Safeguarding public health

MHRA annual statistics 2010/11

Medicines and Healthcare products Regulatory Agency

Contents

Inspection and Standards

Good Manufacturing Practice (GMP)

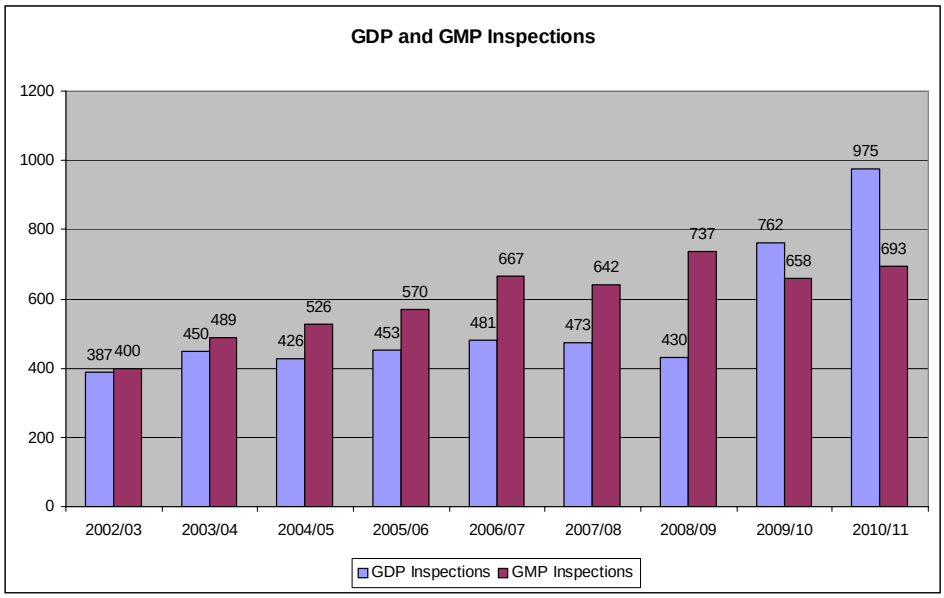
In summary, GMP performed a total of 693 inspections, of which 153 were overseas, of which 39 were EMA inspections.

Defective Medicines Report Centre (DMRC)

2010/11	**830 reports received**	**35 Drug Alerts issued**
2009/10	881 reports received	39 Drug Alerts issued
2008/09	858 reports received	30 Drug Alerts issued
2007/08	465 reports received	34 Drug Alerts issued
2006/07	550 reports received	24 Drug Alerts issued

Good Distribution Practice (GDP)

GDP inspectors performed 975 inspections.



Good Clinical Practice (GCP)

Organisations inspected: 112
Investigator sites done: 35

Good Pharmacovigilance Practice (GPvP)

Pharmacovigilance inspectors undertook 115 UK statutory inspections during 2010/11. Of these, 3 were performed in India, 1 was a CHMP request and 11 were performed to fulfil the EMA Routine Pharmacovigilance Inspection Programme

Good Laboratory Practice Monitoring Authority (GLPMA)

In total, the GLPMA team (GLP, GMP and GCP) conducted 111 inspections:

GLP inspections

Routine biennial	60
Implementation	7
For cause	3
Total	**70**

GMP QC Lab inspections	**28**
GCP Lab inspections	**13**

Manufacturer's and wholesale dealer's licences plus export certificates

Licences issued	**2006/07§**	**2007/08**	**2008/09**	**2009/10**	**2010/2011**
Manufacturer's licences	174	76	48	46	33
Wholesale Dealer's licences	226	202	157	233	264
Manufacturer's licence variations	547	731	846	877	676
Wholesale dealer's licence variations	466	536	500	571	681
Export certificates issued	6,765	6,477	7,549	6,879	5,947

§ New operating procedures were implemented during the year 2006/07 in response to legislative changes. As a result licence holders previously holding one type of licence e.g. a wholesale dealer's (import) licence could instead have to hold a different type of licence e.g. a manufacturer's/importer's licence. Furthermore, licence-holders who previously held a single licence i.e. a combined human/ veterinary licence may have to hold two or more licences.

Import Notification Section

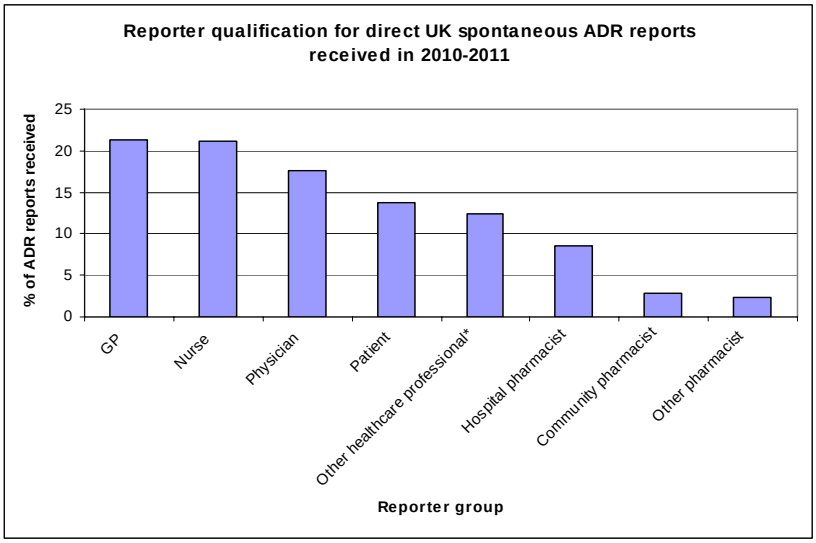
Year	**2006/07**	**2007/08**	**2008/09**	**2009/10**	**2010/11**
Total number of notifications	163,000	51,227	55,099	85,685	86,066
Objections to importation	5,335	817	912	1,267	385
Clinical emergencies	716	1,399	1,236	1,514	1,903

Medicines Testing Scheme

Source of Samples	2007/08	2008/09	2009/10	2010/11
Defect Samples DMRC Inc. Comparators	83	48	56	40
Medicines Inspectorate	25	16	64	88
Enforcement/Borderline	406	341	446	578
Pre-Approval (internal MHRA) Inc. Comparators	163	229	326	327
Market Surveillance Studies	1347	1448	1767	754
EMEA (Centrally Authorised Products)	9	6	10	9
Counterfeit Surveillance Samples - authentication	-	-	608	493
Other (Includes Public, NHS, Contract Analysis and European Collaboration)	176	374	186	152

Pharmacovigilance

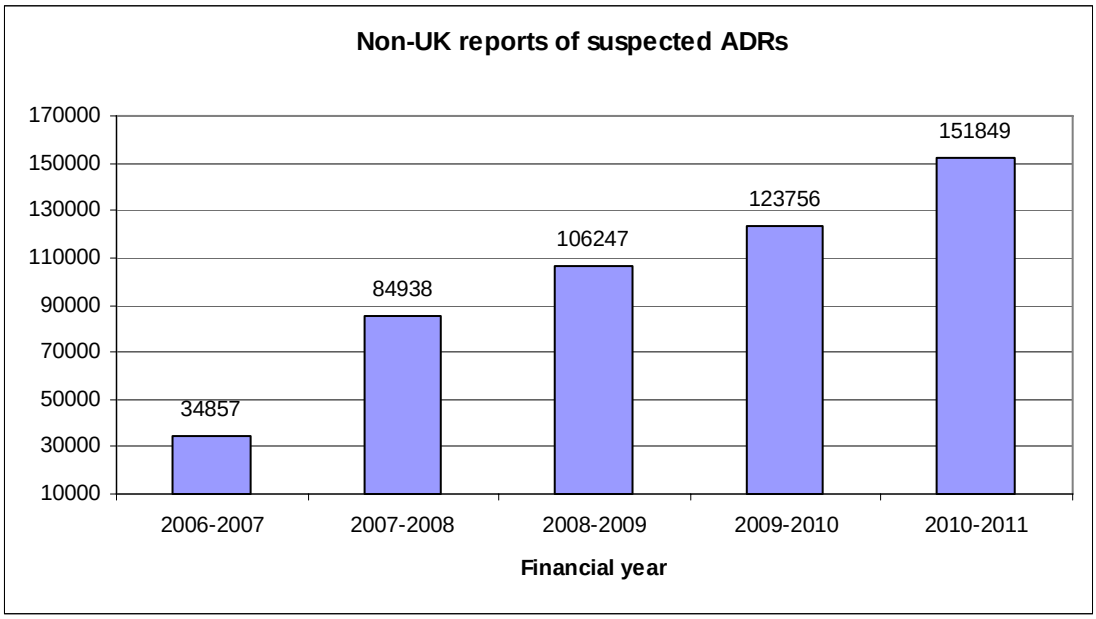
Reporting source of ADRs in the UK received in 2009/10



Reporter Group	Percentage
Community Pharmacist	3%
GP	21%
Hospital Pharmacist	8%
Nurse	21%
Other HCP*	12%
Other Pharmacist	2%
Patient	14%
Physician	18%

* Other Healthcare Professionals (HCPs): include coroner, dentist, optometrist, unspecified healthcare professionals

Non-UK reports of suspected ADRs



Spontaneous UK ADR reports

	Total Reports	Fatal (%)	Serious (%)*
2010-2011	**23465**	**7**	**87**
2009-2010	26293	5	84
2008-2009	24385	5	84
2007-2008	22213	5	86
2006-2007	21498	4	85

* Seriousness excludes reports received for pandemic medicines

Devices

Adverse incident reports, numbers received, sources and outcomes

	2007/08	2008/09	2009/10	2010/11
Incidents reported	8,741	8,884	9,270	10,499
Number investigated	2,897	2,888	2,932	2940
Source of incident				
Manufacturers (%)	46.3	43.3	43.8	48.2
NHS (%)	36.0	37.7	36.5	30.9
Non-government organisations (%)	3.9	0.5	0.7	0.9
Other government departments (%)	4.9	8.6	7.9	8.4
Overseas reporting organisation (%)	5.6	4.9	7.2	6.2
Private healthcare (%)	2.0	3.0	2.8	3.2
Patient/member of the public (%)	1.2	1.2	1.2	2.2

Outcomes*	2007/08	2008/09	2009/10	2010/11
No further action yet – trend only (%)	68	71.1	66.9	70.5
Single faulty device (%)	10	9.4	8.0	8.0
Design change of device, label or packaging (%)	19	11.2	11.9	12.9
Manufacturer changed/improved QA (%)	9	9.1	9.4	9.0
Device recall and field correction (%)	16	8.7	11.8	9.0
Improved maintenance (%)	2	1.8	1.7	1.1
Revised/Additional user training/publicity (%)	4	4.1	3.4	2.9
MHRA Safety warning/manufacturer notice or letter (%)	24	10.9	10.2	9.2
Production ceased (%)	1	1.2	0.3	1.9

*Outcome totals exceed 100% as some incidents fall into more than one category.

Safety warning notices issued

Notices published	2008/09	2009/10	2010/11
Medical Device Alerts – Action	59	54	73
Medical Device Alerts – Immediate action	35	26	34
Medical Device Alerts – Action/Information	-	-	-
Medical Device Alerts – Immediate Action/Information	1	-	-
Medical Device Alerts – Action/Update	3	5	2
Medical Device Alerts – Immediate action/update	-	2	4
Medical Device Alerts – Immediate action/update/Info	1	-	-
Total MDAs issued	**99**	**87**	**113**

Enforcement

Medicines

Council of Europe / EDQM Training
Co-ordination of the training initiative for the European Directorate for Quality Medicines (EDQM) by the Enforcement Group Business & Training Manager as the UK representative on the expert committee for protecting public health from counterfeit medical products continues. The initiative is primarily designed to bring closer working among Police, Customs and Drug Regulatory Authorities in Council of Europe member states. Following a successful training event in Lisbon at the start of the year two further meetings have taken place and a training review and future strategy developed. The MHRA Enforcement Group has now delivered training to over 140 Police, Customs and Regulators in Europe.

Heads of Medicines Agency Working Group of Enforcement Officers (HMA WGEO)
HMA WGEO is established to contribute to the protection of public health and animal health and welfare through ensuring adherence to the regulations of the manufacturing and distribution chains of medicinal products, the disruption of illegal activities and the sharing of information. The HMA WGEO contributes by facilitating Member State/agency liaison, co-operation, co-ordination and exchange of information focusing upon the regulatory responsibility of the HMA. The HMA WGEO shall work in a transparent manner. The purpose of the HMA WGEO meetings are for the enforcement officers to meet every six months (hosted by the EU Presidency country) to make face-to-face contact with European counterparts to discuss aspects of pharmaceutical crime and particularly counterfeit medicines. It presents a valuable opportunity to share experience, expertise and knowledge and further provides a practical training platform. The MHRA Enforcement Group provides the Secretariat function in the WGEO.

INTERPOL Ghana Operation
The MHRA Enforcement Group Intelligence Unit supported INTERPOL Medical Products Counterfeiting and Pharmaceutical Crime Unit (at their request) to provide medicines enforcement training to Ghanaian law enforcement representatives from the medicines regulator, police and customs. The total numbers of attendees for the training were 59 with the most senior official being a Director-General of the Police Criminal Investigations Department. In addition, the Director of INTERPOL Ghana attended. The training covered a range of Enforcement areas from the roles and skills required of a medicines enforcement officer through case study investigative examples focussing on intelligence and evidence gathering as well as how to handle a counterfeit incident.

Operation Singapore
Following a 4 year investigation into the most serious breach of the regulated supply chain in Europe of over 2 million doses of counterfeit medicines, 1 person was convicted and sentenced to 8 years imprisonment. The case involved three prescription only medicines for treatment of psychosis, heart disease and prostate cancer which entered the UK over a 6 month period and were recalled from the market May 2007. The MHRA Enforcement Group seized 1.4 million doses before they reached the market and a further 196,000 doses as a result of the recall, but this left a significant number of products that had reached pharmacies and patients. The investigation involved 12 countries and resulted in a 4 month trial with 100 witnesses giving evidence. At the conclusion of the trial members of the Enforcement Group were commended by the trial Judge for the steps taken to protect public health. Recommendations have been made at a European and National level to strengthen the pharmaceutical supply chain.

Operation PANGEA III
Operation PANGEA III involved 45 countries. Medicines regulators, customs, police and industry investigators participated globally with INTERPOL co-ordinating the operation from Lyon. The operation was reported in over 25 countries in 18 languages and involved the seizure of over 2million doses of illegal medicines worth over US$6m, the closing down of over 300 websites and 87 individuals under arrest/ investigation. In the UK, nearly 300,000 doses of illegal medicines with approx £0.6m were seized with 280,000 of these seized by UKBA officers at Coventry postal hub. National TV, radio and print coverage was obtained. With the assistance of the Metropolitan Police e-Crime unit, 80 websites were taken down by the UK with another 1,000 pending take-down. Partnerships were formed with payment providers to remove payment facilities for websites proven to be acting illegally and continued partnerships with search engines, domain name providers/registrars and Internet Service Providers are being pursued.

Referrals

New Investigations	232
New Intelligence files	273
Referrals dealt with by CRC	2295
Grand Total	**2800**

Number of these referrals relating to counterfeit allegations	
Received through dedicated hotline	58
Received through other channels	35
Grand Total	**93**

Investigation outcomes

Visits conducted	217
Value of medicines seized	£8,237,113
Compliance advice given	105
Formal cautions	36
Prosecutions completed	14
Prosecutions pending	26
Confiscation orders	£138,587
Conviction rate	88.5%

Intelligence Unit outcomes

Covert test purchases	132
Intelligence shared UK agencies	164
Intelligence shared overseas	127

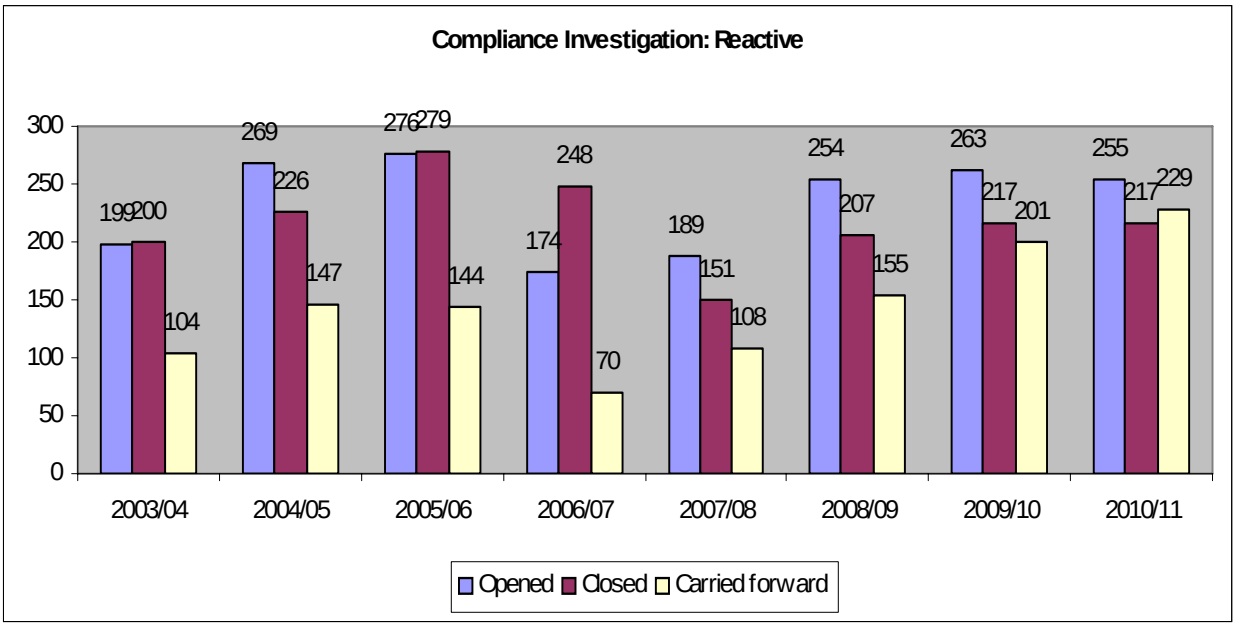
Enforcement Policy Unit outcomes

Parliamentary Questions answered	8
FOI requests answered	13
Ministerial briefings provided	8
Other government briefings provided	47

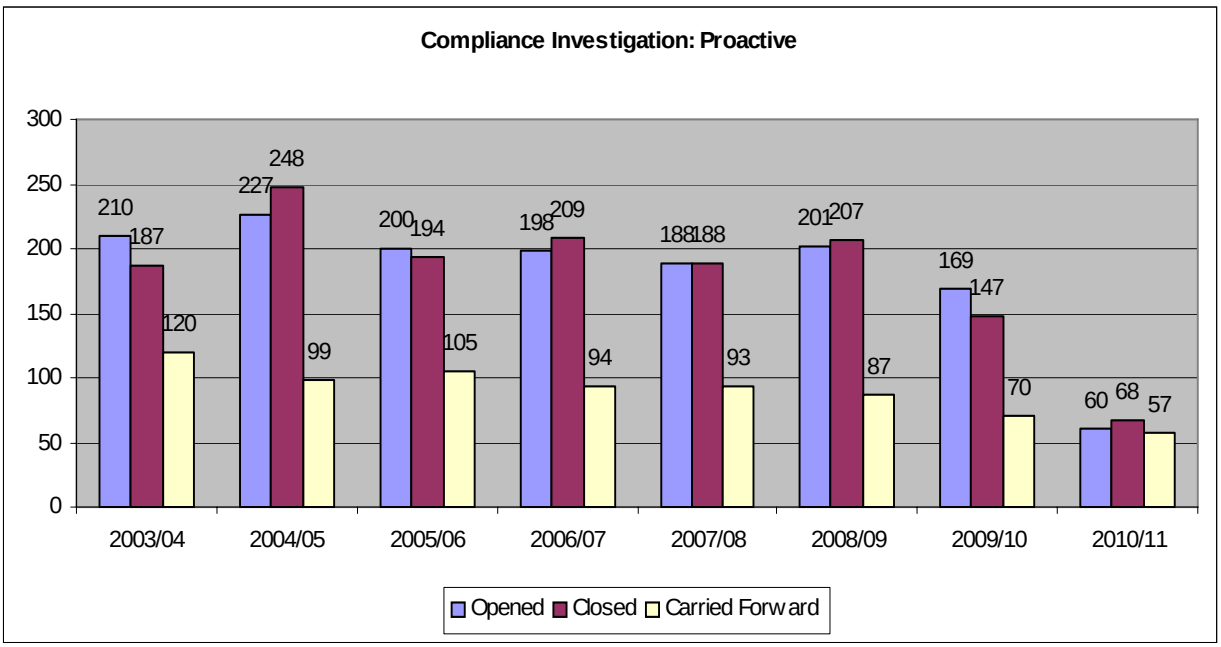
Devices

The agency started 60 proactive cases and completed 68. It opened 225 reactive cases and completed 254. There are currently 229 under investigation. There were 46 on-site inspections to dental Laboratories and spectacle assembles. The Agency issued 2 compliance notices and in addition 12 devices were removed from the market as a result of compliance action and another 14 cases referred to other Member States for Investigation. The Agency also submitted 7 cases for consideration for prosecution. All other cases were resolved satisfactory by working co-operatively with the manufacturers concerned

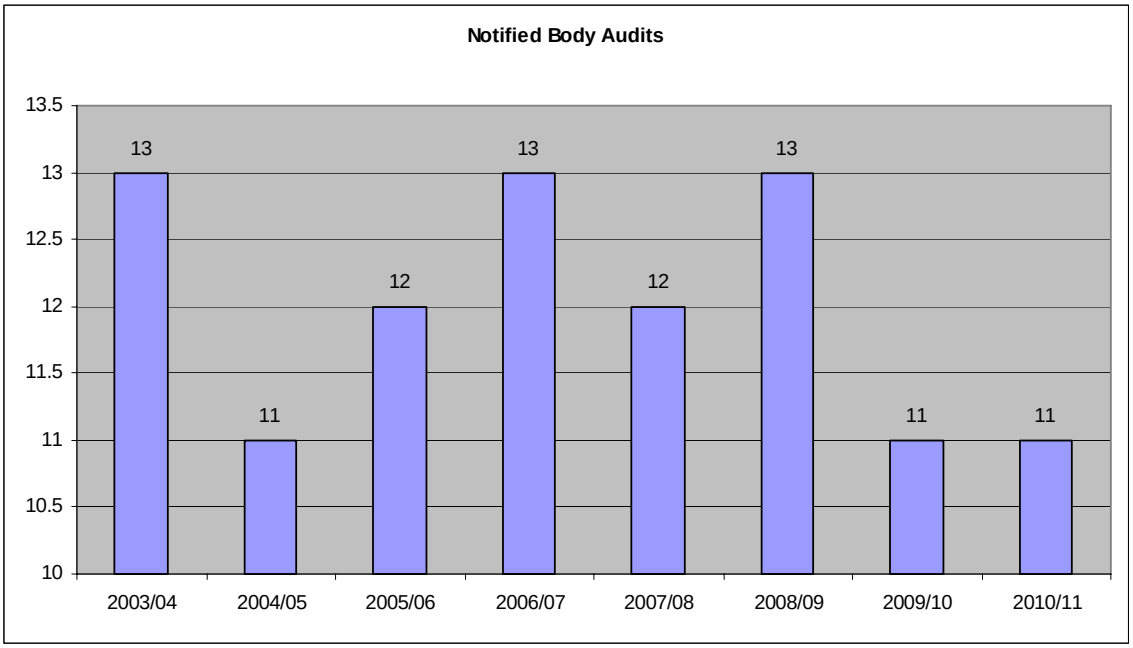
Compliance investigations: Reactive



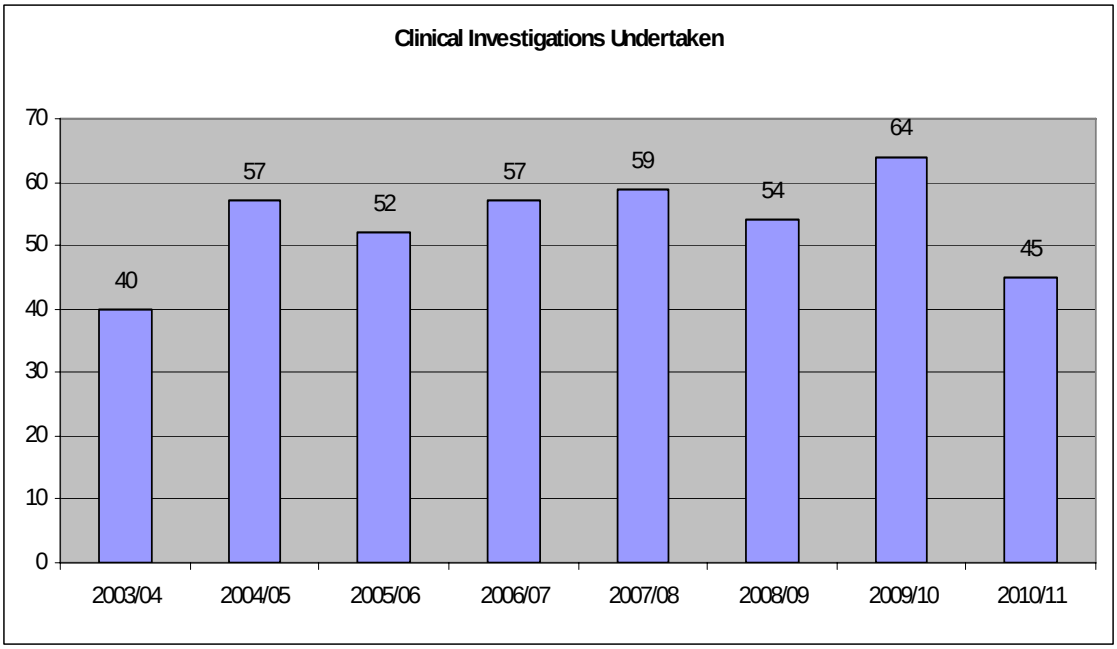
Compliance investigations: Proactive



Notified body audits



Clinical investigations undertaken

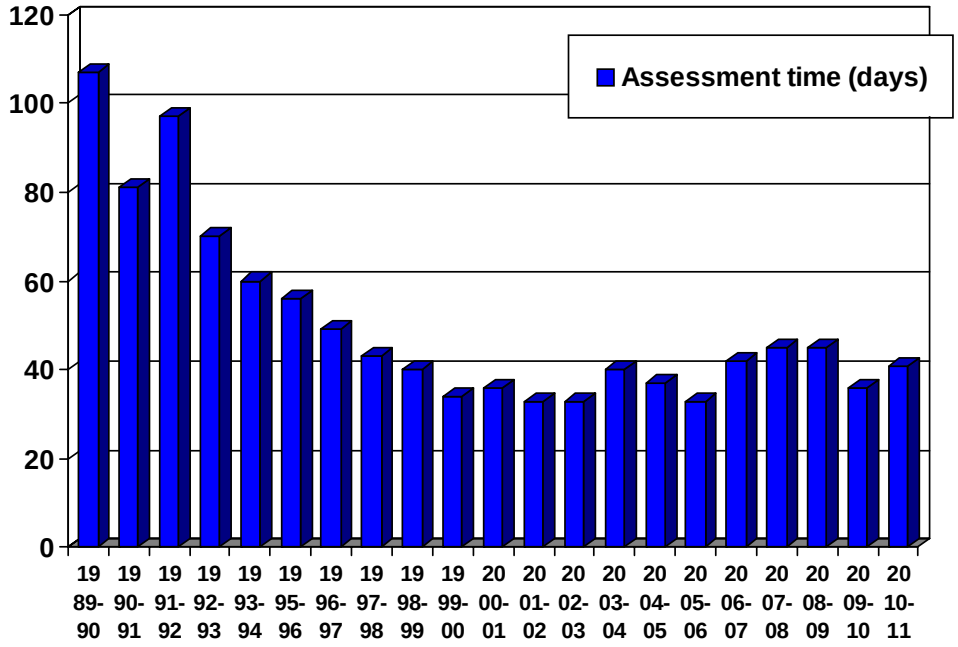


Clinical trial authorisations (CTA)

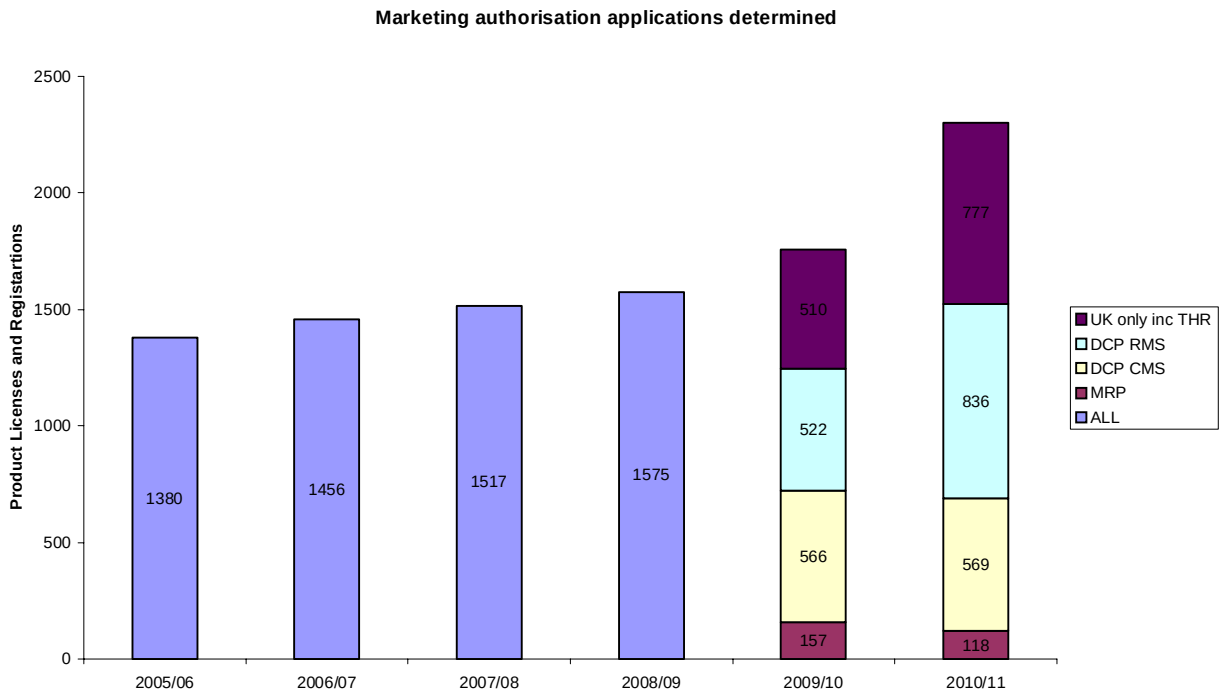
	2008/09	2009/10	2010/11
Number of Phase 1 applications received	236	252	208
Average assessment time for Phase 1 (target 14.0)	12.7	12.3	13.1
Percentage Phase 1 assessed in 30 days (target 98%)	100%	100%	100%
Number of other CTA applications	937	842	747
Percentage approved in 30 days (target 98%)	100%	100%	100%

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

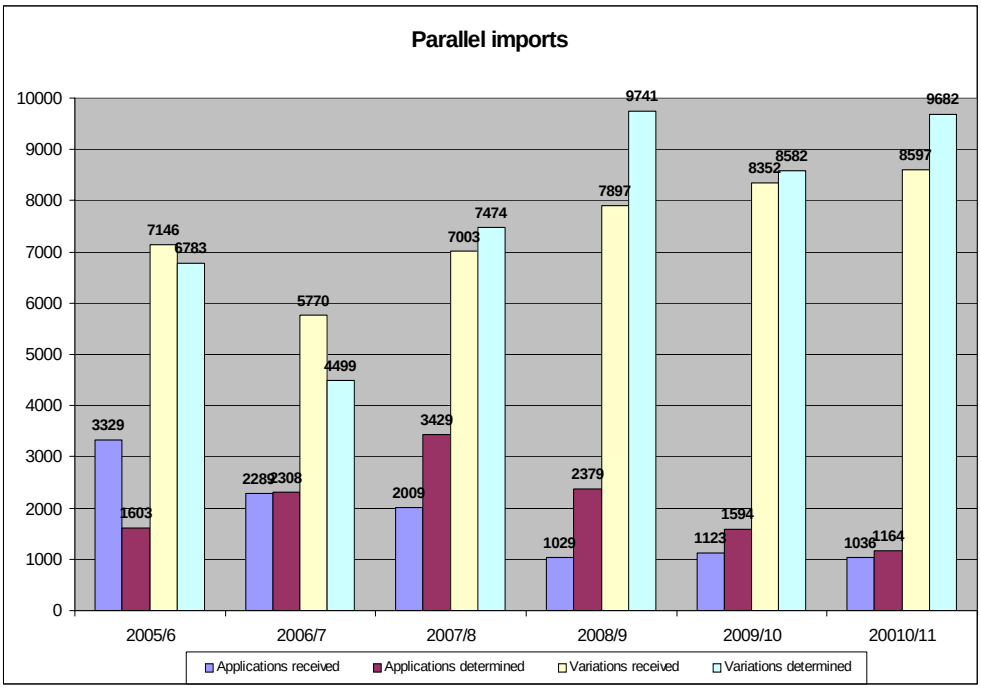
New active substances (NAS) assessed



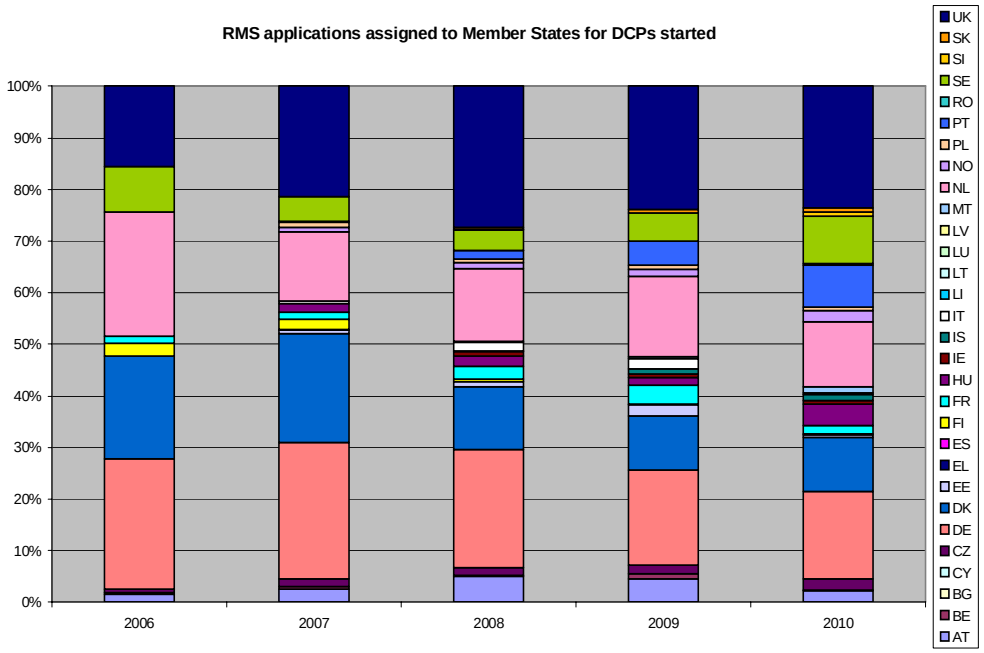
Marketing authorisation applications determined



Parallel imports

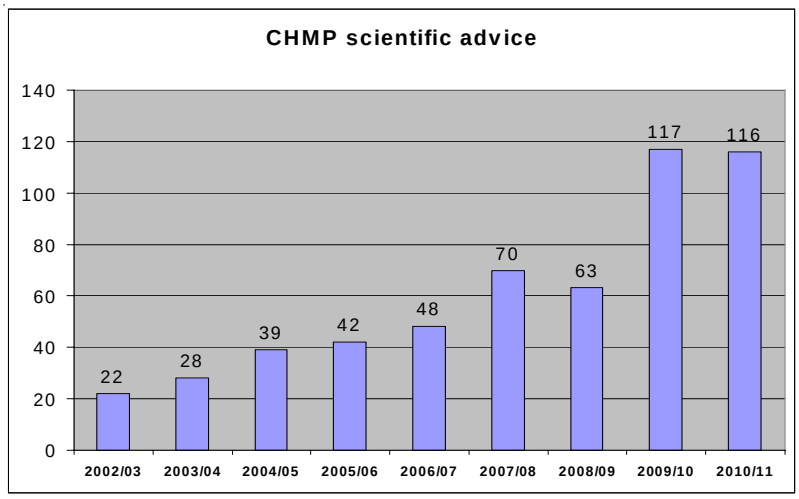


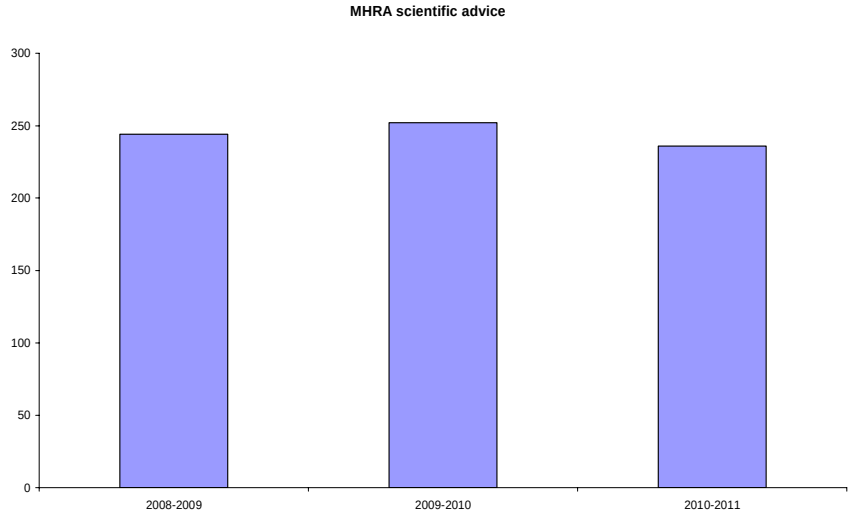
Decentralised Procedures with UK as Reference Member State



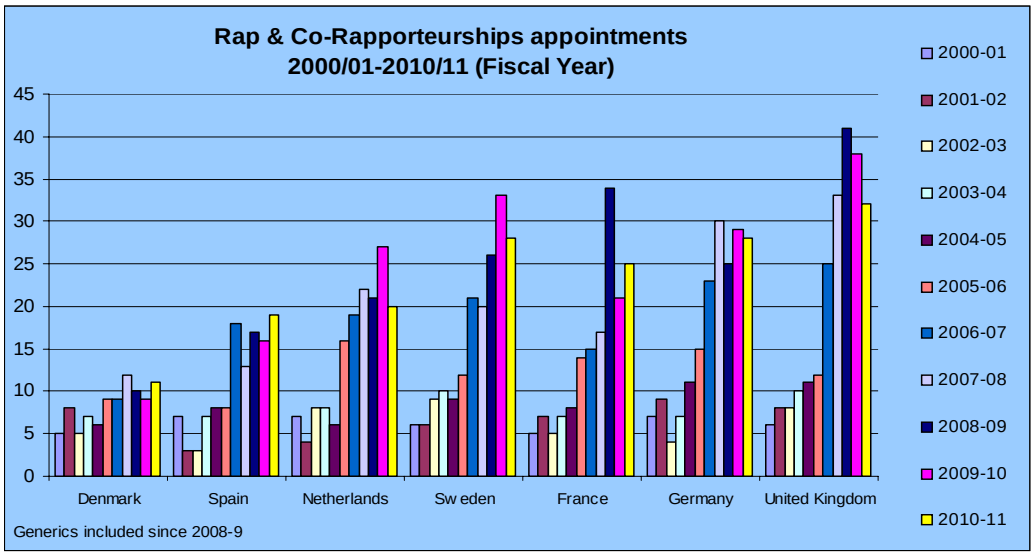
CHMP scientific advice

The UK continues its strong contribution in both CHMP and MHRA scientific advice.





Centralised rapporteur and co-rapporteurships



Renewals

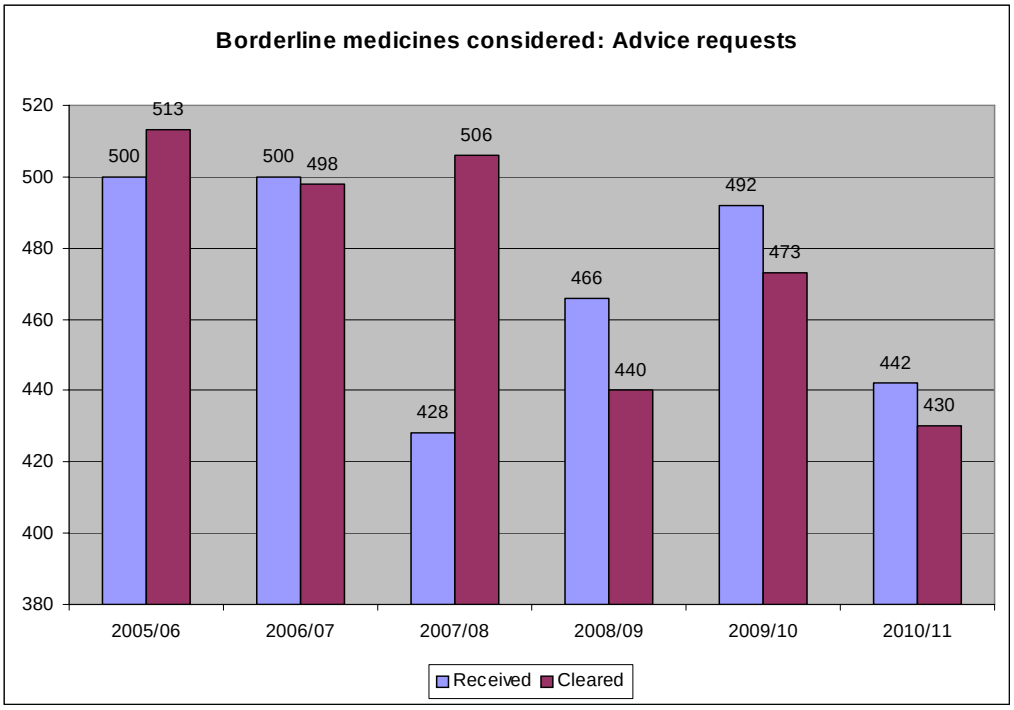
The Agency received an average of 25 national renewal applications per month in 20010/11 which is slightly less than in 2009/10. The UK acted as Reference Member State in 144 MR procedures, which is less than in 2009/10. The UK was Rapporteur or Co-Rapporteur for 13 centralised procedure submissions, which is less than the previous year.

Advertising

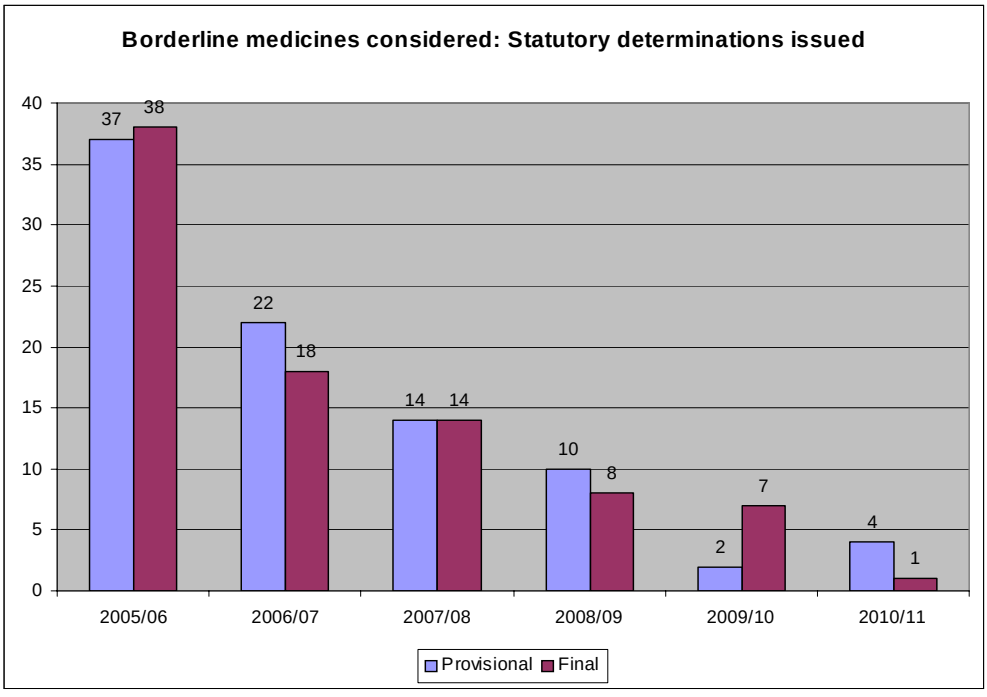
	2007/2008	2008/2009	2009/2010	2010/2011
Number of complaints received	211	199	371	358
Number of advertisements withdrawn or amended as a result of action on complaints	128	107	273	293
Number of advertisements withdrawn or amended as a result of Agency scrutiny	10	6	6	6
Number of Corrective statements published	4	1	4	3
Products for which advertising was reviewed prior to issue	52	55	50	50

Additional information can be found in the Agency's fifth annual report on the regulation of medicines advertising, *Delivering high standards in medicines advertising regulation*. This covers the period from September 2009 to August 2010 and can be found on the MHRA website, www.mhra.gov.uk. The next annual report will cover the period from January to December 2011. It will be published in early 2012.

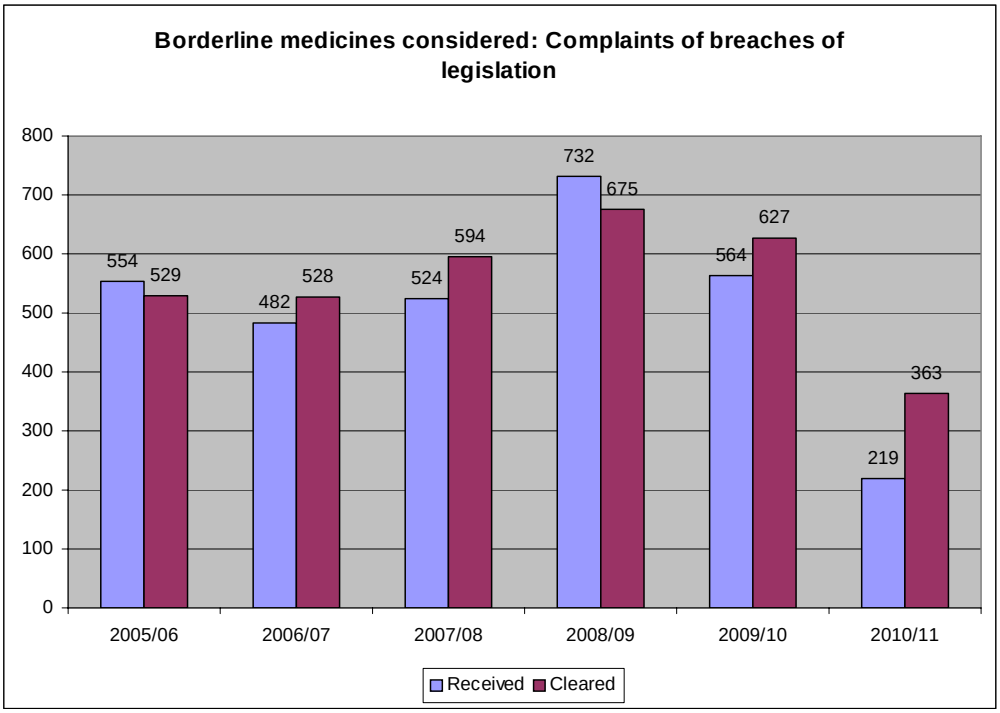
Borderline medicines considered



Statutory determinations issued



Complaints of breaches of legislation



In addition to the regular checks the Agency makes to ensure that licensed medicinal products meet the required quality and safety standards, the Medicines Borderline Section examines products which are not licensed as medicines but which appear to be presented as such or which have therapeutically active ingredients.

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

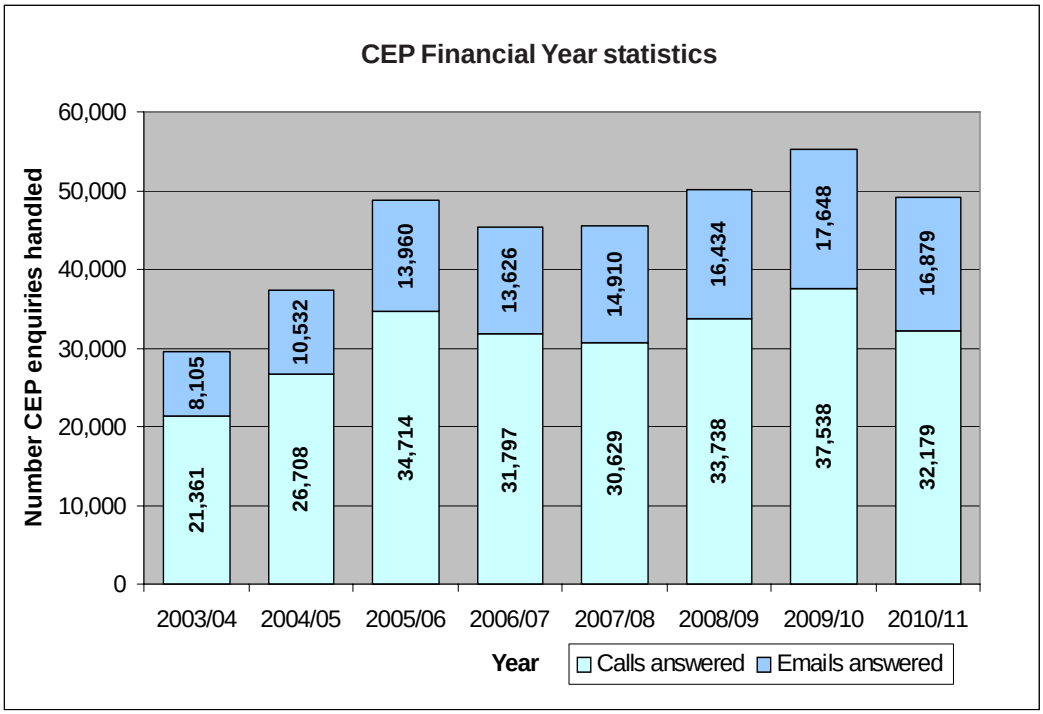
	2005	2007	2008	2009	2010	2011
Sales of BP	2,672	2,792	2,623	2,598	2,324	2,444

Sales of BP Chemical Reference Substances (No. of vials sold)	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11
	10,473	10,305	11,477	11,645	12,461	13,375

Number of Invented Names assessed

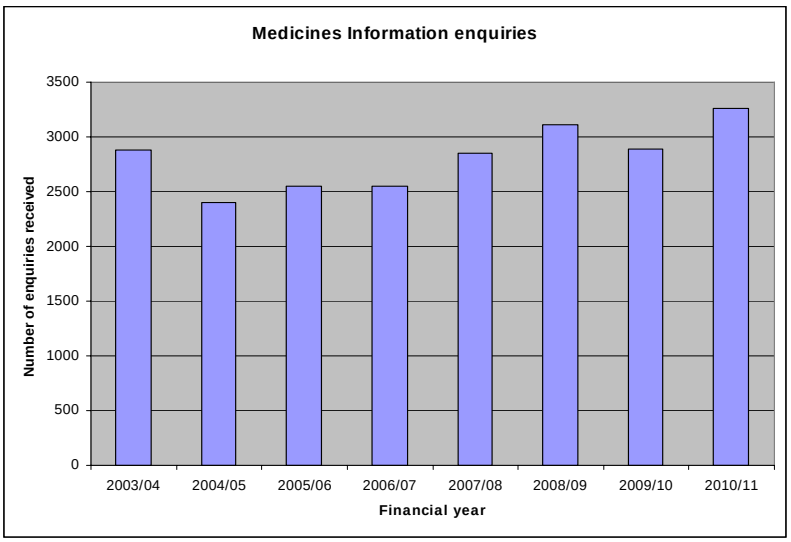
Year	2009/10	2010/11
Number of EMEA Names	554	698
Number of National Names	462	516
Total Number of Names	1016	1214

Central Enquiry Point telephone enquiries



NOTE: 2010/11figures are lower than the actual number of calls received due to lack of access to our statistics package in November and December

Medicines Information enquiries



Press Office