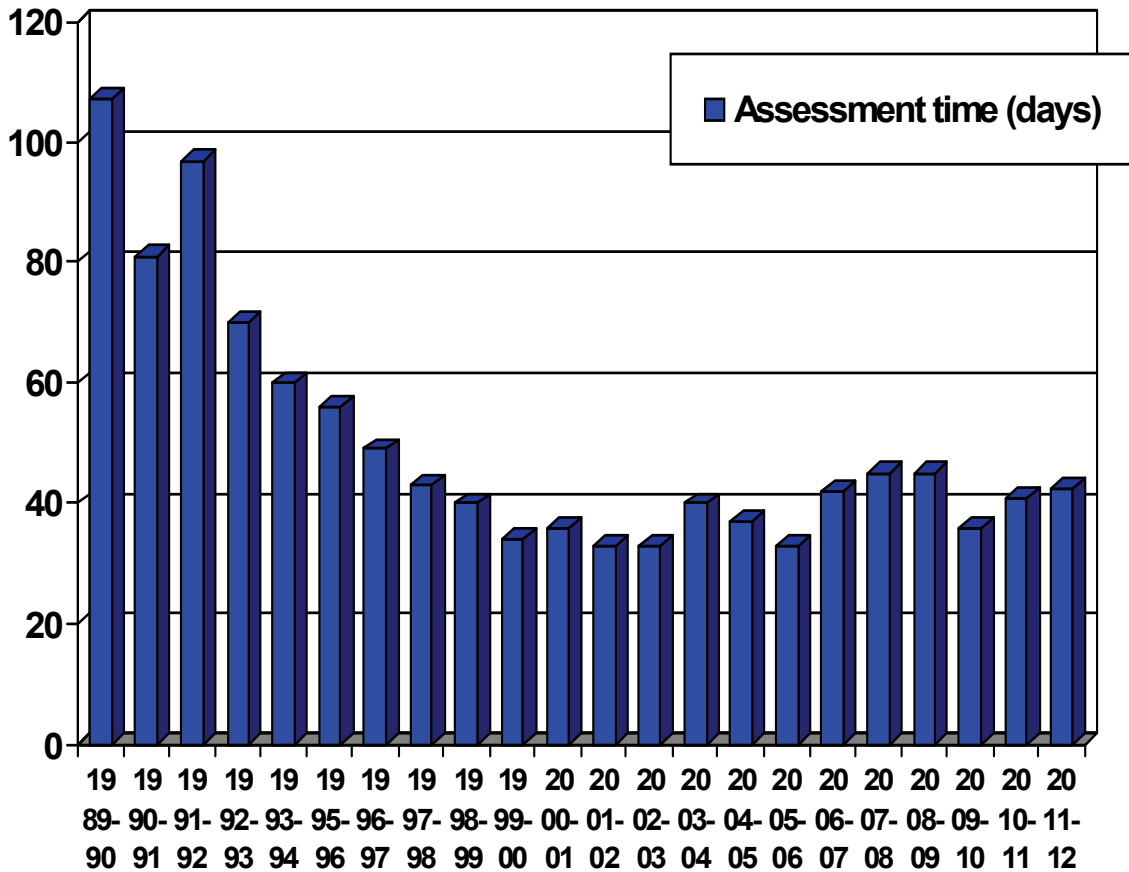
We have also reviewed 11 Supplementary Evaluation Reports prepared by Notified Bodies in respect of devices utilising tissues of animal origin

Clinical trial authorisations (CTA)

Number of Phase 1 applications received	220
Average assessment time for Phase 1 (target 14.0)	12.4
Percentage Phase 1 assessed in 30 days (target 98%)	100%
Number of other CTA applications	700
Percentage approved in 30 days (target 98%)	100%

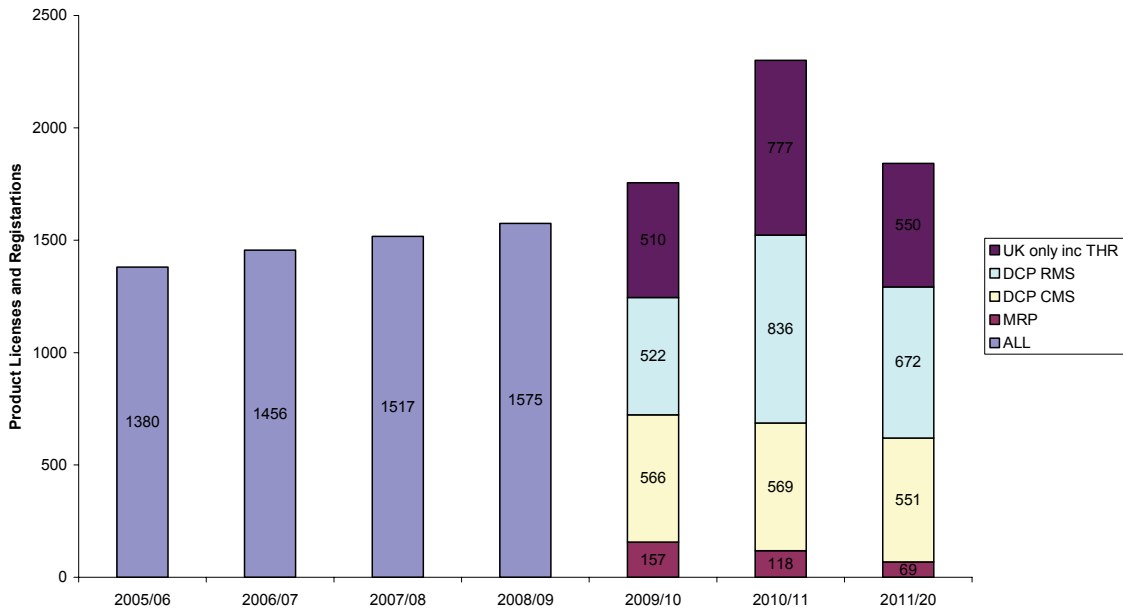
All performance metrics for CTA applications are now published on the MHRA website and updated monthly.

New active substances (NAS) assessed

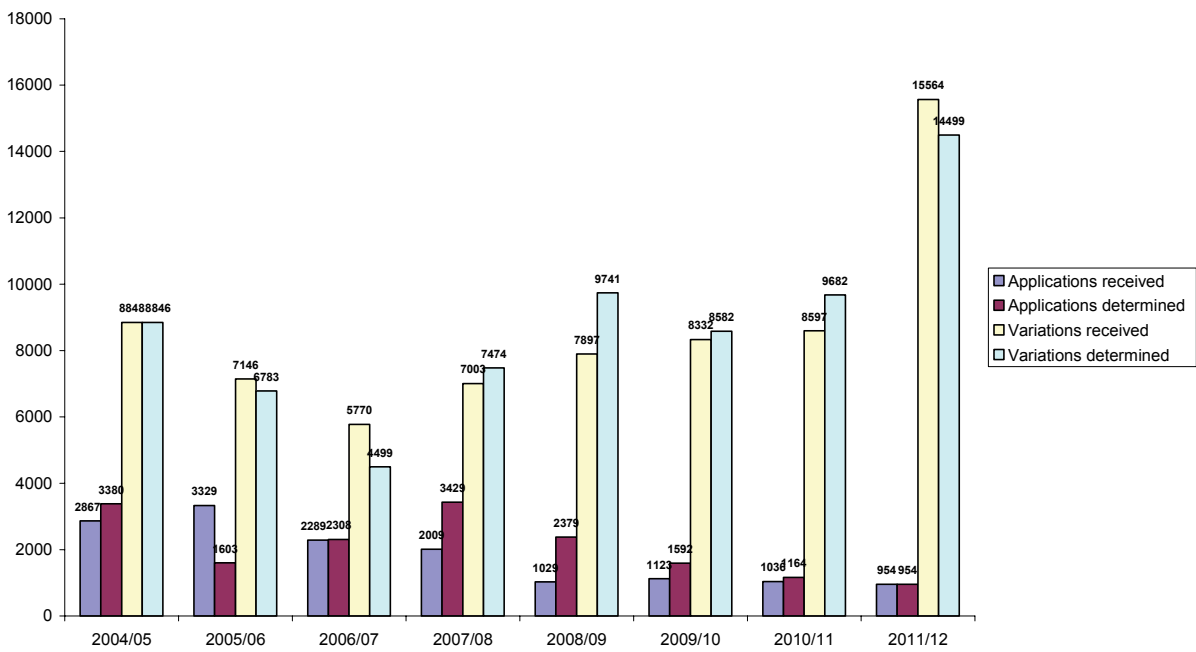


Marketing authorisation applications determined

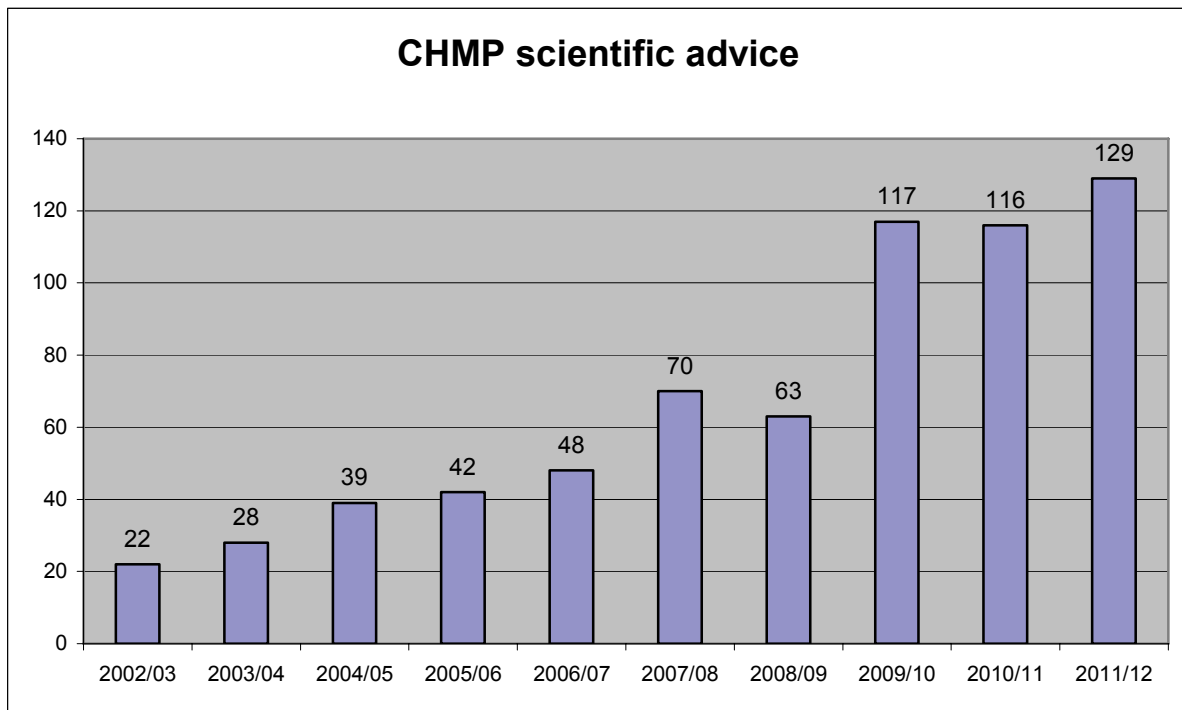
Marketing authorisation applications determined



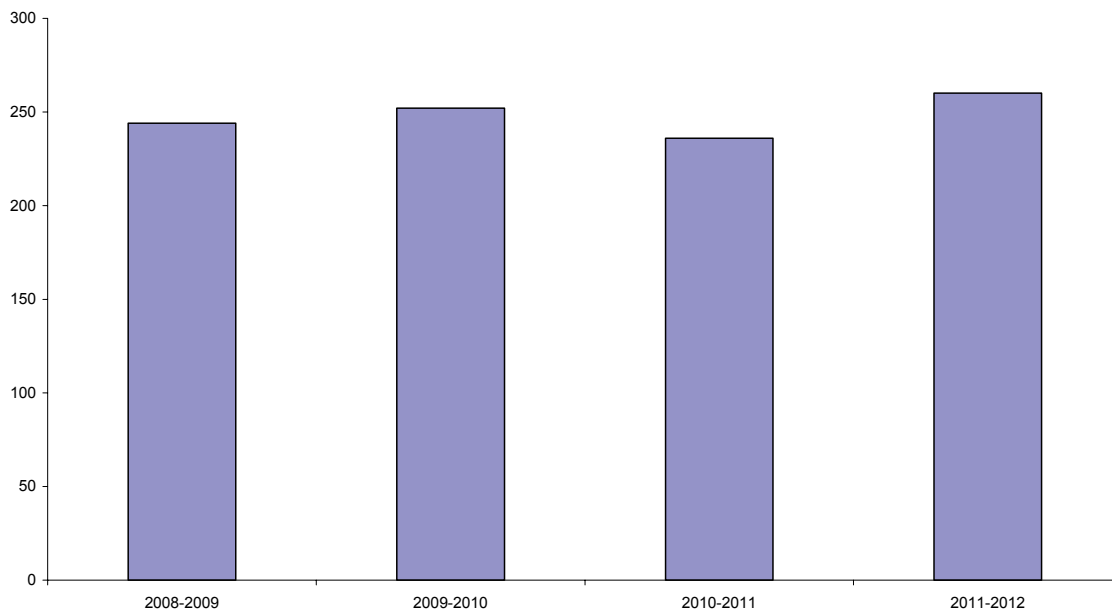
Parallel imports



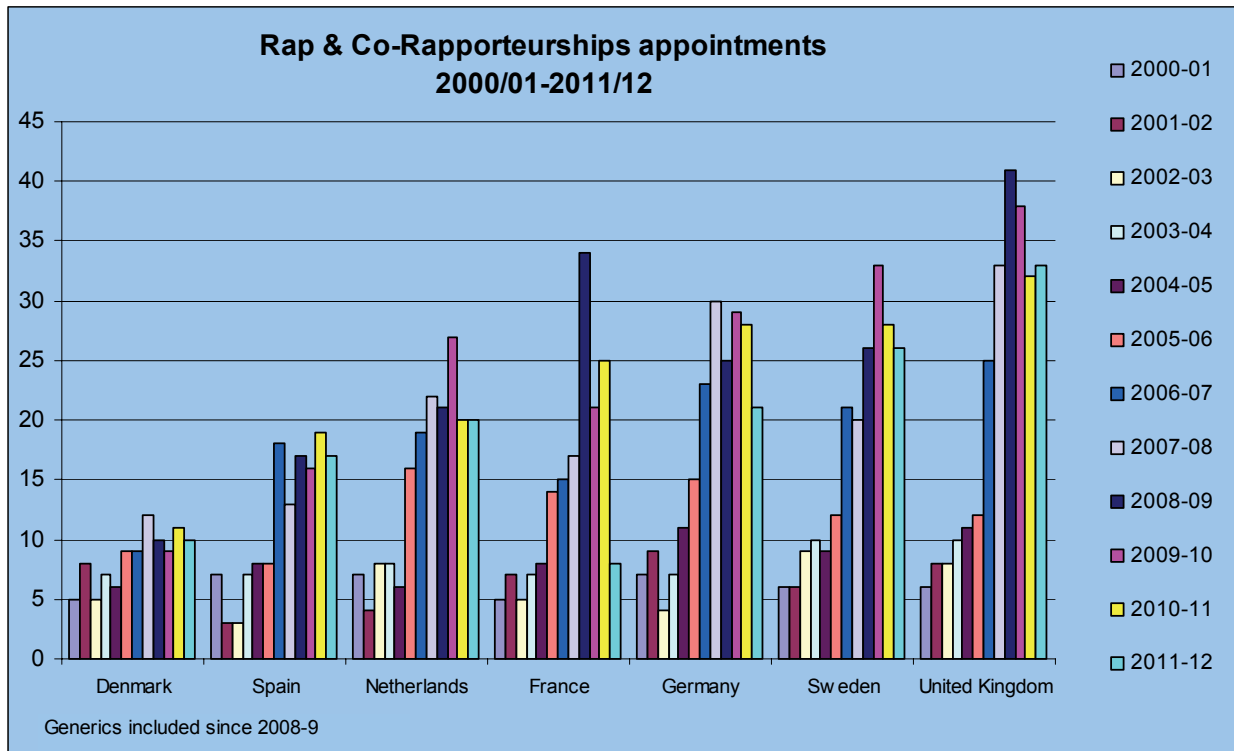
CHMP scientific advice



MHRA scientific advice



Centralised rapporteur and co-rapporteurships



Renewals

The Agency received an average of 25 national renewal applications per month in 2011/2012 which is in line with the figures for 2010/2011. The UK acted as reference member State in 242 MR procedures which is significantly higher than in the previous year. The UK was Rapporteur or Co-Rapporteur for 15 centralised procedures which is a slight increase on the previous year.

Advertising

	2008/2009	2009/2010	2010/2011	2011/2012
Number of complaints received	199	371	358	325
Number of advertisements withdrawn or amended as a result of action on complaints	107	273	293	238
Number of advertisements withdrawn or amended as a result of Agency scrutiny	6	6	6	2
Number of Corrective statements published	1	4	3	2
Products for which advertising was reviewed prior to issue	55	50	50	46

Additional information can be found in the Agency's sixth annual report on the regulation of medicines advertising, *Delivering high standards in medicines advertising regulation*. This covers the period from January 2011 to December 2011 and can be found on the MHRA website, www.mhra.gov.uk. The 2012 annual report will be published in early 2013.

Borderline medicines

Complaints of breaches of legislation: received 276, cleared 226
Advice requests: received 508, cleared 537
Statutory determinations issued: provisional 13, Final 14

Sales of British Pharmacopoeia (BP)/BP Chemical Reference Substances

British Pharmacopoeia 2011 3073 copies; 161 active online subscribers

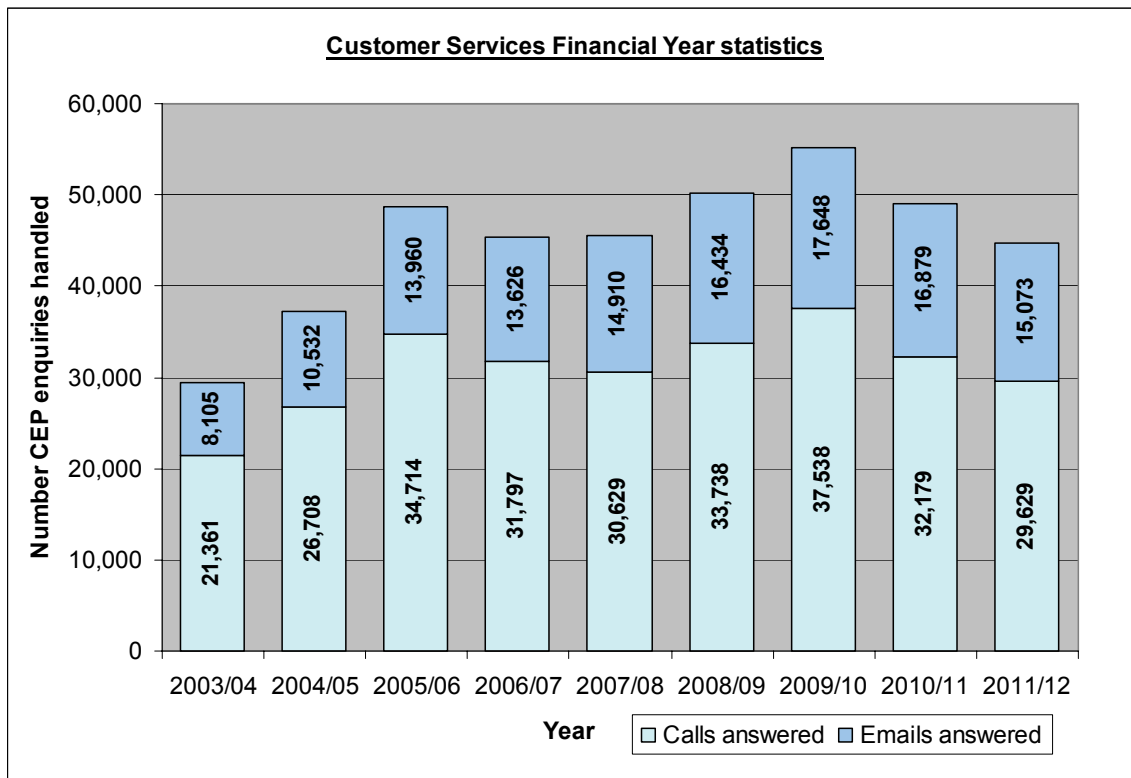
British Pharmacopoeia 2012 (to end June 2012) 2565 copies; 175 active online subscribers

Sales of BP Chemical Reference Substances (No of vials sold)	2008/09	2009/10	2010/11	2011/12
	11,645	12,461	13,375	15,697

Number of Invented Names assessed

Year:	2008/9	2010/11	2011/2012
Number of EMA Names	549	698	963
Number of National Names	461	516	574
Total Number of Names:	1010	1214	1537

MHRA Customer Services enquiries



Medicines Information enquiries

Medicines Information received 3,351 enquiries in 2011/12.

Press Office enquiries

	Number of enquiries	Number of proactive enquiries	Percentage
Apr-11	225	146	64%
May-11	139	67	48%
Jun-11	165	74	45%
Jul-11	159	73	46%
Aug-11	280	199	71%
Sep-11	353	205	58%
Oct-11	165	98	58%
Nov-11	162	87	50%
Dec-11	232	118	51%
Jan-12	257	126	49%
Feb-12	356	171	48%
Mar-12	176	55	3%
Apr-12	163	65	40%