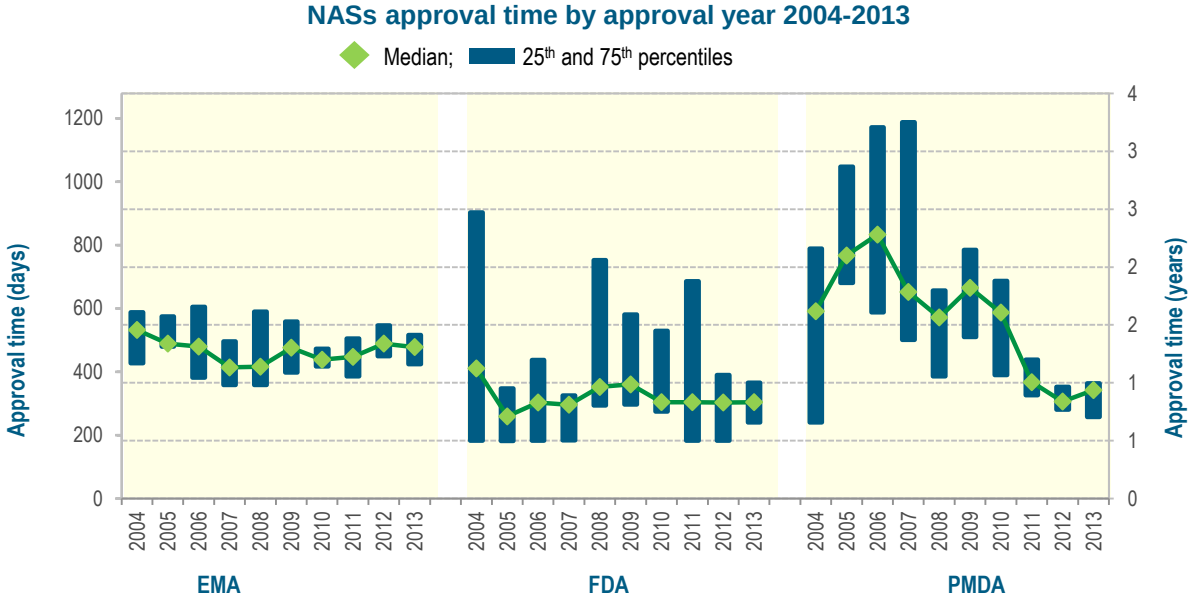
New Drug Approvals in ICH Countries 2004–2013

Focus on 2013



***Note**: The EMA approval time includes the EU Commission time. In Japan, prior to 2004, the data shown represent approval by MHLW.*

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CIRS Centre for Innovation in Regulatory Science

OVERVIEW

In 2013, the overall number of New Active Substances (NASs) approved by EMA, FDA and PMDA was comparable across the three agencies. Nevertheless, despite this similarity, the number of NASs approved by both the FDA and PMDA did not match 2012's high, with a 25% and 20% decrease in the number of NASs approved in the US and Japan respectively compared to 2012. As well as that, although the number of NASs approved by EMA increased by 43% compared to 2012, a number of these compounds had already been approved in the USA in previous years and partly signifies an instance of "catching up" by EMA.

This briefing looks specifically at trends in the number of approvals and approval times across the following agencies: European Centralised, US FDA and Japan PMDA. Approvals are often a measure of the pharmaceutical industry's output and are, along with approval time, used as a marker of the regulatory environment. Observations for 2013 and over the last decade are:

Median approval times for NASs approved in the US and Japan have diverged slightly since 2012. PMDA approval times, having experienced the first increase since 2009, were around 40 days longer than FDA. EMA approval times in 2013 were the highest, about 174 days longer compared to the FDA, though they have decreased slightly by around 11 days since 2012 (Fig. 2). Since last year, the components which make up the EMA review time showed a small reduction in European Commission time and the time that it is taking companies to respond to EMA questions, as well as a median increase of 20 days for the scientific assessment (Fig. 9).

Figure 1

Number of NASs approved by ICH agencies by approval year

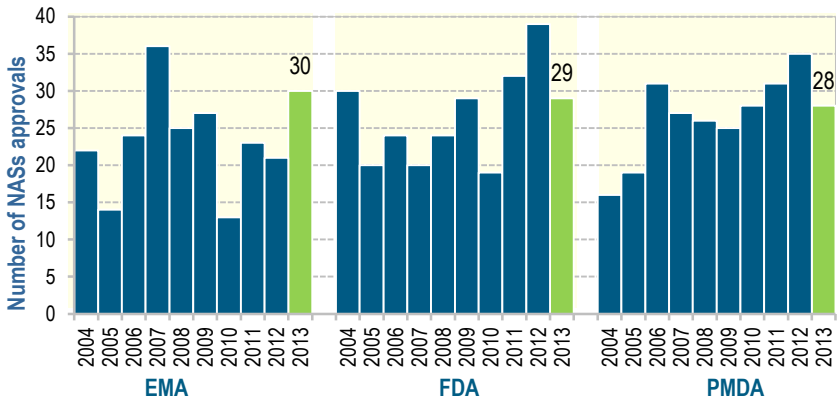
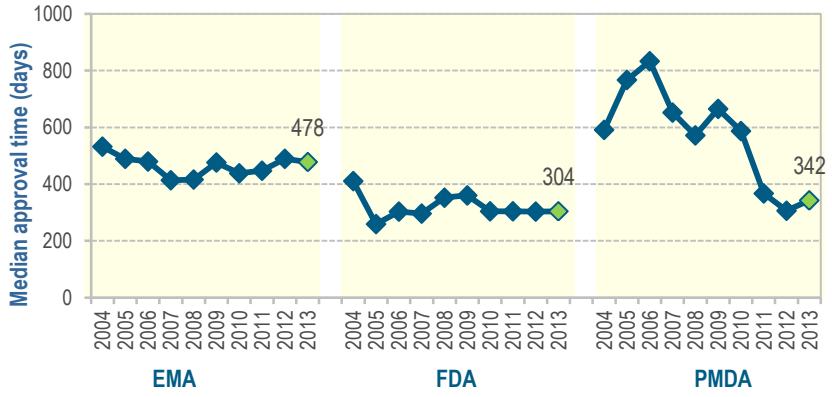


Figure 2

Median approval time of NASs approved by ICH agencies



***Note**: The EMA approval time includes the EU Commission time. In Japan, prior to 2004, the data shown represent approval by MHLW.*

Nevertheless, the variability in approval times was much greater through the FDA and PMDA process compared to EMA (Fig. 3).

Interestingly, between 2004-2008, company size seemed to be an influence on the speed of approvals where approval times for top companies (companies with an R&D spend of >3 billion USD in 2012) were a median 113 days shorter than non-top companies across all three agencies (Fig. 4). In the last five years this difference in approval times has disappeared, thereby perhaps highlighting that the agencies are successfully addressing the needs of smaller companies, and/or that smaller companies are creating better submissions.

For 21 products approved by all three agencies between 2009-2013, 67% of products were submitted first to FDA, 33% to EMA and 10% to PMDA. 76% of the NASs were first approved by FDA and 10% by PMDA, but interestingly, only 14% were first approved by EMA (Fig. 7). In 2012-2013, four out of five compounds approved by all three agencies were approved by PMDA sooner than EMA, despite having been first submitted in Europe (Fig. 8). This may lead to a change in company strategy to these markets.

COMPARISON OF ICH AGENCIES' APPROVALS

Approval Times (Figure 3)

The median approval times for products approved 2004-2013 were 459 days for EMA, 304 days for FDA and 487 days for PMDA. In comparison, the 2013 median was very similar at 478 days for EMA, identical for FDA at 304 days, and 145 days faster for PMDA at 342 days.

The median approval time for PMDA for 2009-2013 was 322 days faster than for the first half of the decade, 2004-2008 (689 days vs. 367 days). For EMA and FDA, the approval times remained similar across the two periods, with 303 vs. 304 days for FDA and slightly longer times for EMA, 451 vs. 468 days, for 2004-2008 and 2009-2013 respectively.

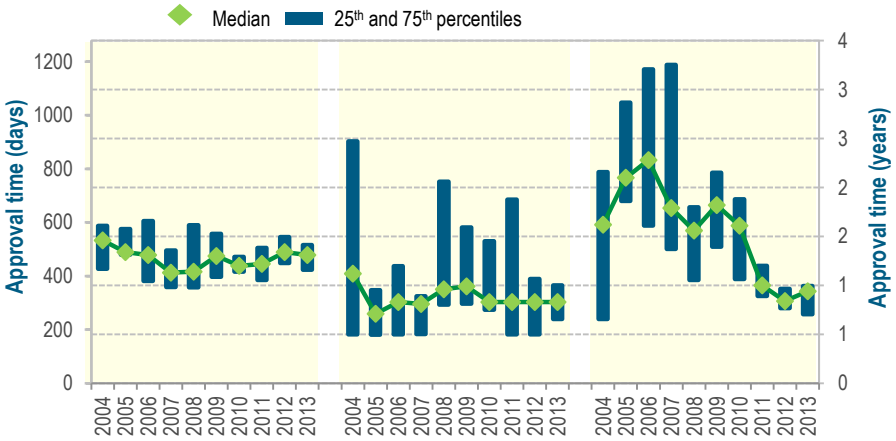
There was a large variability in approval times for individual products across the three agencies as well as within each agency. However the variation in approval times (25th – 75th percentile) was much greater through the FDA and PMDA process compared to EMA. Nevertheless, the past two years have seen a more consistent process in both US and Japan.

Company size (Figure 4)

The influence of company size on approval times has been analysed as an increasing number of NASs being first launched are by small-to-medium enterprises (SME), which have been recognised in recent years as "motors of innovation". Although non-top companies were shown to have longer median approval times across all three agencies, the median approval time gap between top and non-top companies has decreased in 2009-2013 compared to 2004-2008 by 47, 141 and 113 days for EMA, FDA and PMDA respectively. Consequently, in 2009-2013 the approval time gap between small and large companies was the greatest for EMA with 34 days, but was negligible for FDA and PMDA. This decrease may be a result of numerous factors such as the launch of an SME office by EMA in 2005, as well as more companies taking scientific advice from all three agencies.

Figure 3

Approval time of NASs approved by ICH agencies



Overall median approval time (2004-2013)

EMA 459 days

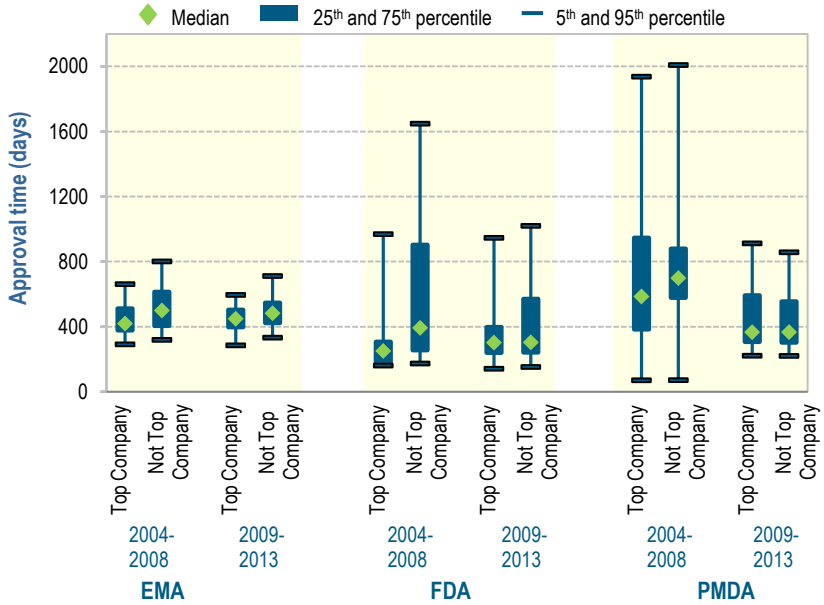
FDA 304 days

PMDA 487days

***Note**: The EMA approval time includes the EU Commission time . In Japan prior to 2004 the data shown represent approval by MHLW.*

Figure 4

NASs approval time by company size by approval year 2009-2013



***Note**: Companies with an R&D spend of >3bn USD in 2012 are classified as a top company*

COMPARISON OF ICH AGENCIES' APPROVALS

Approvals by therapeutic area (Figure 5)

Between 2009-2013, the top five therapy areas approved across all three agencies were anti-cancer and immunomodulators (28% of total NAS approvals), alimentary and metabolism (12%), nervous system (12%), anti-infective (7%) and cardiovascular (6%). The most prevalent changes that have occurred since 2004-2008 are:

A large decrease in approvals of anti-infective NASs which was uniform across all three agencies. For EMA, this reduction was from 18 NASs approved between 2004-2008 to 8 NASs approved between 2009-2013, and for both FDA and PMDA the number of approved NASs declined from 17 to 11 during this time period.

A major increase in approvals of anti-cancer NASs was observed across all three agencies. For EMA, this increase was from 28 NASs approved between 2004-2008 to 43 NASs approved between 2009-2013.

For FDA, the increase was from 27 to 39 NASs and for PMDA from 24 to 32 NASs for the same time period.

For Alimentary and Metabolism NASs, EMA experienced a decrease in NAS approvals from 2004-2008 to 2009-2013 (17 vs. 13 NASs), but there was an increase in approvals for FDA (13 vs. 15 NASs) and PMDA (12 vs. 23).

Similarly, for Nervous System compounds, a decrease in NAS approvals occurred for EMA (15 vs. 9 NASs) and FDA (19 vs. 14 NASs) from 2004-2008 to 2009-2013 but an increase occurred for PMDA (12 vs. 25 NASs), which may be reflective of the drug lag between Japan and the Western markets.

In contrast, Cardiovascular NAS approvals remained similar for EMA (8 vs. 7 NASs), and increased for FDA (7 vs. 11 NASs) but PMDA has seen a decrease (11 vs. 5 NASs) from 2004-2008 to 2009-2013.

Approval time by therapeutic area (Figure 6)

Across all five main therapy areas for 2009-2013, EMA approval times, although the least variable, had a longer median compared to PMDA and FDA. This is summarised in the table below:

Median Approval Time (days) 2009-2013			
	EMA	FDA	PMDA
Alimentary & Metabolism	483	387	432
Nervous System	481	388	378
Cardio vascular	488	335	361
Anti-Cancer	450	240	365
Anti-Infective	500	242	281

The faster median approval times for FDA and PMDA for anti-infective and anti-cancer products reflect the use of priority review pathways to a greater extent within these jurisdictions.

Figure 5

Percentage of NASs approvals by therapeutic area for 2004-2008 and 2009-2013

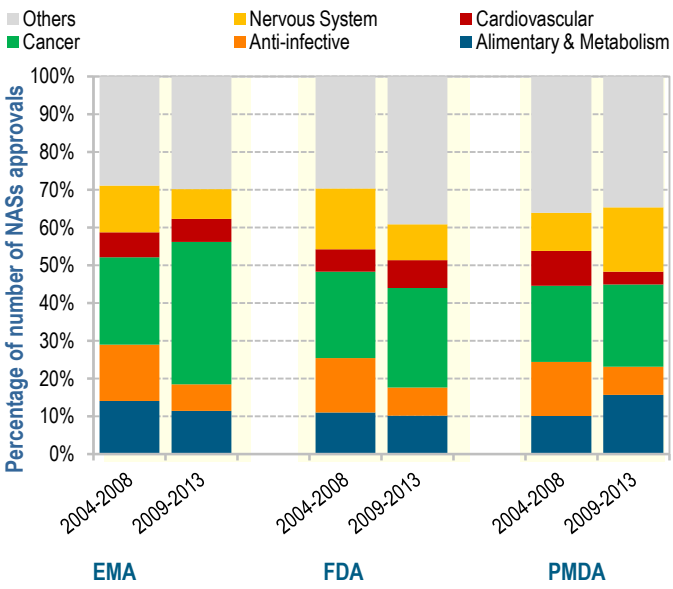
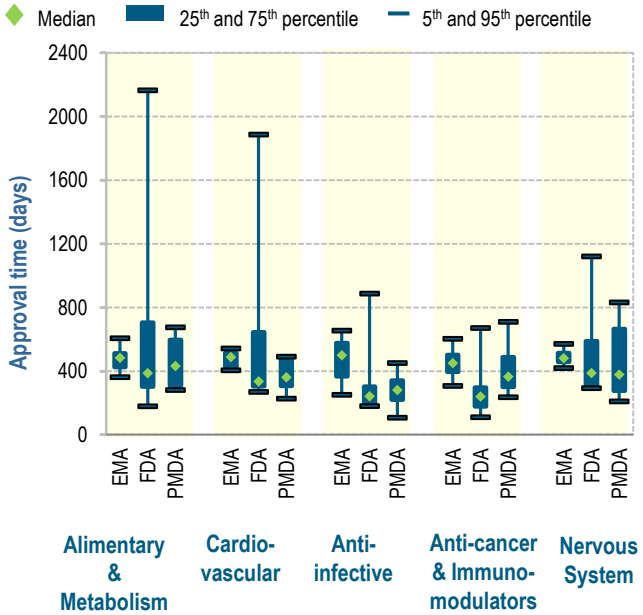


Figure 6

Median approval time by therapeutic area for 2009-2013



COMPARISON OF ICH AGENCIES' APPROVALS

Submission and approval patterns of NAS approved by all ICH agencies 2009-2013 (Figure 7)

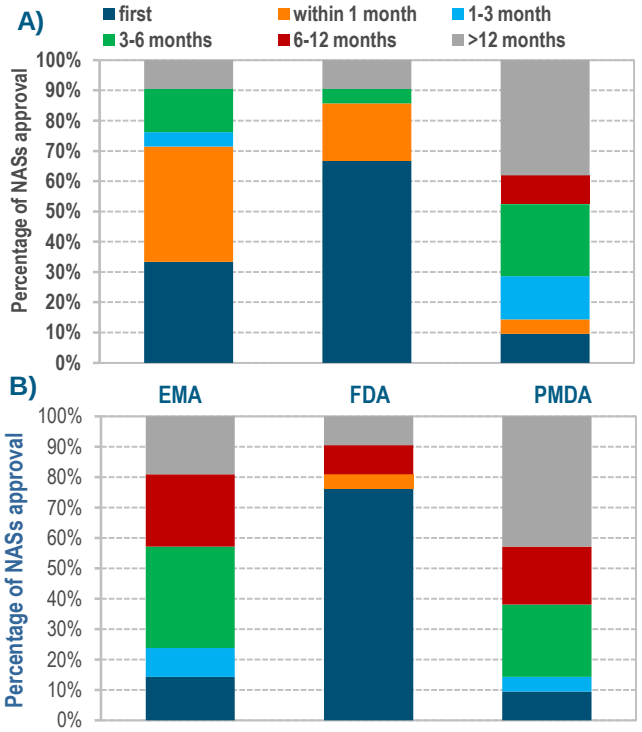
There were 21 NASs approved by FDA, EMA and PMDA within the 2009-2013 timeframe. The submission and approval date for each product varied across authorities. The data was analysed looking at:

A. Submission Timing: A high proportion of the 21 NASs, 67%, were first submitted to FDA, compared to 33% for EMA and 10% for PMDA. 38% and 19% of NASs were submitted to EMA and FDA, respectively, within one month of the first submission, but only 5% were submitted to PMDA within one month. A higher proportion of NASs were submitted later to PMDA, 14% within 1-3 months, 24% 3-6 months and 38% >12 months.

B. Approval Timing: In terms of approvals, FDA dominated the scene with 76% of the 21 NASs approved first in US. Interestingly, despite accounting for a third (33%) of first time submissions, only 14% of NASs were first approved by EMA and although 90% of the 21 applications were made within 6 months of the 1st submission only 55% were approved within 6 months of the first approval. The PMDA approval pattern closely resembled that of the submission timing.

Figure 7

Proportion of 21 NASs approved by all ICH agencies (2009-2013) by A) submission timing* and B) approval timing†



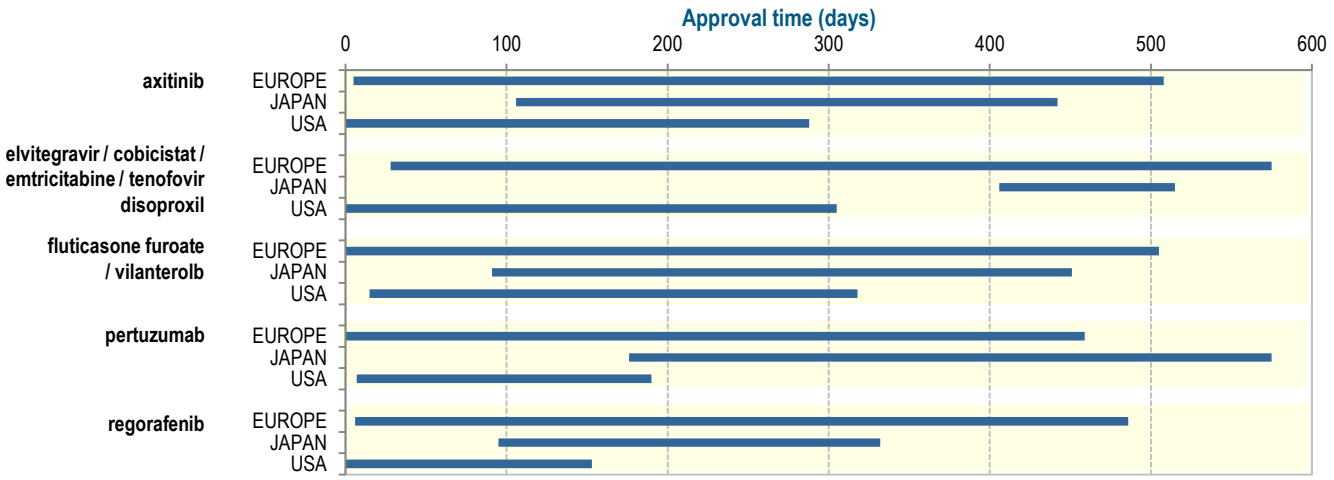
** Submission timing: Calculated from date of 1st submission to the 1st agency*
† Approval timing: Calculated from date of 1st approval in the 1st agency

Individual compounds plot (Figure 8)

There were five NASs approved by FDA, EMA and PMDA within the 2012-2013 timeframe. Three out of five compounds were first submitted to FDA, and the remaining two to EMA. All of the compounds were first approved by FDA. Nevertheless, four out of five compounds approved by all three agencies were approved by PMDA sooner than EMA, despite having been first submitted in Europe.

Figure 8

Individual compound plot for 5 NASs approved by all ICH agencies between 2012-2013



FEATURES OF THE EMA APPROVAL PROCESS

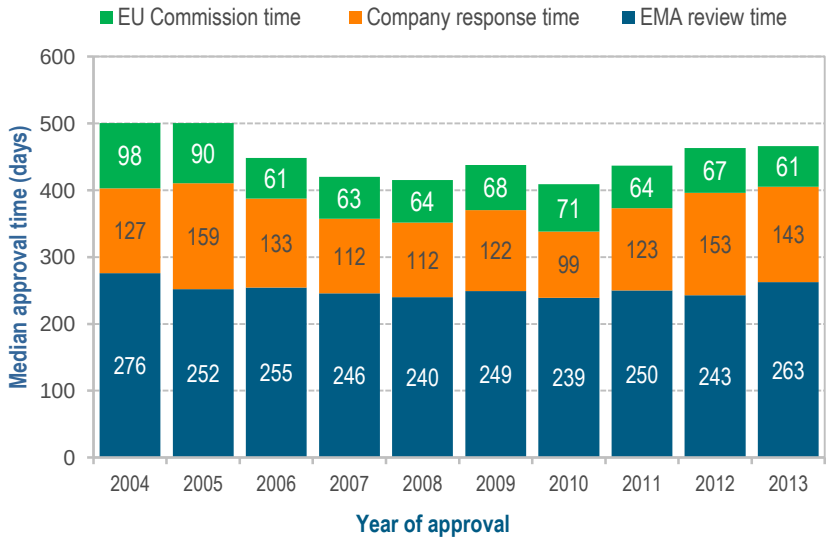
Breakdown of EMA approval time (Figure 9)

The EMA review time showed relative consistency between 2004-2013. The median review time was 251 days for 2009-2013, and decreased by one day from 2004-2008 period. On the other hand, the median company response time has increased by 11 days from 2004-2008 to 2009-2013 (117 vs. 128 days respectively).

A reduction in the time taken by the EU Commission to grant a license has been seen from 97 days (median time 2002-2004) to 64 days (median time 2006-2013) since EU legislative changes in 2005.

Figure 9

Median time of review process for NAS approved by EMA

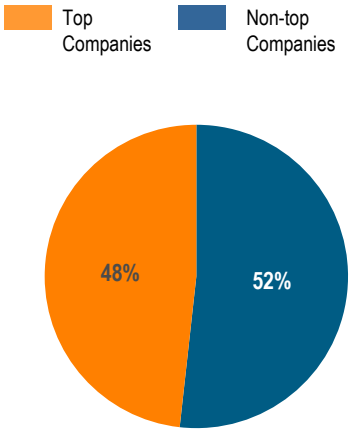


Company time 2009-2013 by company size (Figure 10, Figure 11)

Over the last five years, 2009-2013, 48% of NASs approved by EMA were from top companies and the median approval time gap between top and non-top companies was 34 days. Of all the components of the review, the time companies take to respond to questions raised had the widest variation between top and non-top companies. The median company time gap between top and non-top companies was 22 days in 2009-2013, and the median company time gap for 2010 was the highest for the timeframe, with a median of 50 days. Between 2012 and 2013, the median gap between large and small companies was only 15 days, and the variation between the company types (25-75 percentile) was also narrower in comparison to previous years. It is however too early to tell if this reflects a long-term trend towards a decreasing company time gap between top and non-top companies.

Figure 10

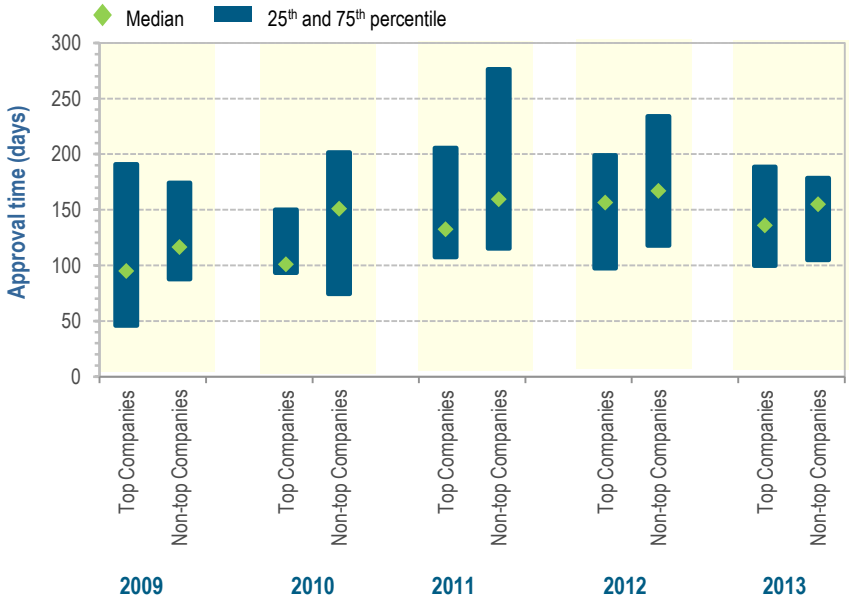
Number of NASs approved by EMA by company size for the year of approval 2009-2013



***Note**: Companies with an R&D spend of >3bn USD in 2012 are classified as a top company*

Figure 11

EMA company time by company size by approval year 2009-2013



FEATURES OF THE FDA APPROVAL PROCESS

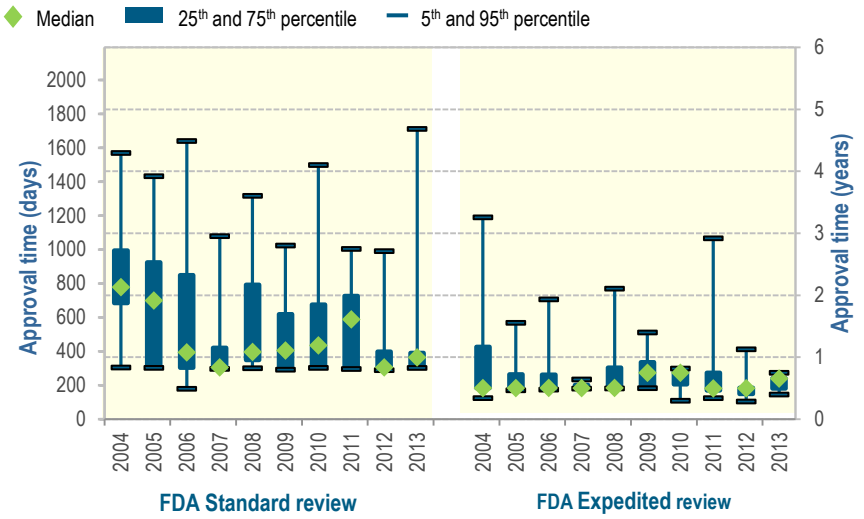
Approval time for FDA by review type (Figure 12)

The FDA review time showed relative consistency between 2004-2013, especially for the priority review.

44% of the 268 FDA approvals 2004-2013 were priority. The median approval time for priority reviews , remained similar between 2004-2008 and 2009-2013 with 183 and 184 days respectively. By comparison, the median approval time for standard review was 365 days between 2009-2013, which is 54 days quicker than the median for 2004-2008. One reason for this may be an increased number of standard products going through one review cycle.

Figure 12

Approval time of NASs approved by FDA by review type



CDER approvals by one review cycle 2009-2013 by company size (Figure 13, Figure 14)

Over the last five years, 2009-2013, only 42% of NASs approved by CDER were from top companies. The number of priority products which were approved in one cycle review has been consistent for the past five years, with standard one cycle reviews also increasing steadily. As well as that, this year has seen an all time high, with 100% of priority reviews, and 80% of standard reviews approved after one cycle (data not shown).

The number of review cycles has been relatively similar regardless of the company size for 2009-2013, which reflects the fact that the approval time gap between top and non-top companies was negligible for CDER in 2009-2013. For top companies, 71% of NASs went through a one cycle review, 26% through a two-review cycle and 3% through a three-review cycle. For non-top companies, all NASs were approved after one or two reviews, with 77% of compounds going through a one-cycle review.

Figure 13

Number of NASs approved by CDER by company size for the year of approval 2009-2013

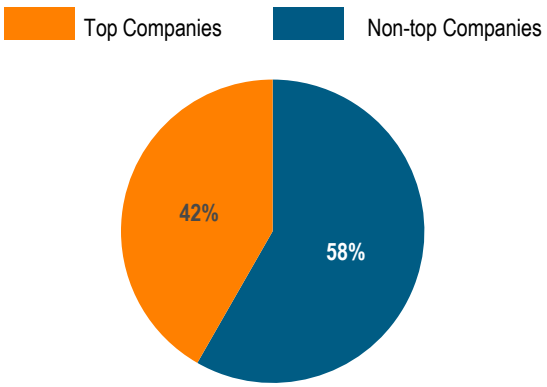
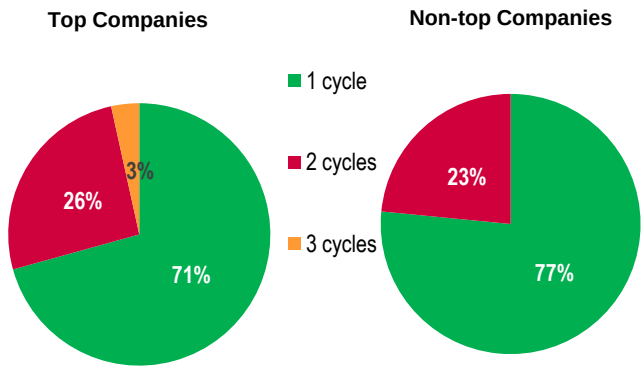


Figure 14

Number of NASs approved by CDER by number of review cycles by company type for the year of approval 2009-2013



***Note**: Companies with an R&D spend of >3bn USD in 2012 are classified as a top company*

FEATURES OF THE PMDA APPROVAL PROCESS

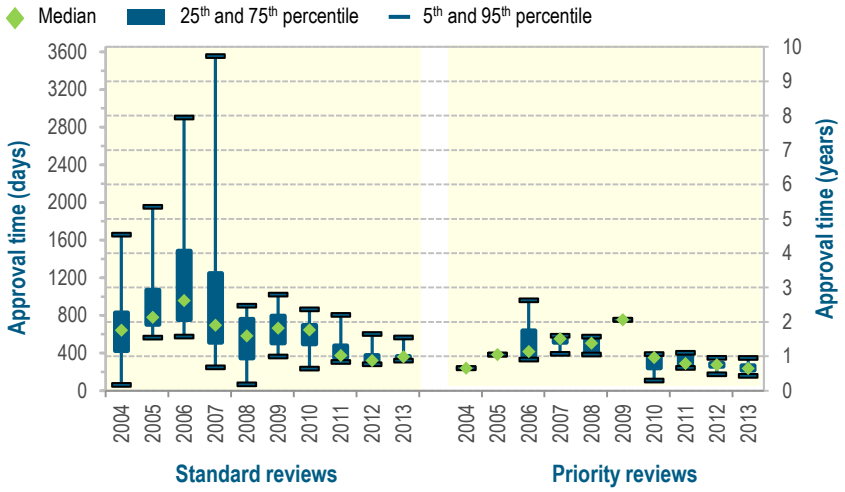
PMDA approvals by review type (Figure 15)

The PMDA review time showed relative consistency in the last five years, 2009-2013, especially for the priority review. The proportion of priority reviews has increased by 5% from 2004-2008 to 2009-2013, and has reached an all time high in 2013 with 40% being priority reviews, 5% higher than FDA for the same year.

The median approval time decreased for both review types, from 753 to 417 days for standard, and from 478 to 270 for priority reviews for 2004-2008 and 2009-2013 timelines respectively.

Figure 15

Approval time of NASs approved by PMDA by review type



Note: *Prior to 2004 the data shown for Japan represent approval by MHLW*

Orphan approvals (Figure 16)

For PMDA, the number of orphan approvals has decreased from 26% between 2004-2008 to 21% between 2009-2013, although in 2013, 29% of NASs received an orphan designation.

The median approval time for orphans and non-orphans was 531 and 722 days in 2004-2008 and 290 and 389 days in 2009-2013 respectively. Consequently, the approval time has decreased for both types, and the approval time gap for orphans and non-orphans has been converging.

Approvals by compound type (Figure 17)

For PMDA, the proportion of new biological entities (NBEs) has increased slightly from 22% to 24% from 2004-2008 to 2009-2013. The variation between new chemical entity (NCE) and NBE approval times has decreased over the decade, with a median 45 day gap for 2004-2008 (666 days for NCE and 712 days for NBE) and a median one day gap for 2009-2013 (367 days for NCE and 368 days for NBE).

Figure 16

Median approval time of NASs approved by PMDA by orphan status for year of approval 2004-2013

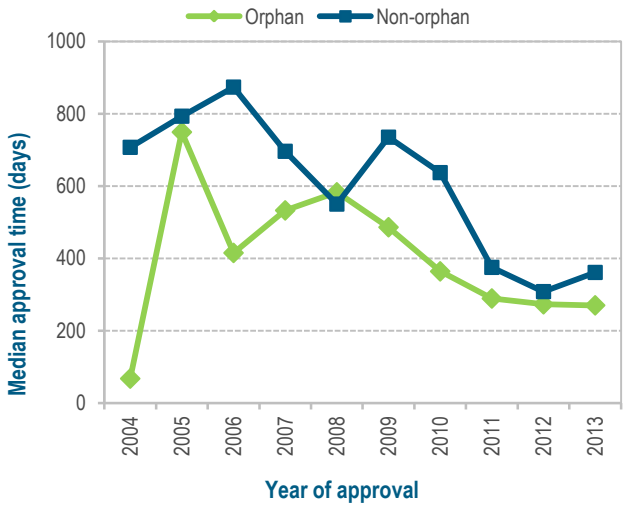
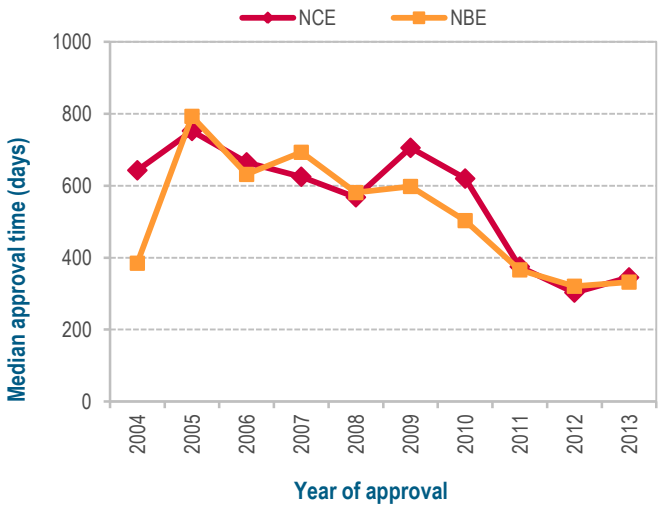


Figure 17

Median approval time of NASs approved by PMDA by compound type for year of approval 2004-2013



EMA NASs APPROVALS IN 2013

Brand Name	Generic Name	Marketing Authorisation Holder	Compound Type	Review Type	Approval Date
Krystexxa	pegloticase	Savient Pharma Ireland Ltd.	NBE	Standard	08/01/2013
Amyvid	florbetapir (18F)	Eli Lilly Nederland B.V.	NCE	Standard	14/01/2013
BindRen	colestilan	Mitsubishi Pharma Europe Ltd.	NCE	Standard	21/01/2013
Tresiba	insulin degludec	Novo Nordisk A/S	NBE	Standard	21/01/2013
Lyxumia	lixisenatide	Sanofi-Aventis	NCE	Standard	01/02/2013
Zaltrap	aflibercept	Sanofi-Aventis Groupe	NBE	Standard	01/02/2013
Selincro	nalmefene hydrochloride dihydrate	H. Lundbeck A/S	NCE	Standard	25/02/2013
Perjeta	pertuzumab	Roche Registration Limited	NBE	Standard	04/03/2013
Jetrea	ocriplasmin	ThromboGenics NV	NBE	Standard	13/03/2013
Bosulif	bosutinib (as monohydrate)	Pfizer Ltd	NCE	Standard	27/03/2013
Stribild	elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil	Gilead Sciences International Limited	NCE	Standard	24/05/2013
Spedra	avanafil	Menarini International Operations Luxembourg S.A.	NCE	Standard	21/06/2013
Xtandi	enzalutamide	Astellas Pharma Europe B.V.	NCE	Standard	21/06/2013
Iclusig	ponatinib	Ariad Pharma Ltd	NCE	Expedited	01/07/2013
Erivedge	vismodegib	Roche Registration Ltd	NCE	Standard	12/07/2013
Lonquex	lipegfilgrastim	Teva Pharma B.V.	NBE	Standard	25/07/2013
Lojuxta	lomitapide	Aegerion Pharmaceuticals	NCE	Standard	31/07/2013
Imnovid	pomalidomide	Celgene Europe Ltd	NCE	Standard	05/08/2013
Aubagio	teriflunomide	Sanofi-aventis Groupe	NCE	Standard	26/08/2013
Tafinlar	dabrafenib	GlaxoSmithKline Trading Services Limited	NCE	Standard	26/08/2013
Stivarga	regorafenib	Bayer Pharma AG	NCE	Expedited	26/08/2013

Note: *The EMA approval procedure includes both the CHMP positive opinion and the EU Commission decision. The products included in the table are those that received Market Authorisation by the EU Commission in 2013 and the approval date is the time when market authorisation is valid throughout the EU.*

EMA NASs APPROVALS IN 2013

Brand Name	Generic Name	Marketing Authorisation Holder	Compound Type	Review Type	Approval Date
Vipidia	alogliptin	Takeda Pharma A/S	NCE	Standard	19/09/2013
Giotrif	afatinib	Boehringer Ingelheim International GmbH	NCE	Standard	25/09/2013
NovoEight	turoctocog alfa	Novo Nordisk A/S	NBE	Standard	13/11/2013
Relvar Ellipta	fluticasone furoate / vilanterol	Glaxo Group Ltd	NCE	Standard	13/11/2013
Xofigo	radium Ra223 dichloride	Bayer Pharma AG	NCE	Expedited	13/11/2013
Invokana	canagliflozin	Janssen-Cilag International N.V.	NCE	Standard	15/11/2013
Kadcyla	trastuzumab emtansine	Roche Registration Ltd	NBE	Standard	15/11/2013
Brintellix	vortioxetine	H. Lundbeck A/S	NCE	Standard	18/12/2013
Opsumit	macitentan	Actelion Registration Ltd	NCE	Standard	20/12/2013

Note: *The EMA approval procedure includes both the CHMP positive opinion and the EU Commission decision. The products included in the table are those that received Market Authorisation by the EU Commission in 2013 and the approval date is the time when market authorisation is valid throughout the EU*

FDA NASs APPROVALS IN 2013

Brand Name	Generic Name	Marketing Authorisation Holder	Compound Type	Review Type	Approval Date
Nesina	alogliptin	Takeda Pharmaceuticals U.S.A., Inc.	NCE	Standard	25/01/2013
Kynamro	mipomersen sodium	Genzyme Corporation	NCE	Standard	29/01/2013
Pomalyst	pomalidomide	Celgene Corporation	NCE	Expedited	08/02/2013
Kadcyla	ado-trastuzumab emtansine	Genentech, Inc.	NBE	Expedited	22/02/2013
Osphena	ospemifene	Shionogi Inc.	NCE	Standard	26/02/2013
Lymphoseek	Technetium Tc99m Tilmanocept	Navidea Biopharmaceuticals, Inc	NCE	Standard	13/03/2013
Dotarem	Gadoterate meglumine	Guebert LLC	NCE	Expedited	20/03/2013
Tecfidera	dimethyl fumarate	Biogen Idec, Inc.	NCE	Standard	27/03/2013
Invokana	canagliflozin	Janssen Research & Development, LLC	NCE	Standard	29/03/2013
Breo Ellipta	fluticasone furoate/vilanterol inhalation powder	GlaxoSmithKline	NCE	Standard	10/05/2013
Xofigo	radium Ra 223 dichloride	Bayer HealthCare Pharmaceuticals	NCE	Expedited	15/05/2013
Tafinlar	dabrafenib mesylate	GlaxoSmithKline, LLC	NCE	Standard	29/05/2013
Mekinist	trametinib	GlaxoSmithKline, LLC	NCE	Standard	29/05/2013
Gilotrif	afatinib	Boehringer Ingelheim Pharmaceuticals, Inc	NCE	Expedited	12/07/2013
Tivicay	dolutegravir	ViiV Healthcare	NCE	Expedited	12/08/2013
Brintellix	vortioxetine	Takeda Pharmaceuticals USA, Inc.	NCE	Standard	30/09/2013
Duavee	conjugated estrogens/bazedoxifene	Wyeth Pharmaceuticals, Inc	NBE	Standard	03/10/2013
Adempas	Riociguat	Bayer Healthcare Pharmaceuticals Inc	NCE	Expedited	08/10/2013
Novoeight	Antihemophilic Factor (Recombinant)	Novo Nordisk Inc.	NBE	Standard	15/10/2013
Opsumit	macitentan	Actelion Pharmaceuticals, LTD	NCE	Standard	18/10/2013
Vizamyl	flutemetamol F 18	GE Healthcare Inc	NCE	Standard	25/10/2013

FDA NASs APPROVALS IN 2013

Brand Name	Generic Name	Marketing Authorisation Holder	Compound Type	Review Type	Approval Date
Gazyva	obinutuzumab	Genentech, Inc.	NBE	Expedited Breakthrough	01/11/2013
Aptiom	eslicarbazepine acetate	Sunovion Inc.	NCE	Standard	08/11/2013
Imbruvica	ibrutinib	Pharmacyclics	NCE	Expedited Breakthrough	13/11/2013
Luzu	luliconazole	Medicis	NCE	Standard	14/11/2013
Olysio	simeprevir	Janssen Research & Development, LLC	NCE	Expedited	22/11/2013
Sovaldi	sofosbuvir	Gilead Sciences, Inc.	NCE	Expedited Breakthrough	06/12/2013
Anoro Ellipta	umeclidinium /vilanterol	GlaxoSmithKline	NCE	Standard	18/12/2013
Tretten	Coagulation Factor XIII A Subunit (Recombinant)	Novo Nordisk Inc.	NBE	Standard	23/12/2013

PMDA NASs APPROVALS IN 2013

Brand Name	Generic Name	Marketing Authorisation Holder	Compound Type	Review Type	Approval Date
Acofide	Acotiamide hydrochloride hydrate	Zeria Pharmaceutical Co., Ltd	NCE	Standard	25/03/2013
Nouriast	Istradefylline	Kyowa Hakko Kirin Co., Ltd.	NCE	Standard	25/03/2013
Regtect	Acamprosate calcium	Nippon Shinyaku Co., Ltd	NCE	Standard	25/03/2013
Inovelon	Rufinamide	Eisai Co., Ltd.	NCE	Expedited	25/03/2013
Voluven	Hydroxyethylated starch 130000	Fresenius Kabi Japan K.K.	NCE	Standard	25/03/2013
Xeljanz	Tofacitinib citrate	Pfizer Japan Inc.	NCE	Standard	25/03/2013
Onglyza	Saxagliptin hydrate	Otsuka Pharmaceutical Co., Ltd.	NCE	Standard	25/03/2013
Metreleptin	Metreleptin (genetical recombination)	Shionogi & Co., Ltd.	NBE	Expedited	25/03/2013
Alabel/Alaglio	Aminolevulinic acid hydrochloride	Nobelpharma Co., Ltd.	NCE	Expedited	25/03/2013
Arzerra	Ofatumumab (genetical recombination)	GlaxoSmithKline K.K.	NBE	Expedited	25/03/2013
Evoltra	Clofarabine	Genzyme Japan K.K.	NCE	Expedited	25/03/2013
Stivarga	Regorafenib hydrate	Bayer Yakuhin, Ltd.	NCE	Expedited	25/03/2013
Stribild	Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate	Japan Tobacco Inc	NCE	Expedited	25/03/2013
Normosang	Hemin	CMIC Holdings Co., Ltd.	NCE	Expedited	25/03/2013
Topiloric/Uriadec	Topiroxostat	Fujiyakuhin Co., Ltd./Sanwa Kagaku Kenkyusho Co., Ltd.	NCE	Standard	28/06/2013
Bisono	Bisoprolol	Toa Eiyo Ltd	NCE	Standard	28/06/2013
Perjeta	Pertuzumab (genetical recombination)	Chugai Pharmaceutical Co., Ltd	NBE	Standard	28/06/2013
Lyxumia	Lixisenatide	Sanofi K.K.	NCE	Standard	28/06/2013
Bonviva IV	Ibandronate sodium hydrate	Chugai Pharmaceutical Co., Ltd.	NCE	Standard	28/06/2013
Xeplion	Paliperidone palmitate	Janssen Pharmaceutical K.K	NCE	Standard	20/09/2013

PMDA NASs APPROVALS IN 2013

Brand Name	Generic Name	Marketing Authorisation Holder	Compound Type	Review Type	Approval Date
Unitalc	Sterile talc	Nobelpharma Co., Ltd	NCE	Standard	20/09/2013
DaTscan	Ioflupane (123I)	Nihon Medi-Physics Co., Ltd.	NCE	Standard	20/09/2013
Oblean	Cetilistat	Takeda Pharmaceutical Company Limited	NCE	Standard	20/09/2013
Vyndaqel	Tafamidis meglumine	Pfizer Japan Inc	NCE	Expedited	20/09/2013
Relvar Ellipta	Vilanterol trifenatate/Fluticasone furoate	GlaxoSmithKline K.K.	NCE	Standard	20/09/2013
Kadcyla	Trastuzumab emtansine (genetical recombination)	Chugai Pharmaceutical Co., Ltd	NBE	Expedited	20/09/2013
Hizentra	pH4-treated normal human immunoglobulin (subcutaneous injection)	CSL Behring K.K	NBE	Standard	27/09/2013
Sovriad	Simeprevir sodium	Janssen Pharmaceutical K.K	NCE	Expedited	27/09/2013

Definitions

Approval time

Time calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.

New Active Substances (NAS)

A chemical, biological, biotechnology or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans. The term NAS also includes:

- An isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available
- A biological or biotech substance previously available as a medicinal product, but differing in molecular structure, nature of source material or manufacturing process and which will require clinical investigation.
- A radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product. Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available.

Applications that are excluded from the study

- Vaccines
- Any other application, where new clinical data were submitted.
- Generic applications.
- Those applications where a completely new dossier was submitted from a new company for the same indications as already approved for another company.
- Applications for a new or additional name, or a change of name, for an existing compound (i.e. a 'cloned' application).

NBE (New Biological Entity):

A substance isolated from animal tissues or product produced by recombinant DNA or hybridoma technology and expressed in cell lines, transgenic animals or transgenic plants)for therapeutic, prophylactic or in vivo diagnostic use in humans.

NCE (New Chemical Entity)

An entity produced by chemical synthesis.

Priority review

This is given to a drug product if it would be a significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease.

EMA Exceptional review

There were "exceptional circumstances" concerning the approval of this medicine. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicine for which authorisation is being sought, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.

WHO ATC classification

- A - Alimentary and metabolism: Drugs for acid related disorders, gastrointestinal disorders, antiemetics and antinauseants, bile and liver therapy, laxatives, antidiarrheals, intestinal antiinflammatory/antiinfective agents, drugs used in diabetes.
- C - Cardiovascular: Cardiac therapy, antihypertensives, beta blocking agents, calcium channel blockers, agents acting on the renin-angiotensin system, serum lipid reducing agents.
- J - Anti-infectives: Antibacterials for systemic use, antimycotics for systemic use, antimycobacterials, antivirals for systemic use, immune sera and immunoglobulins, vaccines.
- L - Anticancer and immunomodulators: Antineoplastic agents, endocrine therapy, immunostimulants, immunosuppressive agents.
- N - Nervous system: Anesthetics, analgesics, antiepileptics, anti-parkinson drugs, psycholeptics, psychoanaleptics, other nervous system.

Report prepared by

Magdalena Bujar, MSc

Research Analyst, Centre for Innovation in Regulatory Science
Email: mbujar@cirsci.org

Neil McAuslane, PhD

Scientific Director, Centre for Innovation in Regulatory Science
Email: nmcauslane@cirsci.org

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Centre for Innovation in Regulatory Science (CIRS)
The Johnson Building, 77 Hatton Garden, London, EC1N8JS, UK
Email: cirs@cirsci.org
Website: www.cirsci.org

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