New drug approvals in ICH countries: 2002-2011

An analysis of

New drug approvals in ICH regions 2002-2011

CIRS Centre for Innovation in Regulatory Science

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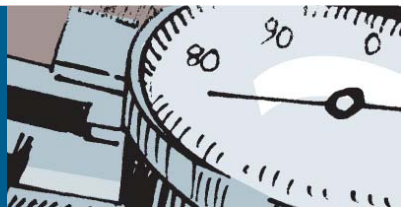
Overview



In 2011, the number of New Active Substances (NASs) approved in all the ICH countries increased compared to 2010, and FDA represented the largest number of new medicines approved this decade (Fig 1). Regulatory approvals are often a measure of the pharmaceutical industries output and are, along with approval time, used as a marker of the regulatory environment.

This briefing looks specifically at trends in the number of approvals and approval times across the European Centralised process, the US FDA process and the Japan PMDA process. Over the last decade the key trends were:

Median approval times for NASs approved in the US were shorter than those seen at EMA and PMDA (Fig 2), although the variability in times was much greater through the FDA and PMDA process compared to EMA (Fig 3).

69 products were approved by all three agencies from 2002-2011, of which 59% of the approvals had an FDA priority review. The median approval time was by 417 days at EMA, 274 days at FDA and 478 days at PMDA. The majority (67%) of the 69 applications were submitted to FDA first, 38% were submitted to EMA and FDA simultaneously, while 77% of these products were submitted to PMDA >1 year later.

The number of review cycles has increased at EMA, although this has not had an influence on overall approval time, and for the FDA approvals, the number approved in one cycle has increased over the decade for both priority and standard products.

45% of the 249 approvals by the FDA (2002-2011) and 17% of the 241 approvals by the PMDA were designated as priority products. This compares to just 5% at EMA.

The availability and use of the Priority review system in the US and Japan can be seen as one of the biggest difference from EMA in terms of determinant of the speed of approvals.

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

Figure 1

Number of NASs approved by ICH agencies by approval year

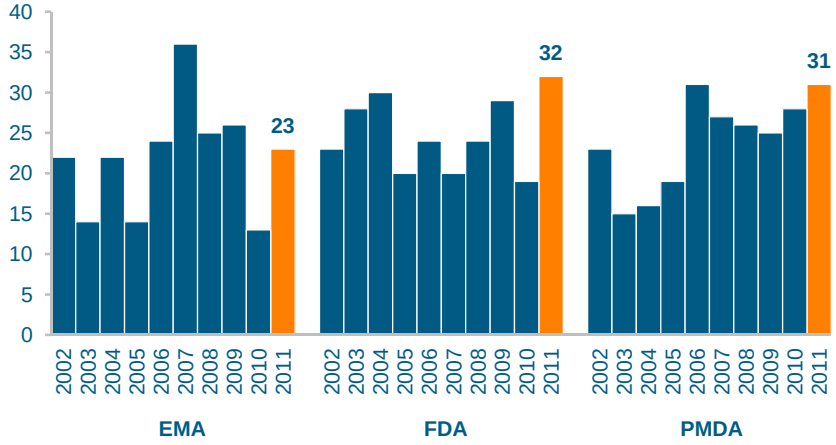
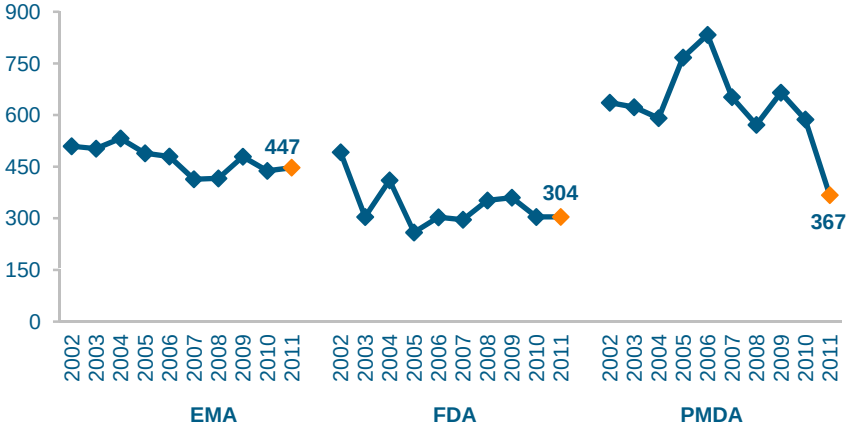


Figure 2

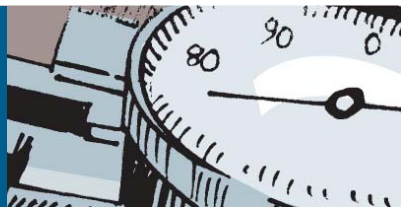
Median approval time of NASs approved by ICH agencies

Time (calendar days)



Note: The EMA approval time includes the EU Commission time

Comparison of ICH agencies' approvals



Approval time (Figure 3)

- Over the last decade 2002-2011, the median approval time (from time of submission to date the licence to market was granted, including both authority and sponsor time) was faster for NASs approved by FDA (304 days) than by EMA (463 days) or PMDA (610 days).

- The median approval time over the last five years 2007-2011 at EMA and PMDA was shorter than the first five years (2002-2006). At EMA, the median approval time was 499 days from 2002-2006 vs. 434 days from 2007-2011; at PMDA, the median approval time was 696 days from 2002-2006 vs. 555 days from 2007-2011. The FDA approval times remained similar across the two time periods.

- There is a wide variation in approval times across agencies as well as within agencies. However the variation in approval time (25th-75th percentile) was smaller and more consistent for EMA compared to FDA and PMDA.

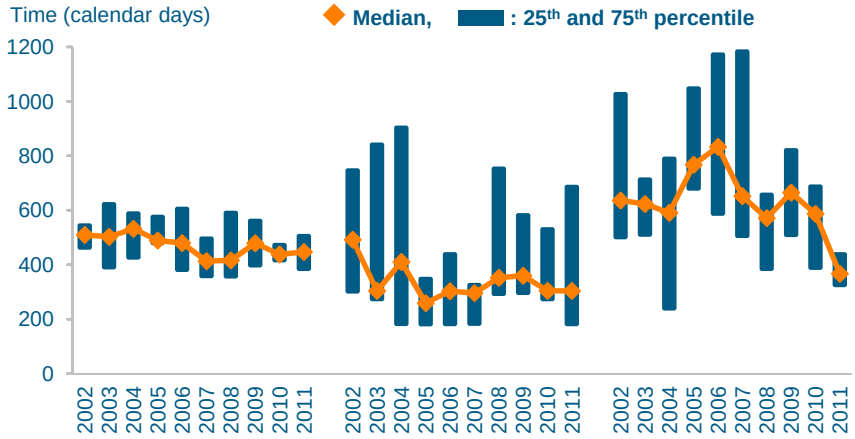
Review type (Figure 4)

- The large variation in approval time at FDA and PMDA can be attributed to the two distinct populations of approvals: standard and priority.

- The proportion of NASs approved by priority review was highest at FDA, 45% of the 249 FDA approvals from 2002-2011 were priority products, compared to 5% of EMA approvals and 17% of PMDA approvals.

Figure 3

Approval time of NASs approved by ICH agencies

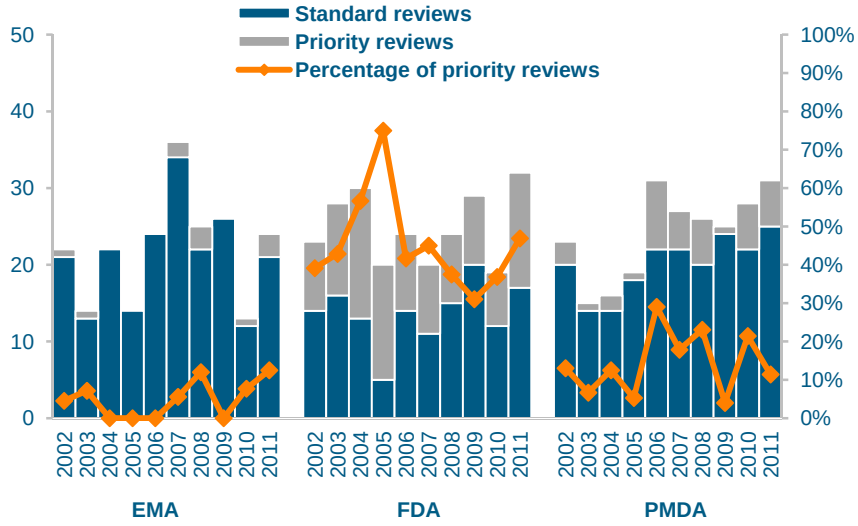


Overall median approval time (2002-2011)	EMA	FDA	PMDA
	463 days	304 days	610 days

Note: The EMA approval time includes the EU Commission time

Figure 4

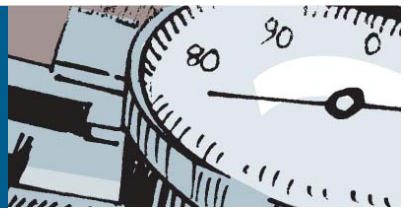
Number of NASs approvals by review type



- For the FDA, the proportion of applications that qualified for a priority designation decreased through the timeframe of this study. The proportion of applications receiving priority designation at FDA from 2002-2006 was 50% compared to 40% from 2007-2011.

- A slight rise in the proportion of priority approvals was seen at PMDA: 15% from 2002-2006 vs.17% from 2007-2011.

Comparison of ICH agencies' approvals



Orphan approvals (Figure 5)

- Over the last five years (2007-2011) products designated as orphan as a proportion of total approvals was 31% by FDA and was similar between EMA and PMDA, 24% and 23% respectively.

- The median approval time for orphan drugs was shorter than non-orphans at FDA and PMDA during 2007-2011. At FDA the median approval time was 273 days for orphan vs. 330 days for non-orphan and 392 days for orphan vs. 575 days for non-orphan at PMDA. At EMA there was little difference in time, 453 days v 431 days, respectively between orphan and non-orphan products [data not shown].

- The median time taken to approve orphan drugs was longest at EMA compared to FDA and PMDA.

- 79% of the FDA orphan approvals were reviewed as priority products, compared to 26% at PMDA, whilst 31% of the EMA orphan products were approved under exceptional circumstances.

Approvals by compound type (Figure 6)

- The number of NCEs approved increased at EMA (69 approvals from 2002-2006 vs. 92 approvals from 2007-2011) and at PMDA (86 approvals from 2002-2006 vs. 102 approvals from 2007-2011. The number of NCEs approved at FDA was the same between the two 5-year cohorts (93 approvals).

- The change in EMA may be a response to the 2005 legislative changes enabling more types of NCE's to be approved by EMA.

- Median approval times from 2002-2011 do not vary greatly depending on type of products at EMA and FDA: 454 days for NCE vs 481 for NBE at EMA, 304 days for both NCE and NBE at FDA.

- The median time taken for PMDA to approve NCEs was longer compared to NBEs, 629 days and 549days respectively from 2002-2011.

Note: Data not shown for orphan or compound type approval times and only information for 2007-2011 are shown in Figures 5 & 6.

Figure 5

Number of NASs approved by orphan status

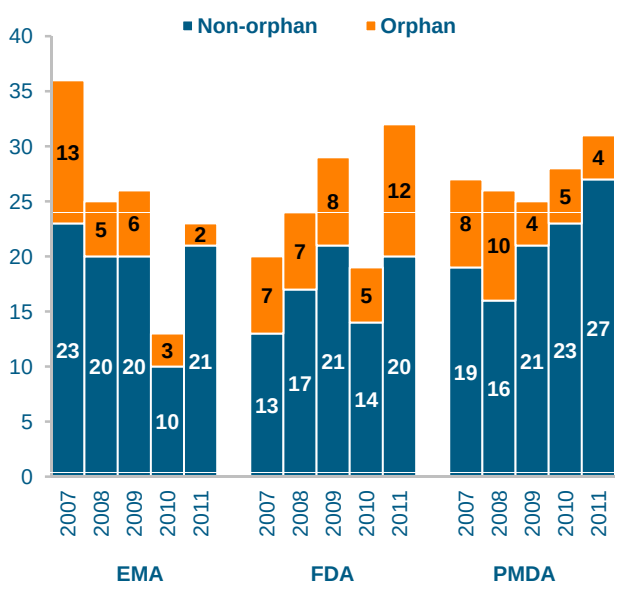
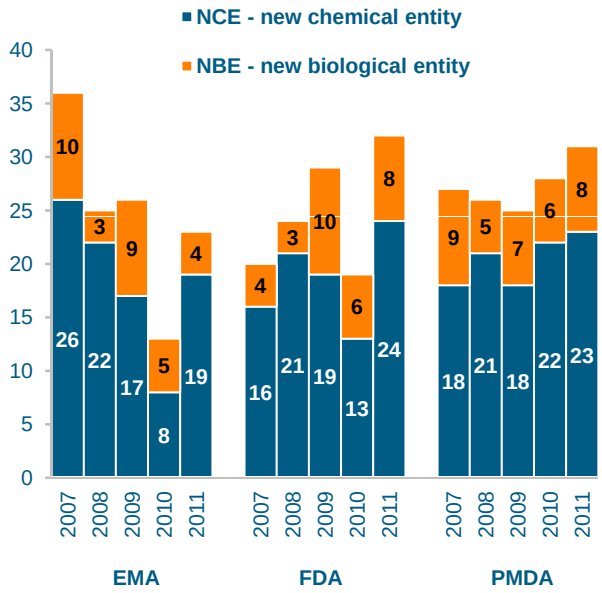
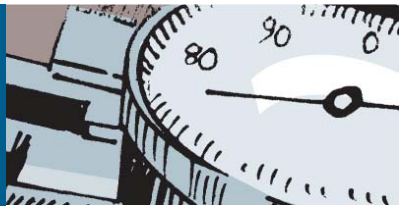


Figure 6

Number of NASs approved by compound type



Comparison of ICH agencies' approvals



Submission pattern of 69 NAS approved by all ICH agencies 2002-2011 (Figure 7)

- There were 69 NASs which were approved by all three ICH agencies within the time frame of this study. The submission date for each product varied across authorities.

- A high proportion of NASs (67%) were submitted to FDA first, compared to 29% at EMA and 7% at PMDA. 38% of the 69 approvals were submitted to FDA and EMA simultaneously (submitted within 1 month).

- The median time difference between submission to each ICH agency following the submission to the first ICH agency was 31 days at EMA, 0 day at FDA and 825 days at PMDA. 77% of the 69 approvals were submitted to PMDA >1 year after submission to EMA or FDA.

Approval time (Figure 8)

- The median approval time for these 69 NASs across the agencies were FDA (274 days), EMA (417 days) and PMDA (478 days).

- The median approval time for the 69 NASs approved by all the ICH agencies was shorter than the median approval time for all approvals at the agencies (see Figure 3), within the time frame of this study.

- Overall the variation in approval time (5^{th}-95^{th} percentile) was smaller at EMA compared to FDA and PMDA, which can be attributed to the mix of priority and standard applications at those agencies.

Review type (not shown)

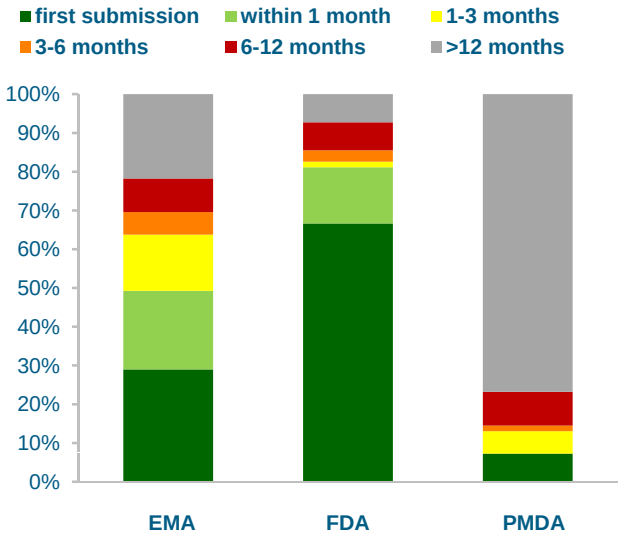
- Of the 69 products approved by all three ICH agencies, 41 were reviewed as priority products by FDA, 21at PMDA and 5 at EMA. The EMA and PMDA products were also granted priority designation at FDA.

- 59% of the approvals had an FDA priority review and the median approval time for those products was 403 days at EMA, 183 days at FDA and 386 days at PMDA.

- The 28 standard approvals at FDA had a median approval time of 434 days; the approval for the same products at EMA was 492 days and 639 days at PMDA.

Figure 7

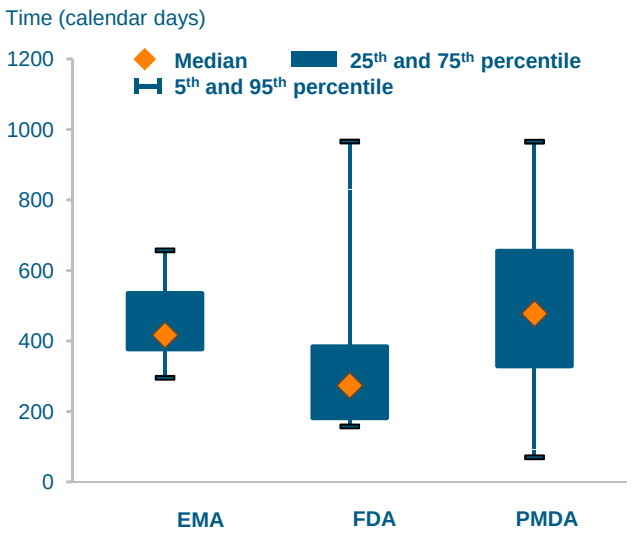
Proportion of 69 NASs approved by ICH agencies by submission timing



Total number of NASs approvals = 69

Figure 8

Approval time of 69 NASs approved by all ICH agencies



Note: The EMA approval time includes the EU Commission time

Features of the EMA approval process

EMA approvals by review cycles (Figure 9)

- The majority of NASs (78%) approved from 2002-2011 were approved with three cycles.

- An increase in the number of NAS approved with 4 or more cycle reviews has been seen over the last 3 years.

- Although the number of review cycles has increased this was not reflected in an increase in approval time.

Breakdown of approval time (Figure 10)

- The EMA actual review time showed relative consistency between 2002-2011. The median review time was 264 days from 2002-2006, and 245 days from 2007-2011.

- A reduction in the time taken by the EU commission to grant a license has been seen since 2005 following the new EU legislative changes, from 94 days (median time 2002-2006) to 67 days (median time 2007-2011).

- A reduction in the time companies took to respond to questions raised by EMA was also seen. The median total company response time from 2002-2006 was 138 days vs. 113 days from 2007-2011.

Figure 9

Proportion of EMA approvals by review cycles

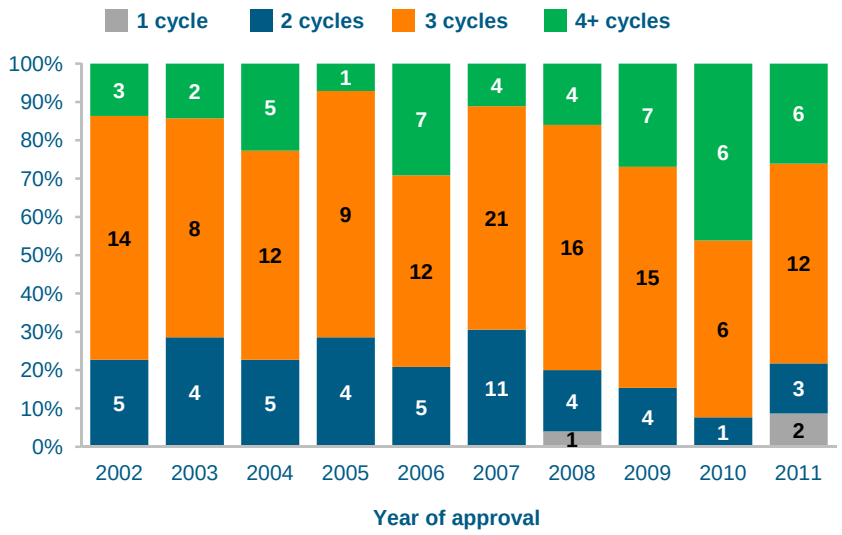
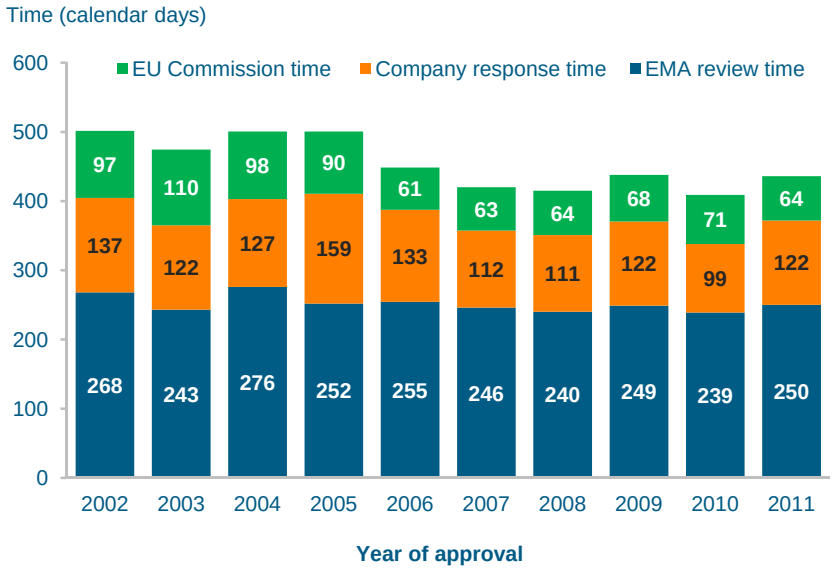


Figure 10

Median time of review process for NASs approved by EMA



Features of the FDA approval process

Approval time for FDA approvals (Figure 11)

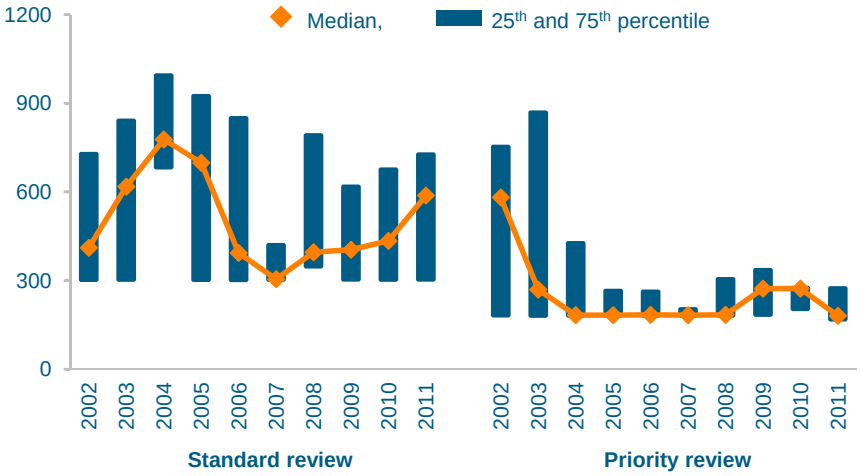
- 45% of the 249 FDA approvals 2002 - 2011 were priority with a median approval time of 186 days.
- By comparison the median approval time for standards over the same time period was 424 days.
- Over the last five years an Increasing median approval time has been found for standard approvals

CDER approvals by one review cycle (Figure 12, 13)

- The median approval time for products with one-cycle reviews was relatively constant for both standard and priority review over the last 10 years.
- The overall median time (2002-2011) for approvals with one cycle review was 182 days for priority products and 304 days for standard products.

Figure 11

Approval time of NASs approved by FDA by review type



- The number of products approved by CDER from 2002-2010 after only one cycle has increased over the decade for both standards and priority NASs.
- The majority of priority approvals at CDER (81%) were reviewed with one cycle, compared to 47% of standard approvals.

Figure 12

Median approval time of NASs approved by CDER by one cycle review

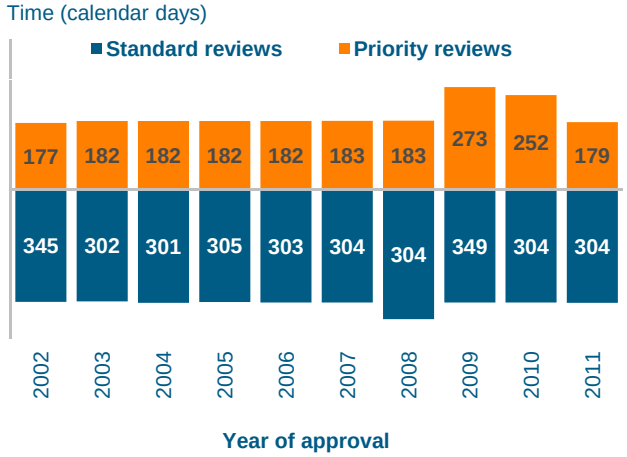
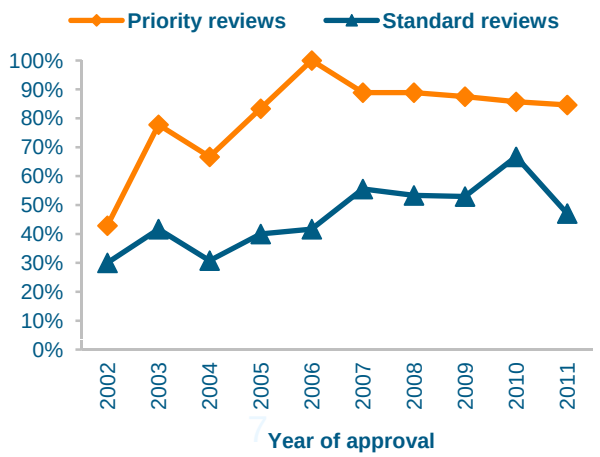


Figure 13

Percentage of NASs approved by CDER by one cycle review



Features of the PMDA approval process

PMDA approvals by review type (Figure 14)

- 17% of the 241 PMDA approvals 2002- 2011 were priority with a median approval time of 386 days.
- By comparison the median approval time for standards was 666 days over this time period.
- There was a wide variation in approval times for standard reviews.Overall the variation in approval time (25th-75th percentile) was smaller and more consistent for priority products.
- Over the time period of this study a reduction in median approval time was observed. The median approval time in 2011 was 227 days for priority reviews and 367 days for standard reviews, which met the 2011 target time at PMDA (9 months for priority and 12 months for standard).

Approval time by therapeutic area (Figure 15)

- Approval time differed between therapeutic areas at PMDA. There was a reduction in the median time taken to approve products in major therapeutic areas from 2002-2006 to 2007-2011.
- However, from 2002 to 2006, the median approval time for cardiovascular and nervous system products was longer than the overall median time at PMDA (696 days); from 2007-2011 the median approval time for nervous system products was longer than the overall median time at PMDA (555 days).

Figure 14

Approval time of NASs approved by PMDA by review type

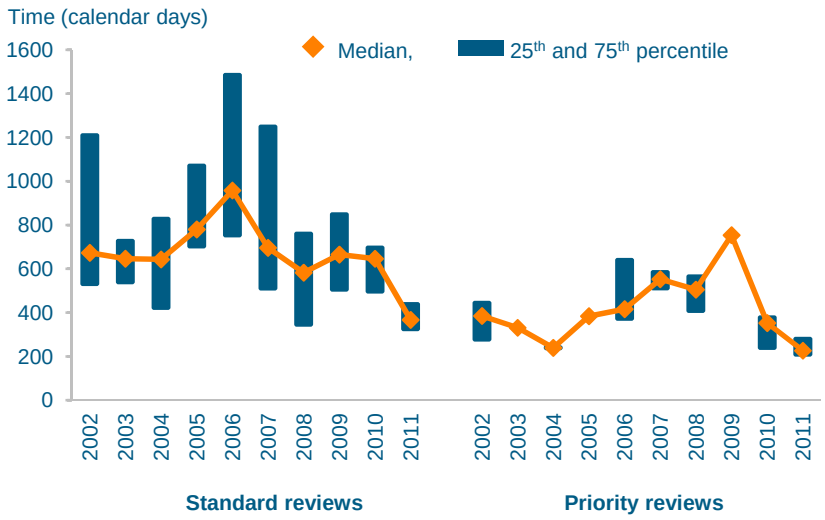
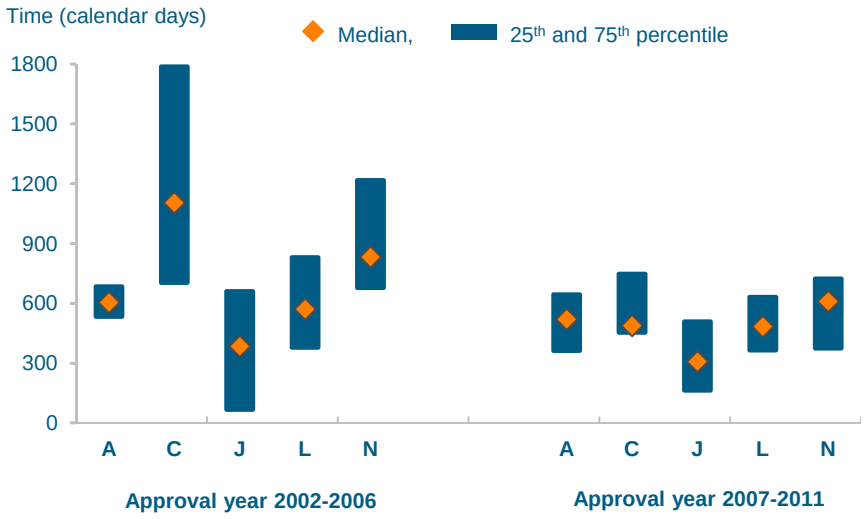


Figure 15

Approval time of NASs approved by PMDA by therapeutic area from 2002-2006 vs. 2007-2011



ATC code

A	Alimentary & Metabolism
C	Cardiovascular
J	Anti-infective
L	Anticancer and immunomodulators
N	Nervous System

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

EMA NASs approvals in 2011

Brand name	Generic name	Marketing authorization holder	Compound type	Review type	Approval Date
Xiapex	collagenase clostridium histolyticum	Pfizer Ltd	NBE	Standard	28/02/2011
Esbriet	pirfenidone	InterMune UK Ltd.	NCE	Standard	28/02/2011
Teysuno	tegafur / gimeracil / oteracil	Nordic Group BV	NCE	Standard	14/03/2011
Jevtana	cabazitaxel	Sanofi-aventis	NCE	Standard	17/03/2011
Halaven	eribulin mesylate	Eisai Europe Ltd.	NCE	Standard	17/03/2011
Gilenya	fingolimod hydrochloride	Novartis Europharm Ltd.	NCE	Standard	17/03/2011
Trobalt	retigabine	Glaxo Group Ltd.	NCE	Standard	28/03/2011
Eliquis	apixaban	Bristol-Myers Squibb / Pfizer EEIG	NCE	Standard	18/05/2011
Yellox	bromfenac sodium sesquihydrate	Croma-Pharma GmbH	NCE	Standard	18/05/2011
Cinryze	C1 inhibitor (human)	ViroPharma SPRL	NBE	Standard	15/06/2011
Nulojix	belatacept	Bristol-Myers Squibb Pharma EEIG	NBE	Standard	17/06/2011
Benlysta	belimumab	Glaxo Group Ltd.	NBE	Standard	13/07/2011
Yervoy	ipilimumab	Bristol-Myers Squibb Pharma EEIG	NBE	Standard	13/07/2011
Victrelis	boceprevir	Merck Sharp & Dohme Ltd.	NCE	Priority	18/07/2011
Fampyra	fampridine	Biogen Idec Ltd	NCE	Standard	20/07/2011
Trajenta	linagliptin	Boehringer Ingelheim International GmbH	NCE	Standard	24/08/2011
Vibativ	telavancin	Astellas Pharma Europe B.V.	NCE	Standard	02/09/2011
Zytiga	abiraterone acetate	Janssen-Cilag International	NCE	Priority	05/09/2011
Incivo	telaprevir	Janssen-Cilag International	NCE	Priority	19/09/2011
Eurartesim	piperaquine tetraphosphate / dihydroartemisinin	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A	NCE	Standard	27/10/2011
Vyndaqel	tafamidis	Pfizer Specialty UK Ltd.	NCE	Standard	16/11/2011
Eviplera	emtricitabine / rilpivirine / tenofovir disoproxil	Gilead Sciences International Ltd.	NCE	Standard	28/11/2011
Dificlir	fidaxomicin	FGK Representative Service GmbH	NCE	Standard	05/12/2011
Edarbi	azilsartan medoxomil	Takeda Global Research and Development Centre (Europe) Ltd.	NCE	Standard	07/12/2011

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 2011 and the approval date is the time when market authorisation is valid through out the EU.

FDA NASs approvals in 2011

Brand name	Generic name	Marketing authorization holder	Compound type	Review type	Approval Date
DaTSCAN	ioflupane (123/I)	GE Healthcare	NCE	Priority	14/01/2011
Natroba	spinosad	ParaPRO Pharmaceuticals, LLC	NCE	Standard	18/01/2011
Viibryd	vilazodone hydrochloride	Forest Labs Inc	NCE	Standard	21/01/2011
Corifact	factor XIII Concentrate (Human)	CSL Behring, GmbH	NBE	Priority	17/02/2011
Edarbi	azilsartan medoxomil	Takeda Pharmaceuticals North America, Inc	NCE	Standard	25/02/2011
Daliresp	roflumilast	Forest Pharmaceuticals, Inc	NCE	Standard	28/02/2011
Benlysta	belimumab	GlaxoSmithKline	NBE	Priority	09/03/2011
Gadavist	gadobutrol	Bayer HealthCare Pharmaceuticals	NCE	Standard	14/03/2011
Yervoy	Ipilimumab	Bristol-Myers Squibb Compan	NBE	Priority	25/03/2011
Horizant	gabapentin enacarbil	Glaxo Group Limited	NCE	Standard	06/04/2011
Caprelsa	vandetanib	AstraZeneca Pharmaceuticals LP	NCE	Priority	06/04/2011
Zytiga	abiraterone acetate	Janssen Biotech	NCE	Priority	28/04/2011
Tradjenta	linagliptin	Boehringer Ingelheim Pharmaceuticals, Inc	NCE	Standard	02/05/2011
Victrelis	boceprevir	Schering Corporation	NCE	Priority	13/05/2011
Edurant	rilpivirine	Tibotec, Inc	NCE	Standard	20/05/2011
Incivek	telaprevir	Vertex Pharmaceuticals, Incorporated	NCE	Priority	23/05/2011
Dificid	fidaxomicin	Optimer Pharmaceuticals, In	NCE	Priority	27/05/2011
Potiga	ezogabine	Valeant Pharmaceuticals North America	NCE	Standard	10/06/2011
Nulojix	belatacept	Bristol-Myers Squibb Company	NBE	Standard	15/06/2011
Arcapta Neohaler	indacaterol	Novartis Pharmaceuticals Corporation	NCE	Standard	01/07/2011
Xarelto	rivaroxaban	Johnson and Johnson Pharmaceutical Research and Development, LLC	NCE	Standard	01/07/2011
Brilinta	ticagrelor	AstraZeneca LP	NCE	Standard	20/07/2011
Anascorp	centruroides (Scorpion) Immune F(ab')2 (Equine) Injection	Rare Disease Therapeutics, Inc.	NBE	Priority	03/08/2011
Zelboraf	vemurafenib	Pfizer Inc.	NCE	Priority	17/08/2011

FDA NASs approvals in 2011

Brand name	Generic name	Marketing authorization holder	Compound type	Review type	Approval Date
Adcetris	brentuximab vedotin	Seattle Genetics, Inc	NBE	Priority	19/08/2011
Firazyr	icatibant	Shire Orphan Therapie	NCE	Priority	25/08/2011
Xalkori	crizotinib	Pfizer Inc.	NCE	Priority	26/08/2011
Ferriprox	deferiprone	ApoPharma, Inc	NCE	Standard	14/10/2011
Onfi	clobazam	Lundbeck ltc	NCE	Standard	21/10/2011
Jakafi	ruxolitinib	Incyte Corporation	NCE	Priority	16/11/2011
Eylea	aflibercept	Regeneron Pharmaceuticals, Inc	NBE	Standard	18/11/2011
Erwinaze	asparaginase Erwinia chrysanthemi	EUSA Pharma USA	NBE	Standard	18/11/2011

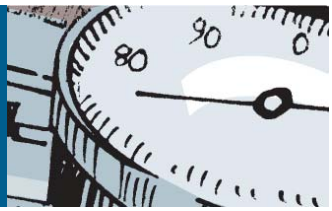
PMDA NASs approvals in 2011

Brand name	Generic name	Marketing authorization holder	Compound type	Review type	Approval Date
Vidaza	azacitidine	Nippon Shinyaku Co., Ltd	NCE	Priority	21/01/2011
Nerbloc	botulinum toxin type B	Eisai co., Ltd.	NBE	Standard	21/01/2011
Prazaxa	dabigatran etexilate methanesulfonate	Nippon Boehringer Ingelheim	NCE	Standard	21/01/2011
Edirol	eldecalcitol	Chugai Pharmaceutical	NCE	Standard	21/01/2011
Feburic	febuxostat	Teijin Pharma ltd	NCE	Standard	21/01/2011
Reminyl	galantamine hydrobromide	Janssen Pharmaceutical K.K.	NCE	Standard	21/01/2011
Memary	memantine hydrochloride	Daiichi Sankyo Co Ltd	NCE	Standard	21/01/2011
Surepost	repaglinide	Dainippon Sumitomo Pharma	NCE	Standard	21/01/2011
Romiplate	romiplostim	Kyowa Hakko Kirin	NBE	Priority	21/01/2011
Stelara	ustekinumab	Janssen Pharceutical K.K	NBE	Standard	21/01/2011
Norspan	buprenorphine	Mundipharma K.K	NCE	Standard	23/02/2011
Suprane	desflurane	Baxter Limited	NCE	Standard	22/04/2011
Lixiana	edoxaban tosilate hydrate	Daiichi Sankyo Co Ltd	NCE	Standard	22/04/2011
Mircera	epoetin beta pegol	Chugai Pharmaceutical	NBE	Standard	22/04/2011
Halaven	eribulin mesylate	Eisai co., Ltd.	NCE	Priority	22/04/2011
Lexapro	escitalopram oxalate	mochida pharmaceutical	NCE	Standard	22/04/2011
Lipacreon	pancrelipase	Abbott Japan Co., Ltd	NBE	Standard	22/04/2011
Exelon	rivastigmine	Ono Pharmaceutical Co., Ltd	NCE	Standard	22/04/2011
Cubicin	daptomycin	MSD K.K.	NBE	Standard	01/07/2011
Nexium	esomeprazole magnesium hydrate	AstraZeneca K.K	NCE	Standard	01/07/2011
Fostoin	fosphenytoin sodium hydrate	Nobelpharma Co Ltd	NCE	Standard	01/07/2011
Simponi	golimumab	Janssen Pharceutical K.K	NBE	Standard	01/07/2011
Onbrez	indacaterol maleate	Novartis Pharma	NCE	Standard	01/07/2011
Trazenta	linagliptin	Nippon Boehringer Ingelheim	NCE	Standard	01/07/2011

PMDA NASs approvals in 2011

Brand name	Generic name	Marketing authorization holder	Compound type	Review type	Approval Date
Betanis	mirabegron	Astellas Pharma	NCE	Standard	01/07/2011
Zolinza	vorinostat	Nippon Boehringer Ingelheim	NCE	Standard	01/07/2011
Ilaris	canakinumab	Novartis Pharma	NBE	Priority	26/09/2011
Gilenya	fingolimod hydrochloride	Novartis Pharma	NCE	Priority	26/09/2011
Proemend	fosaprepitant meglumine	Ono Pharmaceutical Co., Ltd	NCE	Standard	26/09/2011
Faslodex	fulvestrant	AstraZeneca K.K	NCE	Standard	26/09/2011
Telavic	telaprevir	Mitsubishi Tanabe Pharma	NCE	Priority	26/09/2011

Definitions



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 .

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