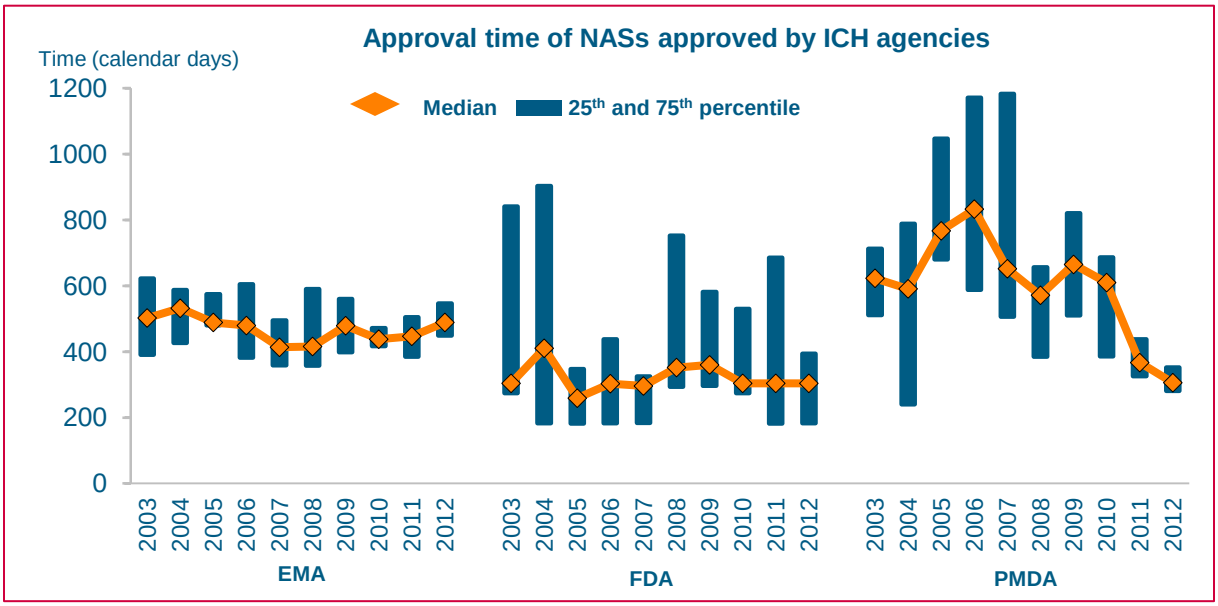
New Drug Approvals in ICH Countries 2003–2012
Focus on 2012



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

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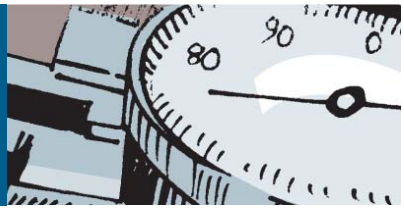
CIRS Centre for Innovation in Regulatory Science

Overview



In 2012, the number of New Active Substances (NASs) approved by both the FDA and PMDA represented the largest number of new medicines approved this decade (figure 1). Regulatory approvals by EMA were lower than the other agencies but were around the average for the agency considering the last 10 years. 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.

This briefing looks specifically at trends in the number of approvals and approval times across the following agencies processes: European Centralised, US FDA and Japan PMDA. Observations for 2012 and over the last decade are:

Median approval times for NASs approved in the US and Japan in 2012 were very similar and shorter than those seen at EMA by around 180 days (figure 2), although the variability in times was much greater through the FDA and PMDA process compared to EMA (figure 3). PMDA have also shown over this decade a substantial improvement in approval times from a median high of 833 days in 2006 to 306 days in 2012.

The increase in the EMA approval times for 2012 seem to be driven by an increasing time that it is taking companies to respond to EMA questions (figure 9).

The availability and use of the priority review system in the US and Japan can be seen as one of the biggest difference from

Figure 1

Number of NASs approved by ICH agencies by approval year

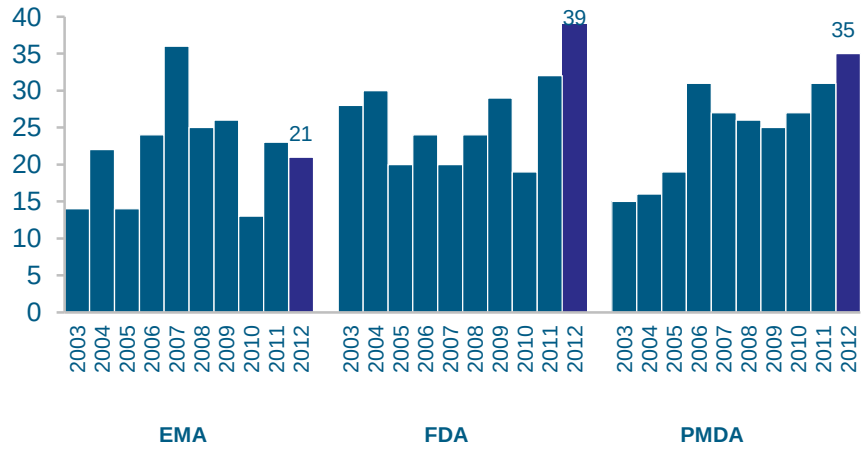
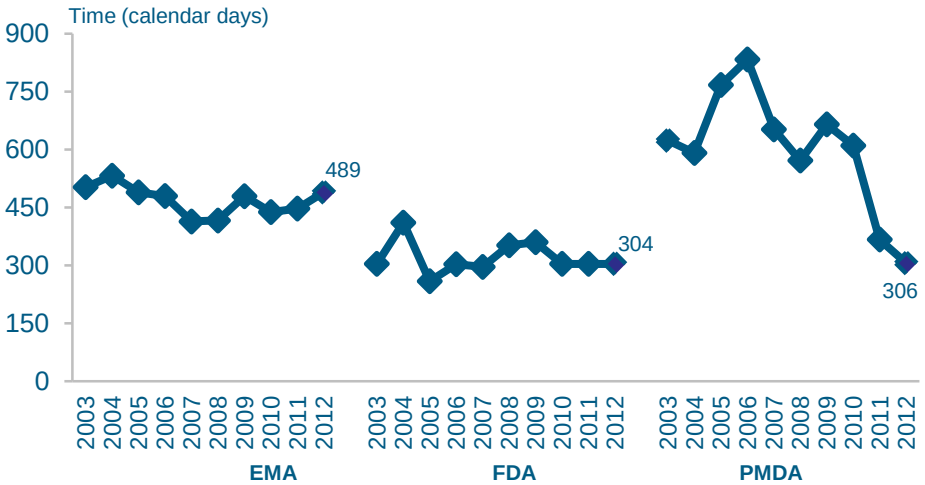


Figure 2

Median approval time of NASs approved by ICH agencies



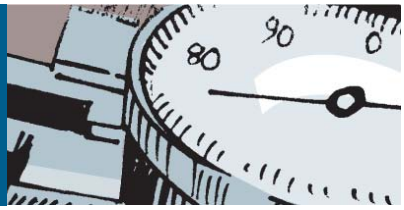
***Note**: The EMA approval time includes the EU Commission time*
Prior to 2004 the data shown for Japan represents approval by MHLW

EMA in terms of determinant of the speed of approvals. 45% of the 265 approvals by the FDA (2003-2012) and 18% of the 252 approvals by the PMDA were designated as priority. This compares to just 5% at EMA (figure 4).

The number of products FDA approved in one cycle has increased over the decade and for standard products in 2012, around 80% of the approvals went through one review cycle (figure 12 & 13).

For 135 products approved by both EMA and FDA , 80% of 135 were both submitted to each agencies within 12 months. (figure 7).

Comparison of ICH agencies' approvals



Approval time (figure 3)

• The median approval times* for all products approved 2003-2011 were 304, 454 and 610 days for FDA, EMA and PMDA, respectively. In comparison, the median time for products approved in 2012 was the same for the FDA, was slower for the EMA (489 days), and was drastically faster for the PMDA (306 days).

• The median approval time over the last five years 2008-2012 at PMDA was shorter than the first five years (2003-2007) – 414 days for 2008-2012 vs.693 days for 2003-2007.

• At EMA, the median approval time was 476 days for 2003-2007 vs. 453 days for 2008-2012;

• The median FDA approval times remained similar across the two time periods at 303 vs. 304 days.

• There is a wide variation in approval times for individual products 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)

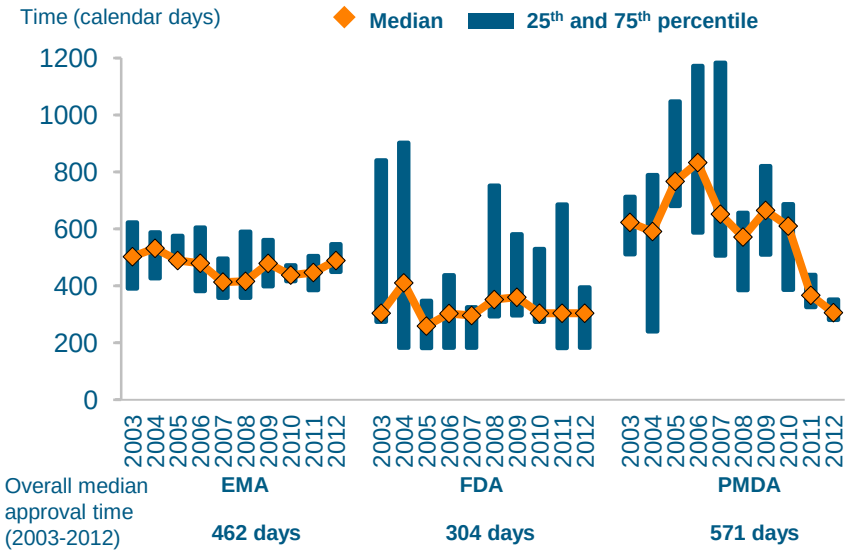
•The large variation in product approval time at FDA and PMDA over the duration of this study can be attributed to there being two distinct populations of approvals: standard and priority.

• For the FDA, the proportion of applications that qualified for a priority designation decreased when comparing with the last five years to 2003-2007. The proportion of applications receiving priority designation at FDA for 2003-2007 was 52% compared to 38% for 2008-2012.

A similar proportion in the percentage of priority approvals was seen at PMDA: 17% from 2003-2007 vs.19 % from 2008-2012 – although in 2012 the percentage of products gaining priority review was 37%.

Figure 3

Approval time of NASs approved by ICH agencies

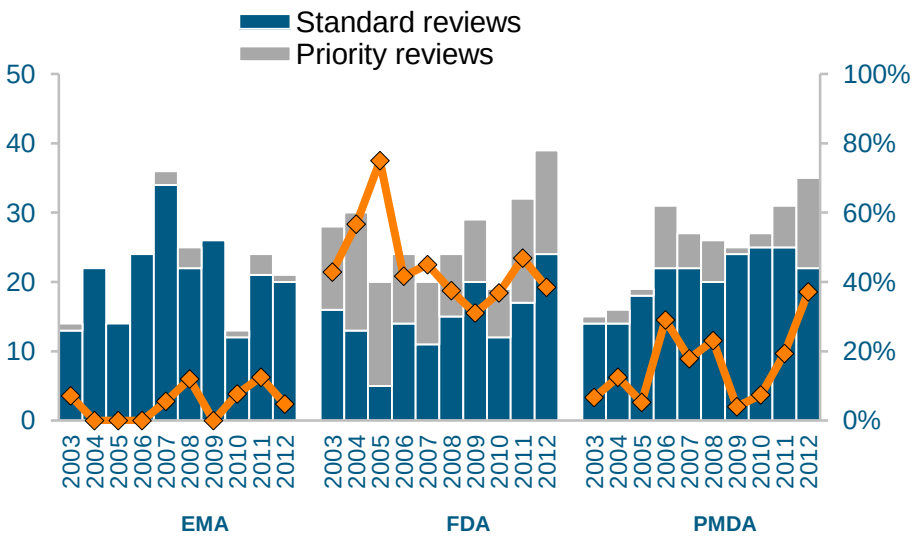


Overall median approval time (2003-2012)	EMA	FDA	PMDA
	462 days	304 days	571 days

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

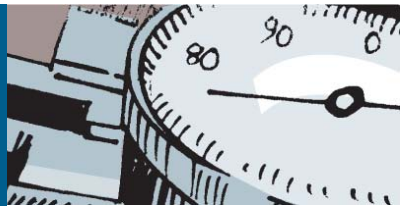
Figure 4

Number of NASs approvals by review type



Note: Median approval times is calculated from the time of submission to the date the licence to market was granted, including both authority and sponsor time

Comparison of ICH agencies' approvals



Orphan approvals (figure 5)

- Over the last five years (2008-2012) products designated as orphan as a proportion of total approvals was 32% by FDA and was similar between EMA and PMDA, 20% and 22% respectively.

- Between 2008–2012, 67% of the 45 FDA orphan approvals were reviewed as priority products. At PMDA 42% of the 32 PMDA orphan approvals, were priority whilst only 18% of the 22 EMA orphan products were reviewed as priority, although 36% were approved under conditional/exceptional circumstances. This compares to only 6% of standard approvals.

- The median approval time for orphan drugs was shorter than non-orphans at FDA and PMDA during 2008-2012. At FDA the median approval time was 274 days for orphan vs. 333 days for non-orphan and at PMDA a similar picture arises – 319 days for orphan vs. 478 days for non-orphan. However at EMA there was little difference in time between orphan and non-orphan products, at a median of 456 vs. 453 days respectively.

- In 2012, the median time taken to approve orphan drugs was longest at EMA compared to FDA and PMDA.

Approvals by compound type (figure 6)

- Over the last five years (2008-2012) NBE products as a proportion of total approvals was very similar across the agencies at 27% (29 of 108) by EMA followed by FDA with 29% (42 of 143) and at PMDA, 24% (35 of 144) respectively.

- Median approval times 2008-2012 do not vary greatly depending on the type of products at EMA, FDA or PMDA: 449 days for NCE vs. 482 for NBE at EMA, 304 days for both NCE and NBE at FDA and for PMDA, 413 days for NCEs compared to a median of 451 days for NBEs.

- EMA had a similar number of approvals by compound type across the time periods 03-07 vs 08-12: 81 vs. 79 NCEs and 28 vs. 29 NBEs respectively.

- FDA has shown an increase in both NCEs and NBEs approved over these two time points: 93 vs. 101 NCEs and 29 vs. 42 NBEs.

- The number of approved NCEs and NBEs has also increased in Japan : 85 NCE approvals from 03-07 vs. 109 approvals from 08-12 and 25 NBEs 03-07 vs. 35 08-12.

***Note**: Fig 5 & 6:* The EMA approval time includes the EU Commission time . In Japan prior to 2004 the data shown represents approval by MHLW

Figure 5

Median approval time by orphan status

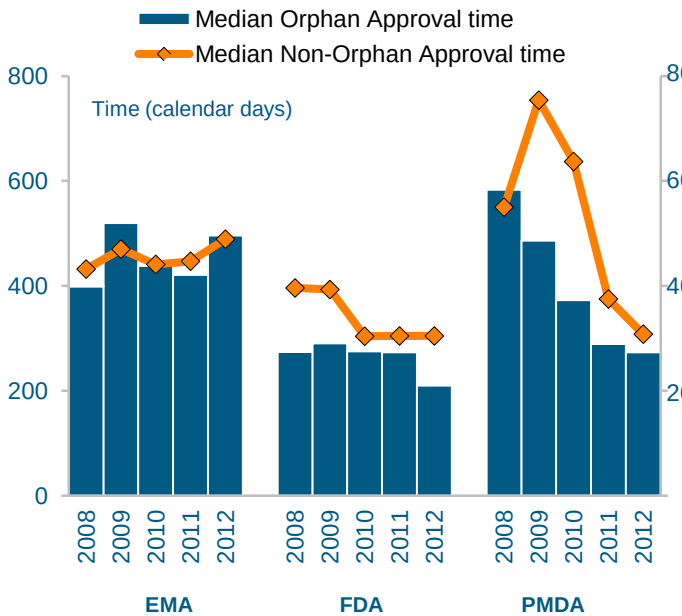
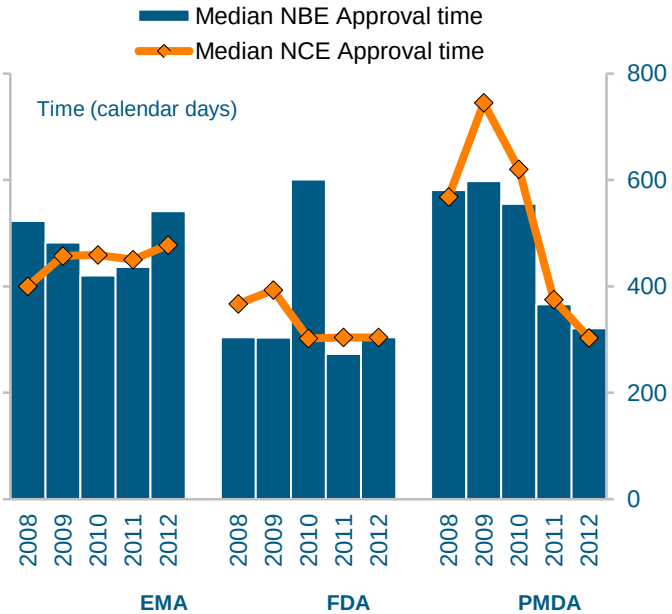
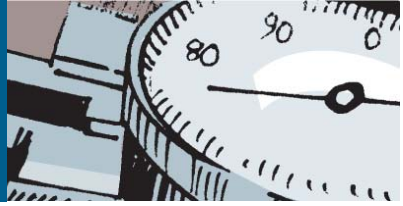


Figure 6

Median approval time by compound type



Comparison of ICH agencies' approvals



Submission pattern of NASs approved by ICH agencies 2003-2012 (figure 7 & 8)

- There were 135 NASs which were approved by both the FDA and EMA within the time frame of this study and 71 products that were approved by all three agencies. The submission date for each product varied across authorities.

- FDA vs. EMA: A high proportion of NASs (67%) were submitted to FDA first, compared to 30% at EMA. Four products (3%) were submitted on the same day and for EMA 69% were submitted within 90 days (figure 7).

- PMDA: 6% of products over the time period were submitted first to PMDA with 70% being submitted greater than 12 months after the first submission. However with the decease in approval times during the last 10 years it will be interesting to observe how this drug lag changes (figure 8).

- The median time difference between submission to each ICH agency for the 71 products following the submission to the first ICH agency was 21 days at EMA, 0 days at FDA and 678 days at PMDA.

Approval time (not shown)

- The median approval time for these 71 NASs across the agencies were FDA (275 days), EMA (419** days) and PMDA (387 days).

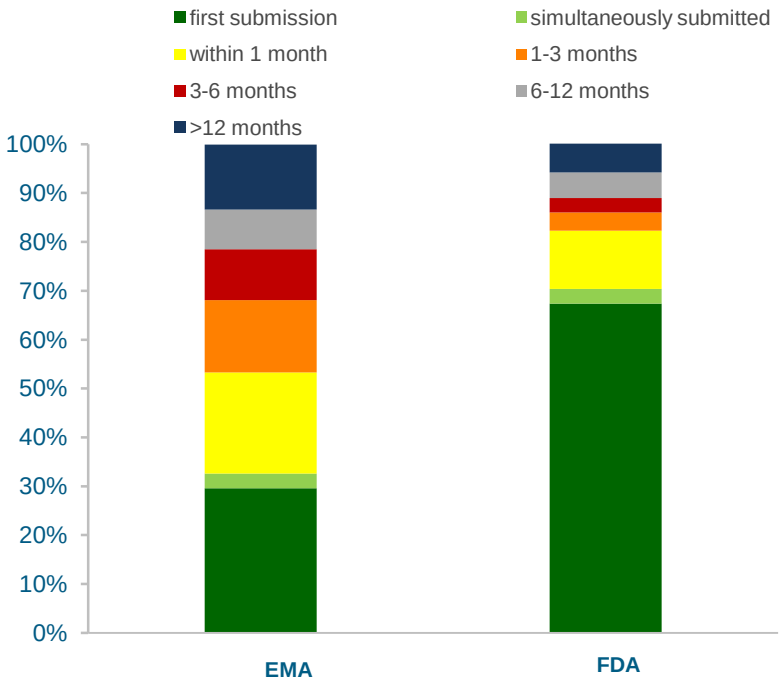
- The median approval time for the 71 NASs approved by all the ICH agencies was shorter than the median approval time for all approvals at the agencies within the time frame of this study.

- Overall the variation in approval time (5th-95th 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.

***Note*: The EMA approval time includes the EU Commission time

Figure 7

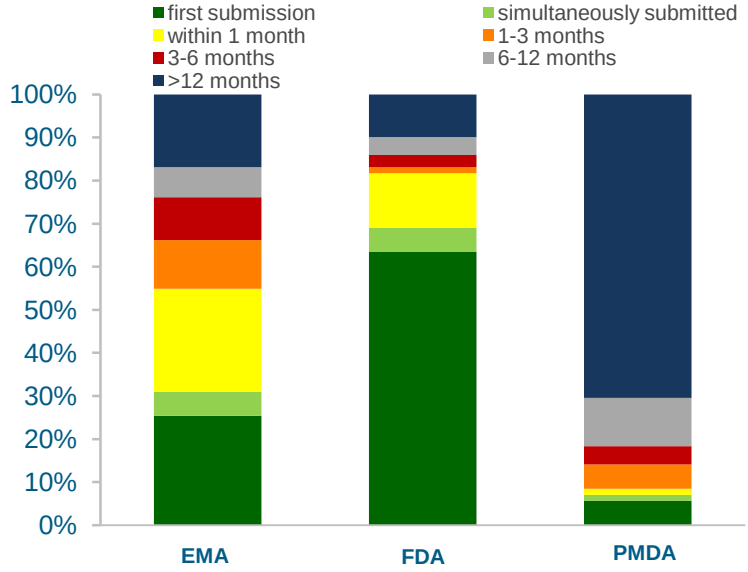
Proportion of 135 NASs approved by both FDA and EMA by submission timing (2003-2012)



Total number of NASs approvals = 135

Figure 8

Proportion of 71 NASs approved by all ICH agencies (2003-2012)



Total number of NASs approvals = 71

Features of the EMA approval process

Breakdown of EMA approval time (figure 9)

- The EMA review time showed relative consistency between 2003-2012 . The median review time was 254 days from 2003-2007 and 243 days from 2008-2012.

- A reduction in the median time taken by the EU Commission to grant a license has been seen after 2005, following the new EU legislation – the median time in 2008-2012 was 67 days.

- The time taken for companies to respond to questions raised by the EMA fluctuates year on year although the median time for 2012 is the highest since 2005.

Range in 2012 EMA approvals by the review components (figure 10)

- Of all the components of the review, the time companies take to respond to questions raised had the widest variation (25-75 percentile) – ranging from 116 days to 199 days.

- The time taken by the agency in the review was consistent, ranging from 236-272 days (25-75 percentile).

- The EU Commission time ranged from 63-96 days (25-75 percentile) and although the median was 67 days, 42% of the products took over 80 calendar days for this part of the process. The percentage for the previous 5 years (2007-2011) was 18% of products.

Figure 9

Median time of review process for NAS approved by EMA

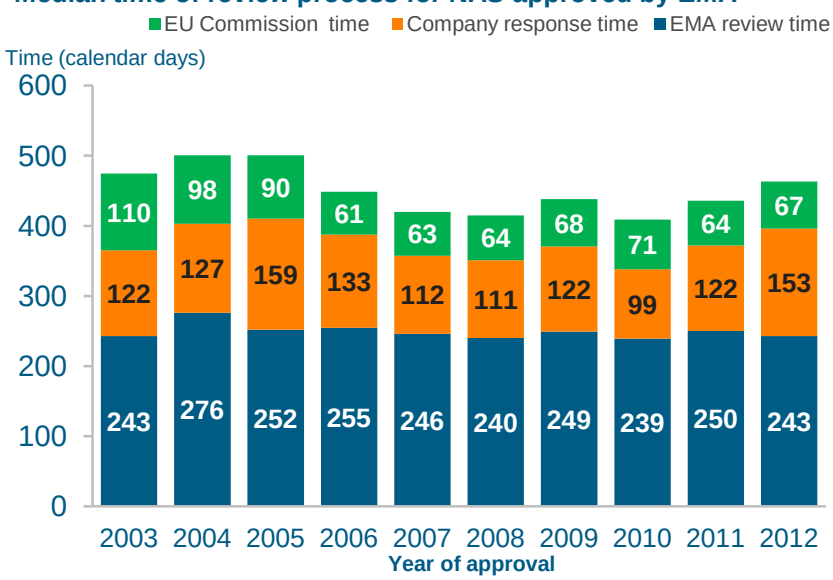
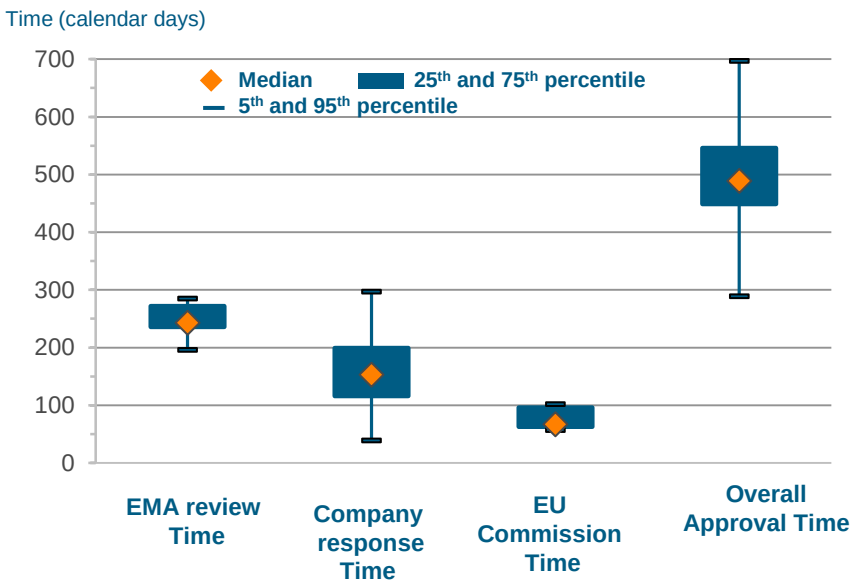


Figure 10

Components of EMA approval time for 21 NASs, approved in 2012



***Note**: Time component calculated using the dates specified in the individual EPARS for 2012 approvals*

Features of the FDA approval process

Approval time for FDA approvals (figure 11)

- 45% of the 265 FDA approvals 2003-2012 were priority, with a median approval time of 183 days.

- By comparison the median approval time for standards over the same time period was 396 days.

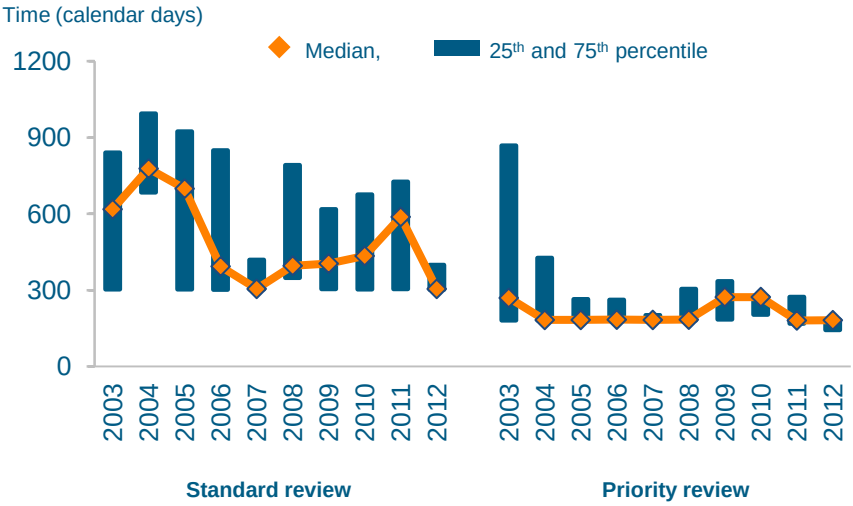
- Median approval time for standards in 2012 was 305, which is quicker than the median for the previous 3 years – 413 days. One reason for this may be the increased number of standard products going through one review cycle.

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.

Figure 11

Approval time of NASs approved by FDA by review type



- The number of products approved by CDER after only one cycle has increased over the decade for standard NASs and although priorities achieve around 80% being reviewed in one cycle over the last five years there has been a small year-on-year decrease.

- Interestingly, in 2012 the number of standard approvals being reviewed within one cycle increased to 78%, which is very similar to that being achieved by priorities (80%).

Figure 12

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

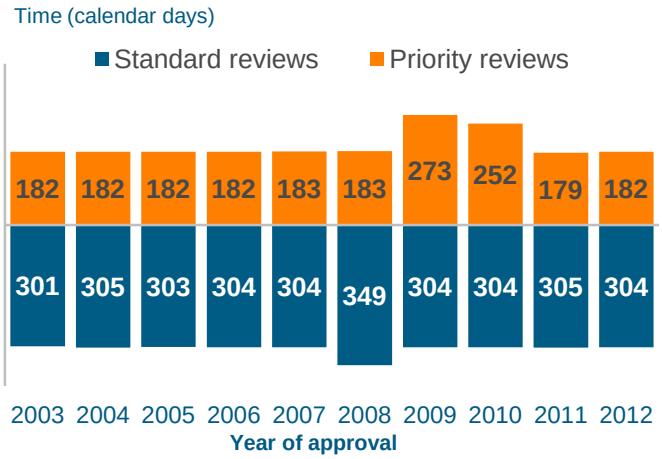


Figure 13

Percentage of NASs approved by CDER by one cycle review

Features of the PMDA approval process

PMDA approvals by review type (figure 14)

• 18% of the 255 PMDA approvals 2003-2012 were priority, with a median approval time of 351 days. By comparison, the median approval time for standards was 620 days over this time period.

• Over the time period of this study a reduction in median approval time was observed as was the increase in the percentage of priority approvals.

• 37% of total approvals in 2012 were priority compared to the average for previous five years (2007-2011) of 14%.

• The median approval time in 2012 was 276 days for priority reviews, but 321 days for standard reviews. These times meet the PMDA target time (nine months for priority and 12 months for standard).

Approval time by therapeutic area (figure 15)

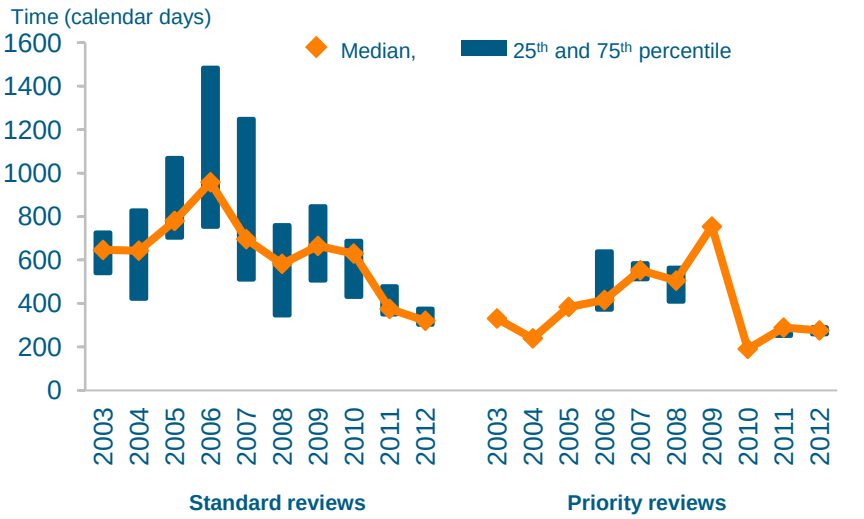
• Approval time differed between therapeutic areas at PMDA over the last five years..

• Anti-infective had the fastest median approval times both for standard and priority products at 343 and 243 days respectively, with Nervous System being the slowest standard approval times with a median of 555 days and Anti-cancer being the therapeutic area with the slowest priority product approval times: median, 388 days

• As would be expected, within each therapeutic area there was a difference between the medians of standard and priority approval time – drugs within the Nervous System category had a difference of 285 days whereas Anti-cancer products had just 58 days. This shows that the standard review approval time for Anti-cancer drugs is similar to the priority review.

Figure 14

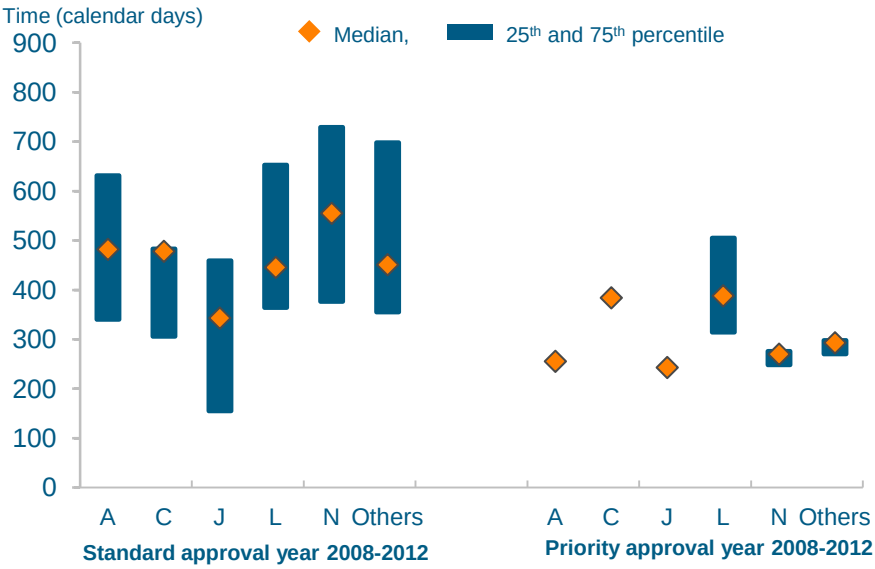
Approval time of NASs approved by PMDA by review type



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

Figure 15

Standard vs priority approval time of NASs approved by PMDA by therapeutic area from 2008-2012



ATC code

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

EMA NASs approvals in 2012

Brand name	Generic name	Marketing authorisation holder	Compound type	Review type	Approval date
Zelboraf	vemurafenib	Roche Registration Ltd.	NCE	Standard	17/02/2012
Caprelsa	vandetanib	AstraZeneca AB	NCE	Standard	17/02/2012
Signifor	pasireotide diaspartate	Novartis Europharm Ltd.	NCE	Standard	24/04/2012
Pixuvri	pixantrone dimaleate	CTI Life Sciences Ltd.	NCE	Standard	10/05/2012
Rienso	ferumoxytol	Takeda Global Research and Development Centre (Europe) Ltd.	NCE	Standard	15/06/2012
Genuair (Eklira, Bretaris)	aclidinium bromide	Almirall, S.A.	NCE	Standard	20/07/2012
Kalydeco	ivacaftor	Vertex Pharmaceuticals (U.K.) Ltd.	NCE	Expedited	23/07/2012
Fycompa	perampanel	Eisai Europe Ltd.	NCE	Standard	23/07/2012
Zinforo	ceftaroline fosamil	AstraZeneca AB	NBE	Standard	23/08/2012
Jakavi	ruxolitinib	Novartis Europharm Ltd.	NCE	Standard	23/08/2012
Revestive	teduglutide	Nycomed Danmark ApS	NBE	Standard	30/08/2012
Inlyta	axitinib	Pfizer Ltd.	NCE	Standard	03/09/2012
NovoThirteen	catridecacog	Novo Nordisk A/S	NBE	Standard	03/09/2012
Dacogen	decitabine	Janssen-Cilag International N V	NCE	Standard	20/09/2012
Xalkori	crizotinib	Pfizer Ltd.	NBE	Standard	23/10/2012
Adcetris	brentuximab vedotin	Takeda Global Research and Development Centre (Europe) Ltd.	NBE	Standard	25/10/2012
Forxiga	dapagliflozin propanediol monohydrate	Bristol-Myers Squibb / AstraZeneca EEIG	NBE	Standard	12/11/2012
Picato	ingenol mebutate	LEO Pharma A/S	NCE	Standard	15/11/2012
Eylea	aflibercept	Bayer Pharma AG	NBE	Standard	22/11/2012
Constella	linaclotide	Almirall, S.A.	NCE	Standard	26/11/2012
Betmiga	mirabegron	Astellas	NCE	Standard	20/12/2012

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 2012 and the approval date is the time when market authorisation is valid through out the EU.

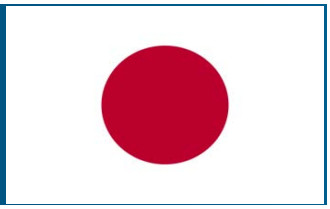
FDA NASs approvals in 2012

Brand name	Generic name	Marketing authorisation holder	Compound type	Review type	Approval date
Voraxaze	glucarpidase	BTG International Inc.	NBE	Expedited	17/01/2012
Picato	ingenol mebutate	Leo Pharma AS	NCE	Standard	23/01/2012
Inlyta	axitinib	Pfizer	NCE	Standard	27/01/2012
Erivedge	vismodegib	Genetech	NCE	Expedited	30/01/2012
Kalydeco	ivacaftor	Vertex Pharms	NCE	Expedited	31/01/2012
Zioptan	tafluprost	Merck Sharp Dohme	NCE	Standard	10/02/2012
Surfaxin	lucinactant	Discovery Labs	NBE	Standard	06/03/2012
Omontys / Omontys preservative free	peginesatide acetate	Affymax	NBE	Standard	27/03/2012
Amyvid	florbetapir f-18	Avid Radiopharms Inc	NCE	Expedited	06/04/2012
Stendra	avanafil	Vivus	NCE	Standard	27/04/2012
Elelyso	taliglucerase alfa	Pfizer	NBE	Standard	01/05/2012
Perjeta	pertuzumab	Genetech	NBE	Expedited	08/06/2012
Belviq	lorcaserin hydrochloride	Eisai Inc	NCE	Standard	27/06/2012
Myrbetriq	mirabegron	Astellas	NCE	Standard	28/06/2012
Prepopik	citric acid; magnesium oxide; sodium picosulfate	Ferring Pharms AS	NCE	Standard	16/07/2012
Kyprolis	carfilzomib	Onyx Pharms	NCE	Standard	20/07/2012
Tudorza pressair	aclidinium bromide	Forest Labs Inc.	NBE	Standard	23/07/2012
Zaltrap	ziv-aflibercept	Sanofi Aventis US	NBE	Expedited	03/08/2012
Stribild	cobicistat; elvitegravir; emtricitabine; tenofovir disoproxil fumarate	Gilead Sciences Inc.	NCE	Standard	27/08/2012
Neutroval	tbo-filgrastim	Sicor Biotech	NBE	Standard	29/08/2012
Linzess	linaclotide	Forest Labs Inc	NBE	Standard	30/08/2012
Xtandi	enzalutamide	Astellas	NCE	Expedited	31/08/2012
Bosulif	bosutinib monohydrate	Wyeth Pharms Inc	NCE	Standard	04/09/2012
Aubagio	teriflunomide	Sanofi Avenis US	NCE	Standard	12/09/2012

FDA NASs approvals in 2012

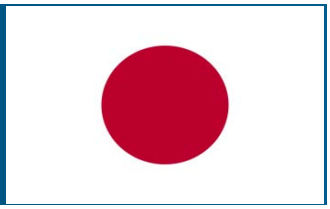
Brand name	Generic name	Marketing authorisation holder	Compound type	Review type	Approval date
Stivarga	regorafenib	Bayer Healthcare	NCE	Expedited	27/09/2012
Jetrea	ocriplasmin	Thrombogenics Inc	NBE	Expedited	17/10/2012
Fycompa	perampanel	Eisai Inc	NCE	Standard	22/10/2012
Synribo	omacetaxine mepesuccinate	Ivax Intl	NBE	Standard	26/10/2012
Xeljanz	tofacitinib citrate	Pfizer	NCE	Standard	06/11/2012
Cometriq	cabozantinib s-malate	Exelixis	NCE	Expedited	29/11/2012
Iclusig	ponatinib	Ariad Pharmaceuticals	NCE	Expedited	14/12/2012
Raxibacumab	raxibacumab	Human Genome Sciences Inc.	NBE	Expedited	14/12/2012
Signifor	pasireotide diaspartate	Novartis Pharms	NBE	Standard	14/12/2012
Bivigam	Immune Globulin Intravenous (Human)	Biotest	NBE	Standard	19/12/2012
Gattex	teduglutide	NPS Pharmaceuticals Inc.	NBE	Standard	21/12/2012
Juxtapid	lomitapide mesylate	Aegerion Pharmaceuticals Inc	NCE	Standard	21/12/2012
Eliquis	apixaban	Bristol Myers Squibb	NCE	Expedited	28/12/2012
Sirturo	bedaquiline	Janssen R and D	NCE	Expedited	28/12/2012
Fulyzaq	crofelemer	Salix Pharms	NCE	Expedited	31/12/2012

PMDA NASs approvals in 2012



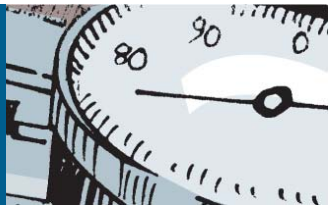
Brand name	Generic name	Marketing authorisation holder	Compound type	Review type	Approval date
Azilva	azilsartan	Takeda Pharmaceutical Company Limited	NCE	Standard	18/01/2012
Xarelto	rivaroxaban	Bayer Yakuhin	NCE	Standard	18/01/2012
Lunesta	eszopiclone	Eisai co., Ltd.	NCE	Standard	18/01/2012
Aiphagan	brimonidine tartrate	Senju Pharmaceutical Co., Ltd.	NCE	Standard	18/01/2012
Samtirel	atovaguone	GlaxoSmithKline K.K.	NCE	Priority	18/01/2012
Cancidas	caspofungin acetate	MSD K.K.	NBE	Standard	18/01/2012
Ranmark	denosumab	Daiichi Sankyo Co Ltd.	NBE	Standard	18/01/2012
Kiklin	bixalomer	Astellas Pharma	NCE	Standard	30/03/2012
Apokyn	apomorphine hydrochloride hydrate	Kyowa Hakko Kirin	NCE	Priority	30/03/2012
Pulmozyme	dornase alfa	Chugai Pharmaceutical	NBE	Priority	30/03/2012
Brazaves	miglustat	Actelion Pharmaceuticals Japan Ltd.	NCE	Priority	30/03/2012
Poteligeo	mogamulizumab	Kyowa Hakko Kirin	NBE	Priority	30/03/2012
Xalkori	crizotinib	Pfizer Japan Inc.	NCE	Priority	30/03/2012
Edurant	rilpivirine hydrochloride	Janssen Pharmaceutical K.K.	NCE	Priority	18/05/2012
Tenelia	teneligliptin hydrobromide hydrate	Mitsubishi Tanabe Pharma	NCE	Standard	29/06/2012
Gonax	degarelix acetate	Astellas Pharma	NCE	Standard	29/06/2012
Kolbet	iguratimod	Toyama Chemical Co., Ltd./Eisai	NCE	Standard	29/06/2012
Amitiza	lubiprostone	Sucampo Pharma	NCE	Standard	29/06/2012
Somatuline	lanreotide acetate	Teijin Pharma ltd	NBE	Standard	29/06/2012
Inlyta	axitinib	Pfizer Japan Inc.	NCE	Standard	29/06/2012
Suiny/Beskoa	anagliptin	Sanwa Kagaku Kenkyusho Co., Ltd/Kowa Pharmaceutical Co. Ltd.	NCE	Standard	28/09/2012
Elyea	aflibercept	Bayer Yakuhin	NBE	Standard	28/09/2012
Tresiba	insulin degludec	Novo Nordisk Pharma Ltd.	NBE	Standard	28/09/2012

PMDA NASs approvals in 2012



Brand name	Generic name	Marketing authorisation holder	Compound type	Review type	Approval date
Diacomit	stiripentol	Meiji Seika Pharma Co., Ltd.	NCE	Priority	28/09/2012
Buphenyl	sodium phenylbutyrate	CMIC Holdings Co., Ltd.	NCE	Priority	28/09/2012
Seebri	glycopyrronium bromide	Novartis Pharma K.K.	NCE	Standard	28/09/2012
Votrient	pazopanib hydrochloride	GlaxoSimthKline K.K.	NCE	Priority	28/09/2012
Tygacil	tigecycline	Pfizer Japan Inc.	NBE	Priority	28/09/2012
Toviaz	fesoterodine fumarate	Pfizer Japan Inc.	NCE	Standard	25/12/2012
Cimzia	certolizumab pegol	UCB Japan Co. Ltd.	NBE	Standard	25/12/2012
Malarone	atovaquone and proguanil hydrochloride	GlaxoSimthKline K.K.	NCE	Priority	25/12/2012
Ameparomo	paromomycin sulfate	Pfizer Japan Inc.	NBE	Standard	25/12/2012
Neupro	rotigotine	Otuka Pharmaceutical Co., Ltd.	NCE	Standard	25/12/2012
Eliquis	apixaban	Bristol-Myers Squibb	NCE	Standard	25/12/2012
Xenazine	tetrabenazine	Alfresa Pharma	NCE	Priority	25/12/2012

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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