# New drug approvals in six major authorities 2011-2020:

## Focus on Facilitated Regulatory Pathways and Worksharing

This Briefing presents the results from the Centre for Innovation in Regulatory Science (CIRS) annual analysis of New Active Substance (NAS) approvals by six major regulatory agencies: the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), the Japan Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, Swissmedic and the Australian Therapeutic Goods Administration (TGA). The analysis focuses on 2020 as well as looking back at 2011-2020. Although median approval times can be a marker of agency performance and the time it takes to make medicines available to patients, other factors need to be taken into account. This Briefing focuses on two such factors, namely facilitated regulatory pathways (FRPs) and worksharing, where regulators review different parts of the dossier to ensure timely availability of medicines globally.

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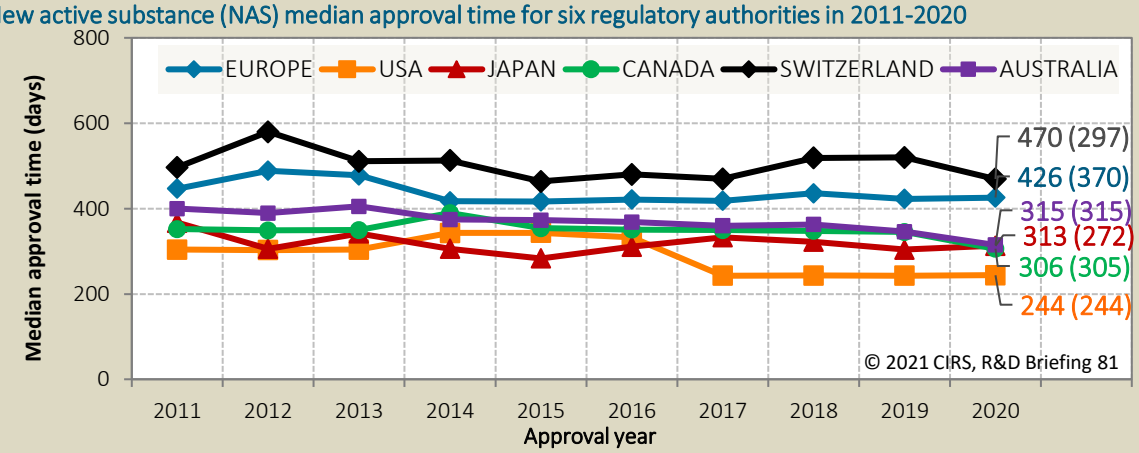
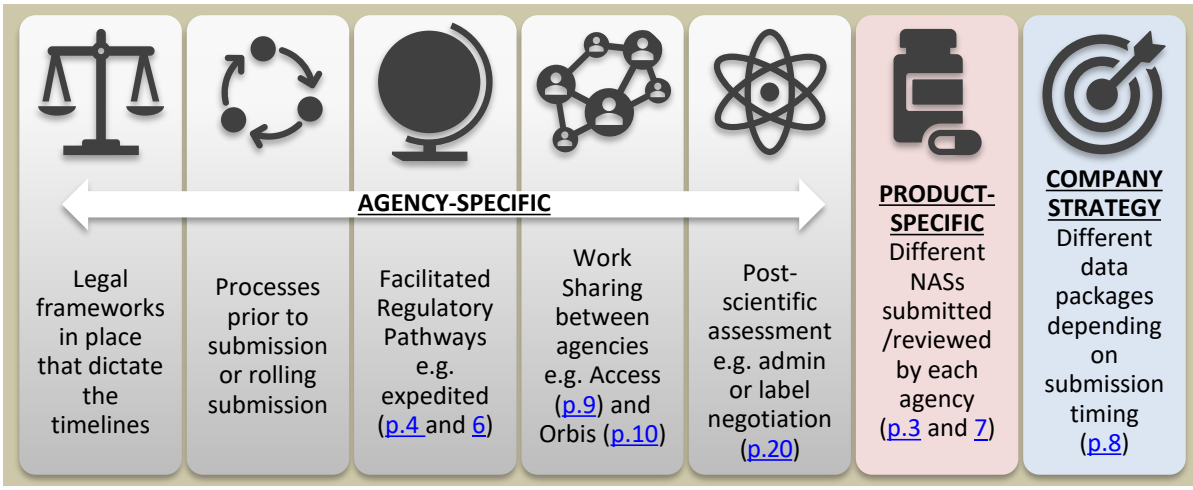
New active substance (NAS) median approval time for six regulatory authorities in 2011-2020




*Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. N1 = median approval time for products approved in 2020; (N2) = median time from submission to the end of scientific assessment (see p.20) for products approved in 2020.*

Differences in median time to marketing authorisation can be attributed to a number of factors that are agency-specific, product-specific or related to company strategy, as detailed in the infographic below.



# Key messages

- In 2020, FDA (CDER and CBER combined) approved the highest number of NASs (Fig. 1). **The overall number of NASs approved by the six agencies** has generally increased over the last decade, but has flattened for the past 5 years, except for FDA, which has continued to increase.
- Despite recent **convergence in approval times** over the last 20 years, there were still differences in the median approval times across the six agencies (cover page), particularly for EMA and Swissmedic compared to the other four regulators. However, this difference was a lot narrower when comparing the **median time from submission to end of scientific assessment** (see Definitions).
- FDA was the agency with the shortest **median approval time** (244 days), which is likely due to the extensive use of facilitated regulatory pathways (FRPs). This was followed by Health Canada (306 days), PMDA (313 days), TGA (315 days), EMA (426 days) and Swissmedic (470 days) (Fig. 2).
- All six agencies now offer an **expedited process** designed to hasten the review process of promising NASs (Fig. 3). TGA implemented its priority system in 2017 and 11 expedited approvals were granted by TGA 2018-2020. For EMA, in 2020, nine NASs were designated initially as expedited; but of those, six NASs were reverted. In addition, for seven NASs, the applicant requested expedited but EMA did not agree.
- FDA approved the highest number of NASs through **FRPs** to enable the availability, review and/or approval of medicines for unmet need (Fig. 7 and 8).
- The number of NASs with an **orphan designation** has increased across EMA, FDA, PMDA, Swissmedic and TGA, from 31% between 2011-2015 to 38% between 2016-2020 (Fig. 5).
- Between 2016-2020, **the top 5 therapeutic areas (TA)** by number approved across all six agencies, made up 77% of all approvals. Anti-cancer and immunomodulators made up 49% of the top 5 TA approvals (Fig. 9).
- **The number of products approved by all six agencies in a five-year period** decreased slightly from 40 NASs in 2011-2015 to 2016-2020 (36 NASs), compared to analyses in the past years where there was an increase (see R&D Briefing 70, 77), suggesting that the pace of internationalisation may be levelling off (Fig. 11).
- In 2018-2020, 7 NASs were approved by one or more agencies participating in the **Access Consortium** (Fig. 12). As part of this worksharing initiative, the agencies review different parts of the dossier.
- In 2020, 3 NASs were approved through **Project Orbis** by FDA, Health Canada and TGA (Fig. 15), demonstrating that global regulatory collaboration can deliver faster access to new therapies for patients with cancer.

**The availability and use of expedited as well as other facilitated regulatory pathways is key to addressing areas of unmet need and other public health emergencies such as COVID-19 (see CIRS R&D Briefing 75).**

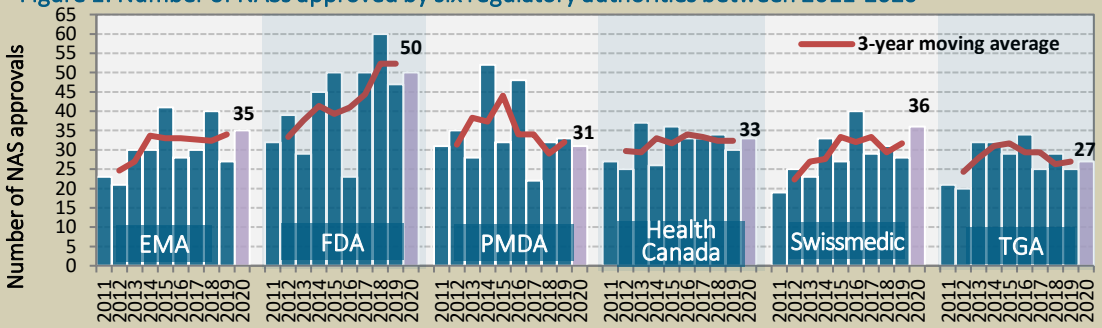
**Regulatory models are also being challenged by the pandemic; CIRS R&D Briefing 80 summarises activities that evolved as a result of the COVID-19 pandemic as well as lessons learned.**

**2020 numbers include remdesivir authorized for emergency use to treat COVID-19. Analyses in the coming years may demonstrate the impact of the pandemic on NAS approvals by the agencies.**


| EMA | FDA | PMDA | Health Canada | Swissmedic | TGA |
|---|---|---|---|---|---|
| p.12 | p.13 | p.14 | p.15 | p.16 | p.17 |

# Overall approvals

Figure 1: Number of NASs approved by six regulatory authorities between 2011-2020



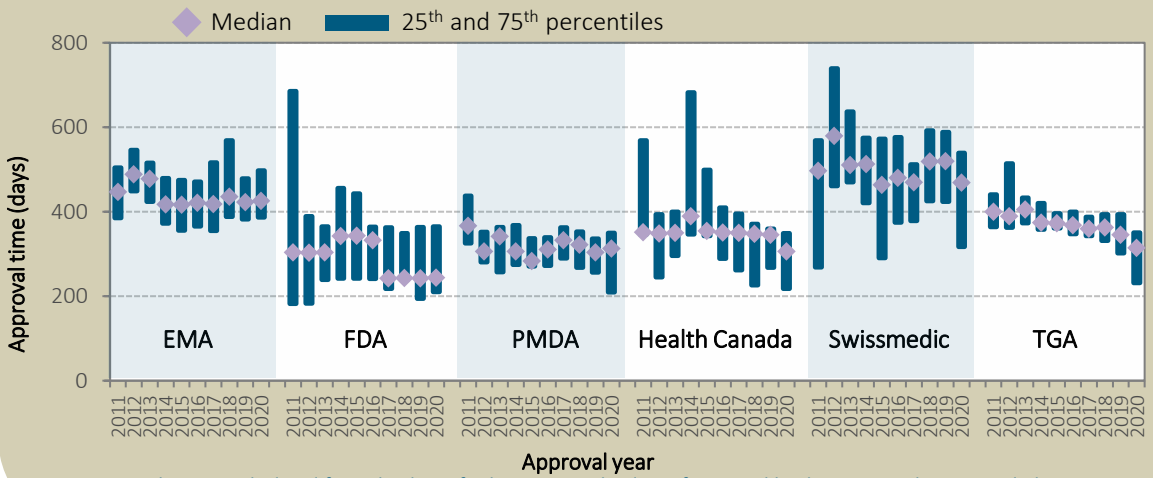



**In 2020, FDA (CDER and CBER combined) approved the highest number of NASs (50) (Fig. 1). The overall number of NASs approved by the six agencies has generally increased over the decade, but has flattened for the past five years, except for FDA, where there was an increase during 2011-2020.** The rationale for the typically higher number of approvals by FDA compared to other agencies may be the availability of FRPs, or that some of the medicines approved by FDA, particularly from smaller companies, do not become internationalised. A comparison of the NAS numbers during the two halves of the decade, 2011-2015 and 2016-2020, revealed that the biggest difference in the number of approvals was seen for Swissmedic, with a 29% increase, followed by FDA (18%), EMA (10%), Health Canada (8%), TGA (4%), whereas for PMDA there was a decrease of 7%. The variance in the number of products approved by each agency may be explained by a number of factors, such as different submission strategies to each agency, depending on company size, unmet medical need and review speed.

**2020 numbers include remdesivir authorized for emergency use to treat COVID-19. Analyses in the coming years may demonstrate the impact of the pandemic on NAS approvals by the agencies.**

Figure 2: NAS approval time for six regulatory authorities between 2011-2020



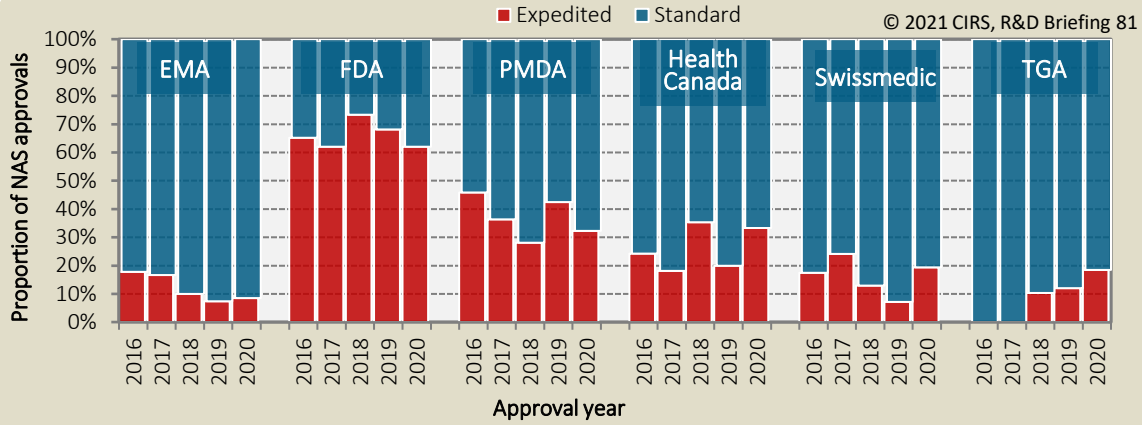



*Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.*

**In 2020, FDA had the shortest median approval time (244 days), which is likely due to the wide use of FRPs. This was followed by Health Canada (306 days), PMDA (313 days), TGA (315 days), EMA (426 days) and Swissmedic (470 days) (Fig. 2).** Despite convergence in approval times over the last 20 years (data not shown), there were still differences in median approval times across the six agencies (cover page; 226 days between FDA and Swissmedic). However, this difference was a lot narrower when comparing the median time from submission to the end of scientific assessment (53 days between FDA and Swissmedic). For FDA, Health Canada and TGA, the overall approval time and the time to end of scientific assessment were the same or similar, which indicates that very few activities occur after the end of scientific assessment. However, for the other agencies, there are additional steps following the end of scientific assessment (outlined on p. 20), such as administrative activities or negotiations with the sponsor, like in the case of Swissmedic to negotiate the label. However, besides regulatory review, other evaluations need to occur before patient access, namely health technology assessment (HTA). HTA outcomes in Australia, Canada and Europe have also been analysed by CIRS.

# Characteristics: Review type

Figure 3: Number of NAS approvals by review type for six regulatory authorities between 2016-2020

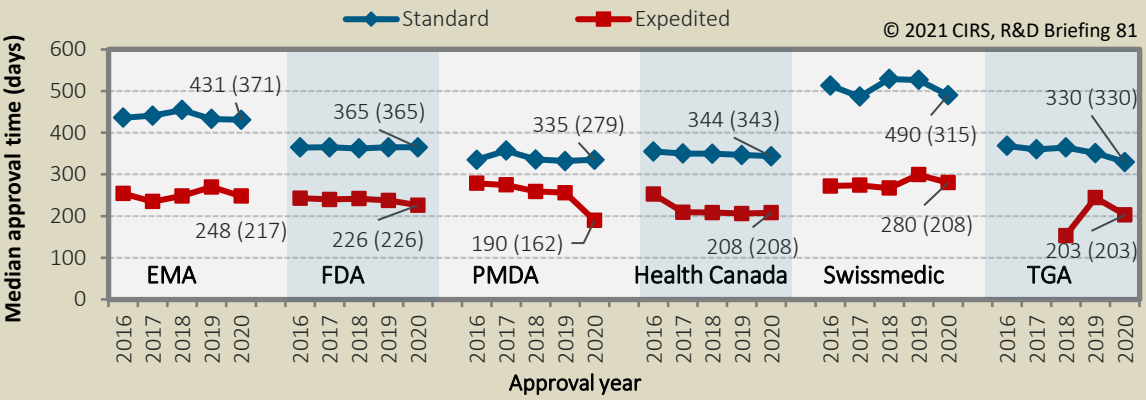



*'Expedited review' refers to EMA 'Accelerated Assessment', Swissmedic 'Fast Track' and FDA/PMDA/Health Canada/TGA 'Priority Review'. TGA introduced an expedited (priority) review programme in 2017.*

**All six agencies offer an expedited process designed to hasten the review process of promising NASs (Fig. 3). In 2020, the ratio of expedited approvals to standard reviews was highest for FDA (62%), followed by Health Canada (33%), PMDA (32%), Swissmedic (19%) and EMA (9%). TGA implemented its priority system in 2017; three expedited approvals were granted in 2018, another 3 in 2019 and five in 2020.** The proportion of expedited approvals has been consistently high for FDA and increased from 49% between 2011-2015 (results not shown) to 67% between 2016-2020. For EMA, the number of expedited approvals remains the lowest, which is partially because the review type can be reverted to standard review if timelines cannot be met by the sponsor. In 2020, six NASs initially designated by EMA as expedited were reverted, whereas for seven NASs, the applicant requested expedited review but EMA did not agree.

The availability and use of expedited pathways as well as other FRPs (see p. 6) has been key to addressing areas of unmet need and other public health emergencies such as COVID-19.

Figure 4: NAS median approval time by review type for six regulatory authorities between 2016-2020

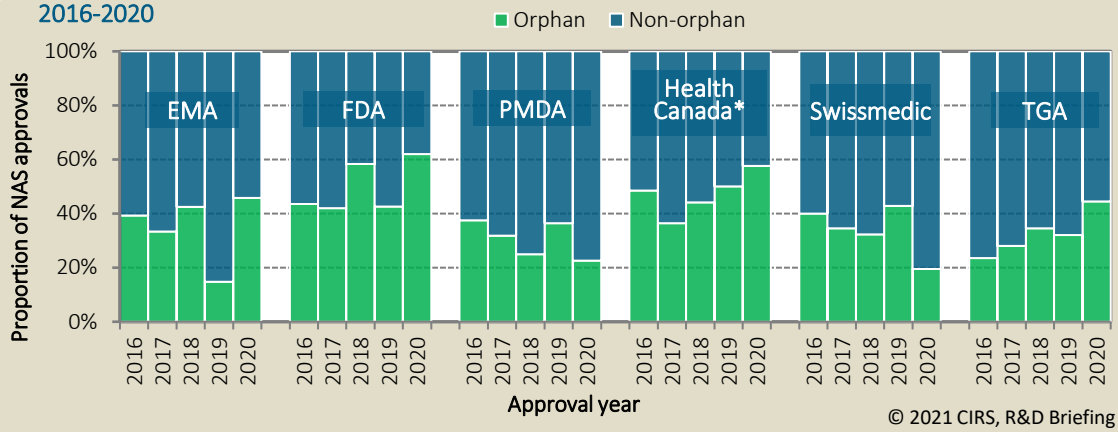



*'Expedited review' refers to EMA 'Accelerated Assessment', Swissmedic 'Fast Track' and FDA/PMDA/Health Canada/TGA 'Priority Review'. TGA introduced an expedited (priority) review programme in 2017. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. N1 = overall approval time for 2020; (N2) = time from submission until the end of scientific assessment (see p.20) for 2020.*

**Although Swissmedic had the longest median approval time for standard and expedited NASs in 2020, the median time from submission to end of scientific assessment (see p. 20 for definitions) was 315 days for standard and 208 days for expedited, which is similar to the other agencies. Interestingly, for EMA and Swissmedic, the additional activities taking place following the end of scientific assessment were taking approximately half the time for products designated as expedited compared to standard (Fig. 4).** For EMA, this is due to the European Commission time being expedited, while for Swissmedic, it may be a result of label negotiations and other administrative activities being carried out more quickly for high unmet need products. For the five NASs approved through the TGA priority process in 2020, the median approval was 203 days, which is in line with the other agencies.

# Characteristics: Orphan designation

Figure 5: Proportion of NAS approvals by orphan designation for six regulatory authorities between 2016-2020

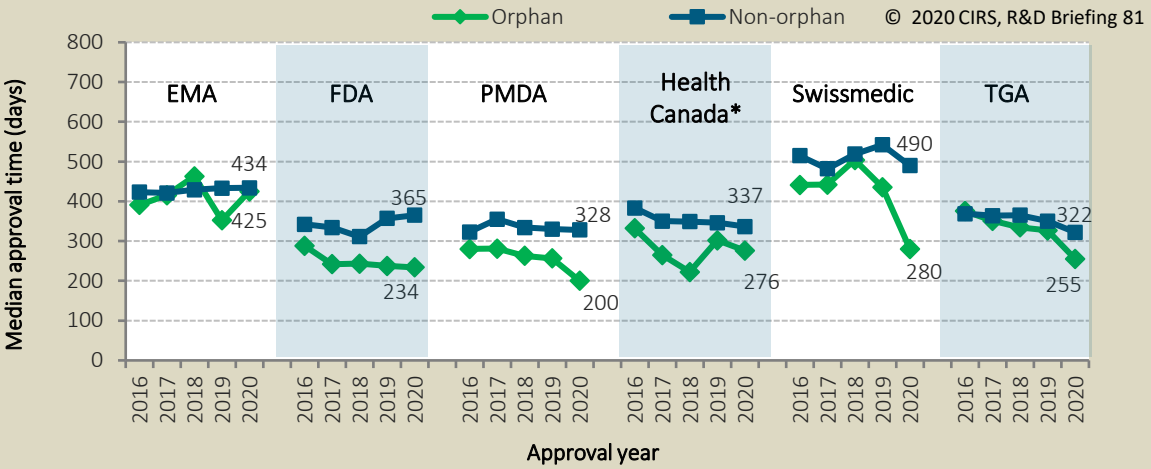





** Health Canada does not currently have an orphan policy; this data shows the number of medicines that were approved by Health Canada that were classified as orphan by either FDA, EMA or TGA.*

**The number of NASs with an orphan designation has increased across EMA, FDA, PMDA, Swissmedic and TGA, from 31% between 2011-2015 (results not shown) to 38% between 2016-2020. From 2016-2020 (Fig. 5), the proportion of orphans varied year-on-year but was generally high. This may be due to disease stratification and companies' growing R&D pipelines, and is consistent with increased commitment from agencies to tackle unmet medical needs.** In 2020, FDA and Swissmedic had the highest proportion of orphans approved (62%) while Swissmedic had the lowest (19%). This variance across agencies may be due to the types of products submitted to each agency as well as differences in orphan designation criteria across the agencies, or the indication submitted by the sponsor. Although Health Canada does not currently have an orphan policy, 58% of the NASs approved by the agency in 2020 were classified as orphan by either FDA, EMA or TGA.

Figure 6: NAS median approval time by orphan designation for six regulatory authorities between 2016-2020




*Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.*

**Health Canada does not currently have an orphan policy; this data shows the number of medicines that were approved by Health Canada that were classified as orphan by either FDA, EMA or TGA.*

**Approval timelines for orphans and non-orphans were compared across the six agencies between 2016-2020 (Fig. 6).** All orphan NASs approved in Japan went through expedited review, due to an incentive from PMDA to address unmet needs. PMDA had the fastest median approval time for orphans in 2020 (200 days). FDA had the second fastest median approval time for orphans in 2020 (234 days), as 81% of these products were approved through expedited review. Health Canada does not currently have an orphan policy; however, for the 19 NASs approved by Health Canada in 2020 that were classified as orphan by either FDA, EMA or TGA, the median approval time was 276 days. For the 16 orphans approved by EMA in 2020, the median approval time was 425 days, where three (19%) of the NASs were expedited by the agency. 33% of orphan drugs approved by TGA in 2020 were approved with the recently introduced priority review and its median approval time was 67 days faster than that for non-orphans.

# Characteristics: Facilitated Regulatory Pathways (FRPs)

Of the six agencies, FDA approved the highest number of NASs through FRPs to enable the availability, review and/or approval of medicines for unmet need (Fig. 7 and 8).

Figure 7: Proportion of NASs approved by each agency in 2020 that benefited from at least one FRP

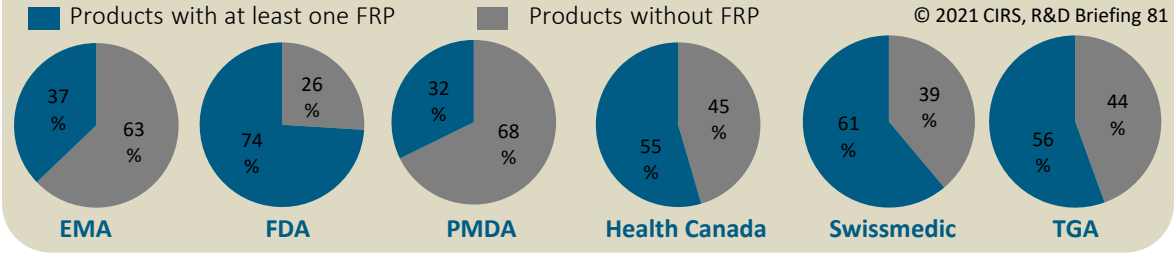



**Figure 8: Facilitated regulatory pathway (FRP) timelines across six agencies; focus on 2020**

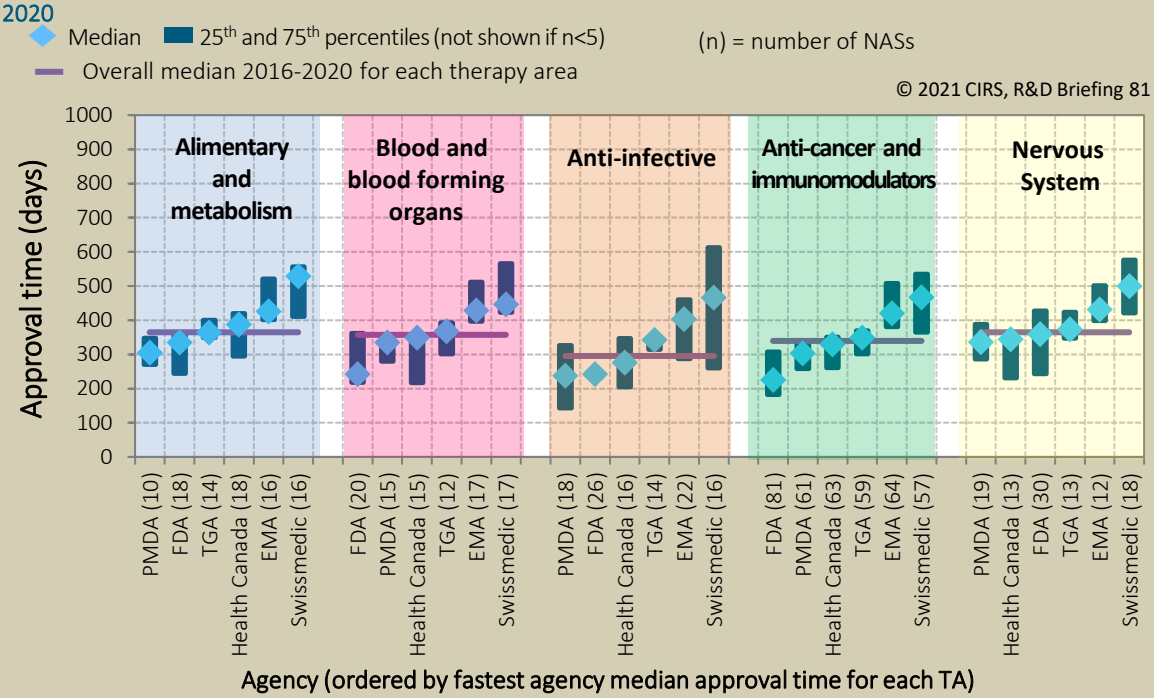
| © 2021 CIRS, R&D Briefing 81 | New Active Substance (NAS) approval type | 2020 NAS approvals, number | 2020 NASs, % | Expedited, % of 2020 approvals | 2020 median approval time, days |
|---|---|---|---|---|---|
| **EMA** | Accelerated Assessment (referred to in this Briefing as Expedited) | 3 | 9% | | 248 |
| | Conditional Approval | 10 | 29% | 10% | 480 |
| | Exceptional Circumstances | 1 | 3% | 0% | 534 |
| | PRIME | 8 | 23% | 38% | 344 |
| **FDA** | Priority (referred to in this Briefing as Expedited) | 31 | 62% | | 226 |
| | Accelerated Approval | 13 | 26% | 100% | 226 |
| | Breakthrough Designation | 21 | 42% | 90% | 211 |
| | Fast Track | 16 | 32% | 69% | 244 |
| | RTOR | 2 | 4% | 100% | 137 |
| | Project Orbis | 3 | 6% | 100% | 154 |
| **PMDA** | Priority (referred to in this Briefing as Expedited) | 10 | 32% | | 190 |
| | Sakigake | 3 | 10% | 100% | 162 |
| | Conditional Early Approval | 2 | 6% | 100% | 190 |
| **Health Canada** | Priority (referred to in this Briefing as Expedited) | 11 | 33% | | 208 |
| | Conditional Approval (Notice of Compliance with Conditions) | 3 | 9% | 0% | 276 |
| | Access worksharing | 3 | 9% | 0% | 306 |
| | Project Orbis | 3 | 9% | 67% | 179 |
| **Swiss-medic** | Fast-Track (referred to in this Briefing as Expedited) | 7 | 19% | | 280 |
| | Procedure with prior notification | 4 | 11% | | 379 |
| | Conditional Approval | 6 | 17% | 0% | 570 |
| | Art.13 TPA | 2 | 6% | 0% | 370 |
| | Art.14 TPA | 1 | 3% | 0% | 527 |
| | Access worksharing | 1 | 3% | 0% | 295 |
| | Project Orbis | 1 | 3% | 0% | 122 |
| **TGA** | Priority (referred to in this Briefing as Expedited) | 5 | 19% | | 203 |
| | Provisional Approval (Conditional) | 5 | 19% | 0% | 322 |
| | Access worksharing | 4 | 15% | 0% | 273 |
| | Project Orbis | 2 | 7% | 50% | 210 |

*TGA introduced an expedited (priority) review and provisional approval programme in 2017. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.*

**The approval time for remdesivir varied from 3-148 days across the six agencies. To achieve this, agencies utilised various expedited pathways and other FRPs such as conditional, FDA fast track and the use of rolling review e.g. by EMA and FDA. See CIRS R&D Briefing 75 for an overview of Emergency Use Pathways available to agencies for use during public health emergencies.**

# Characteristics: Therapeutic area

Figure 9: NAS median approval time by top 5 therapeutic areas (TA) for six regulatory authorities between 2016-2020




*Therapy areas relate to the WHO ATC codes. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.*

**The top 5 TAs by number approved across all six agencies made up 77% (790/1023) of all approvals between 2016-2020, with anti-cancer and immunomodulators making up 49% (385) of the top 5 TAs approvals (Fig. 9).** Anti-infective therapies were approved marginally faster with an overall median of 296 days, compared with 340 days for anti-cancer and immunomodulators, 357 days for blood and blood forming organs, 365 days for nervous system and 365 days for alimentary and metabolism NASs. PMDA was fastest for 3/5 therapy areas whereas FDA was fastest for anti-cancer and immuno-modulators as well as blood and blood forming organs. Nevertheless, as noted by the 25th-75th percentile bars, there were also wide variations for certain jurisdictions across therapy areas. This may reflect the more frequent use of expedited review pathways by agencies across the 5 therapy areas (Fig. 10).

Remdesivir was one of the fastest anti-infective approvals across all the agencies. Analysis in the coming years might show the impact of COVID-19 on approval times across other therapeutic areas.

Figure 10: NAS overall median approval time by top 5 therapeutic areas in relation to expedited approvals for six regulatory authorities between 2016-2020

| © 2021 CIRS, R&D Briefing 81 | Alimentary and metabolism | | Blood and blood forming organs | | Anti-infective | | Anti-cancer and immuno-modulators | | Nervous system | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Approval time, days (proportion of expedited approvals) | | | | | | | | | |
| EMA | 427 | (19%) | 429 | (18%) | 404 | (14%) | 421 | (11%) | 432 | (17%) |
| FDA | 335 | (56%) | 243 | (60%) | 243 | (88%) | 226 | (79%) | 360 | (47%) |
| PMDA | 305 | (50%) | 335 | (27%) | 238 | (61%) | 304 | (56%) | 336 | (16%) |
| Health Canada | 388 | (28%) | 349 | (33%) | 276 | (44%) | 330 | (22%) | 345 | (38%) |
| Swissmedic | 529 | (0%) | 447 | (0%) | 466 | (31%) | 467 | (25%) | 500 | (11%) |
| TGA | 365 | (7%) | 369 | (17%) | 343 | (0%) | 349 | (10%) | 374 | (0%) |

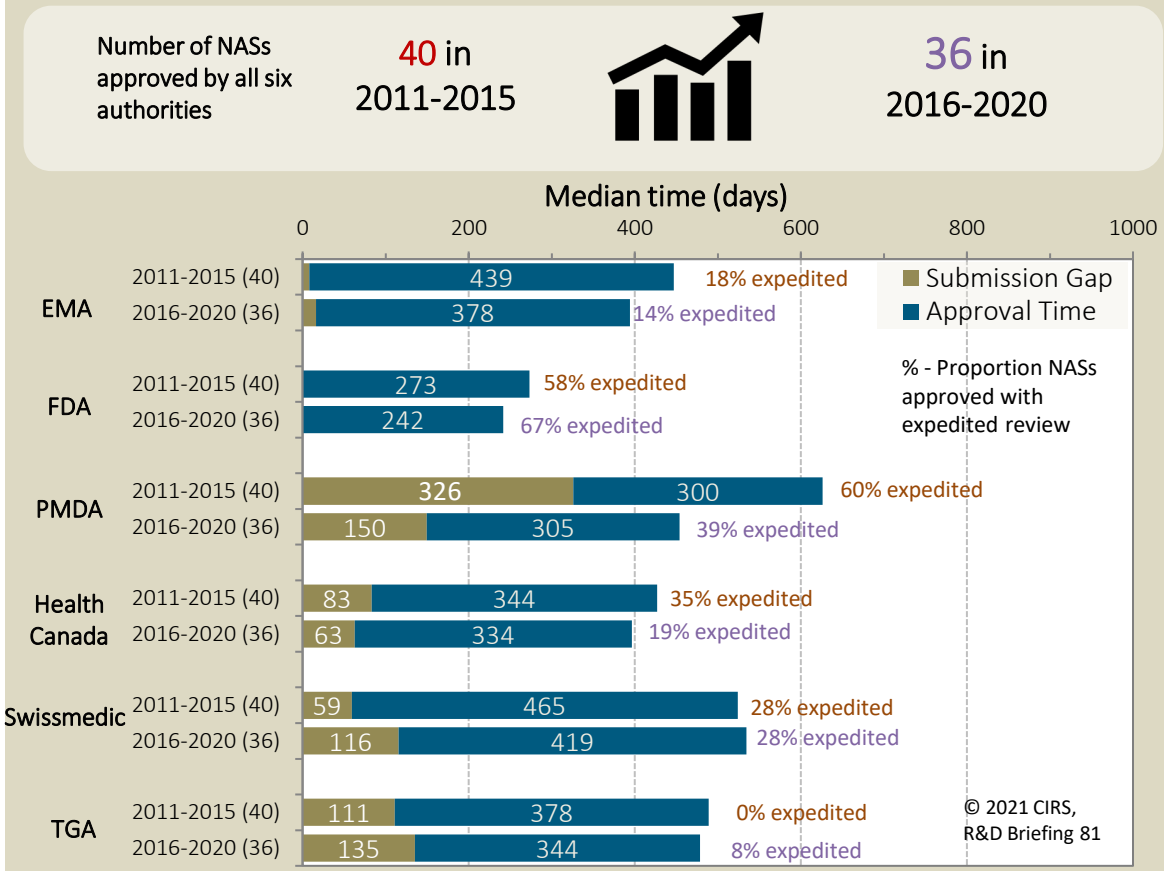
*Therapeutic areas relate to the WHO ATC codes. 'Expedited review' refers to EMA 'Accelerated Assessment', Swissmedic 'Fast Track' and FDA/PMDA/Health Canada/TGA 'Priority Review'. TGA introduced an expedited (priority) review programme in 2017, therefore the numbers in parentheses only relate to 2018, 2019 and 2020 approvals. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.*

# Common approvals: six regulatory agencies

**A true comparison of regulatory performance can be derived from studying the review of compounds that were approved by all six agencies. This comparison was carried out for two time cohorts in the last decade, namely 2011-2015 and 2016-2020, to determine whether any trends could be identified. The number of products approved by all six agencies in a five-year period decreased slightly from 40 NASs in 2011-2015 to 2016-2020 (36 NASs), compared to analyses in the past years where there was an increase (see R&D Briefing 70, 77), suggesting that the pace of internationalisation may be levelling off.** The overall length of time to registration, consisting of the submission gap and approval time (Fig. 11), may be a result of potential factors that impact registration of NASs. This may include company strategy to submit as well as the use of expedited pathways within agencies to address unmet medical needs with promising medicines. This Briefing, as in past Briefings, shows that there is no change in the waves of submission to agencies: first to EMA and FDA, then to Health Canada, Swissmedic and TGA, and then to PMDA. The quickest time to registration was at FDA for both cohorts, as a result of companies submitting there first and quick regulatory review times. Submissions to EMA occurred almost simultaneously with FDA, and the overall time to registration decreased for both EMA and FDA when comparing the two halves of the decade. For the other four agencies, the submission gap was generally similar for Health Canada and TGA, with a slight increase between the two time frames for Swissmedic. However, for PMDA the submission gap was reduced by 176 days between the two time frames. When looking across the agencies in terms of total time to approval from 1st submission to the 1st agency, the difference between the two cohorts show that for PMDA, this time has decreased, but for EMA, FDA, Health Canada, TGA and Swissmedic there were little differences in total time between the two cohorts.

COVID-19 may have an impact on the internationalisation of medicines in the coming years.

Figure 11: Median submission gap and median approval time for NASs approved by all six authorities in 2011-2015 (40) compared with 2016-2020 (35), as well as the proportion of NASs approved as expedited




*Submission gap is calculated as the time from date of submission at the first regulatory agency to the date of regulatory submission to the target agency. Expedited review' refers to EMA 'Accelerated Assessment', Swissmedic 'Fast Track' and FDA/PMDA/Health Canada/TGA 'Priority Review'. TGA introduced an expedited (priority) review programme in 2017, therefore the numbers for 2016-2020 only relate to 2018-2020 approvals. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.*

# Focus: Access Worksharing Consortium

**The Access Consortium is a medium-sized coalition, which was formed in 2007 by 'like-minded' regulatory authorities (Australia, Canada, Singapore, Switzerland and since Oct 2020, UK) to promote greater regulatory collaboration and alignment of regulatory requirements.** Its goal is to maximise international cooperation, reduce duplication, and increase each agency's capacity to ensure patients have timely access to high quality, safe and effective therapeutic products. As part of the worksharing process, the agencies review different parts of the dossier. Although the review is shared, each regulator makes an independent decision regarding approval (market authorisation) of the new medicine. This model of worksharing is being watched to see if this could be a model for other like-minded agencies to share resource both within and across regions and to streamline company interactions.

Figure 12: Characteristics of NASs approved by the Access Consortium in 2018-2020 © 2021 CIRS, R&D Briefing 81

**Out of the five agencies participating in Access, NAS review times were analysed for: Health Canada, Swissmedic and TGA**

**Between 2018-2020, 7 NAS** were approved, **5** of which are **anticancer and immunomodulators**

**6/7 NAS were reviewed as standard** by the agencies, whereas 1 was expedited (apalutamide)

**All 7 NAS** approved were from **top companies** (R&D spend > USD 3 bln in 2020)

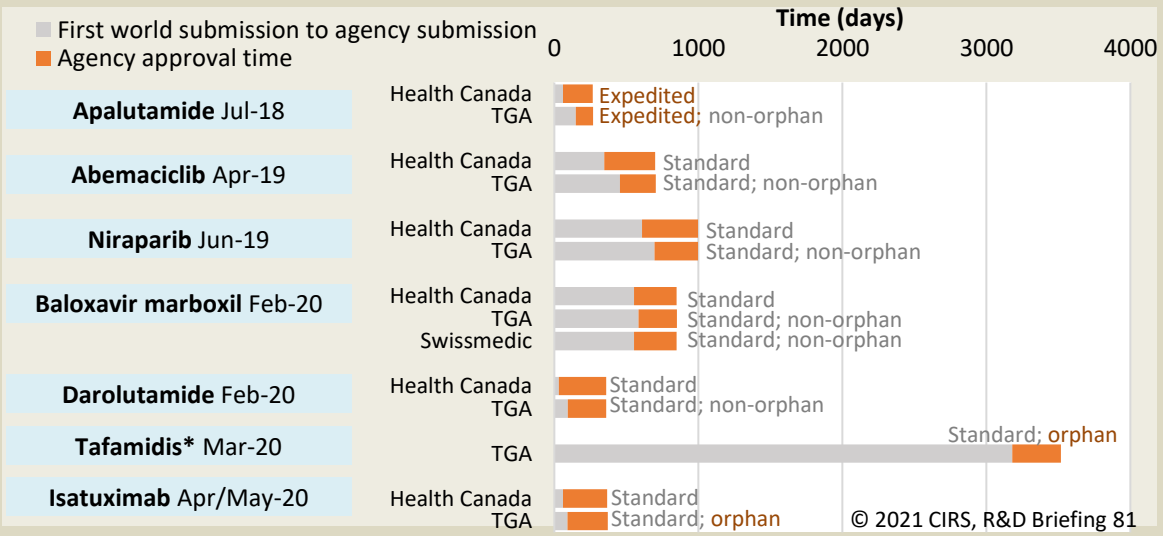
**Health Canada** median approval time for **6 NASs: 318 days**

**Swissmedic** median approval time for **1 NAS: 295 days**

**TGA** median approval time for **7 NASs: 266 days**

**NAS approvals were analysed across Health Canada, Swissmedic and/or TGA as part of the New Chemical Entities Work Sharing Initiative in 2018-2020, where 7 NASs were approved by one or more of the agencies (Fig. 12).** The initial collaboration for the three NASs approved in 2018-2019 was between Health Canada and TGA, but since 2020, the approvals have also included Swissmedic and HSA, Singapore (data not shown). Differences in median submission and approval times, can be accounted for by the pilot nature of the initiative in 2018-2019, where candidates were retrospectively identified by TGA and Health Canada based on common submissions that had already been received by both agencies. Since that time the process has been formalised and sponsors are now required to submit an expression of interest 3-6 months before their proposed submission. Applications should be submitted to each participating agency simultaneously, ideally within 15 calendar days. In the future, it is likely that there will be no submission gap, though some may remain due to differences in agency processes e.g. TGA pre-submission planning form occurring.

Figure 13: Submission lag and approval times for NASs approved by the Access Consortium between 2018-2020 (by month-year of approval)




*Submission gap is calculated as the time from date of submission at the first regulatory agency to the date of regulatory submission to the target agency. 'Expedited review' refers to Health Canada/TGA 'Priority Review' and Swissmedic 'Fast Track'. Health Canada does not currently have an orphan policy. Approval time is calculated from the date of submission to the date of approval by the agency. *Worksharing with HSA, Singapore (data not shown)*

## Focus: Project Orbis

**Project Orbis, an initiative of the FDA Oncology Center of Excellence (OCE), provides a framework for concurrent submission and review of oncology products among international partners.** This may allow patients with cancer to receive earlier access to products in other countries where there may be significant delays in regulatory submissions, regardless of whether the product has received FDA approval. With a framework for concurrent submission and review of oncology drugs, Project Orbis facilitates a collaborative review to identify any regulatory divergence across review teams. The project is coordinated by the FDA, and similarly to Access involves TGA, Health Canada, MHRA, HSA, Swissmedic with the addition of ANVISA, which does not currently participate in the Access Consortium.

Figure 14: Project Orbis; Characteristics of NASs approved in 2020



**Out of the six agencies participating in Orbis, NAS review times were analysed for: FDA, Swissmedic, Health Canada and TGA**

**In 2020, 3 NAS** were approved, **all** of which are a**nticancer and immunomodulators**

**1/3 NAS were reviewed as expedited by all three agencies; for other NASs it varied by agency, as did the Orphan status (see Fig. 15)**

**All 3 NAS** approved were from **non-top companies** (R&D spend < USD 3 bln in 2020)

**FDA** median approval time for **3 NASs: 154 days**

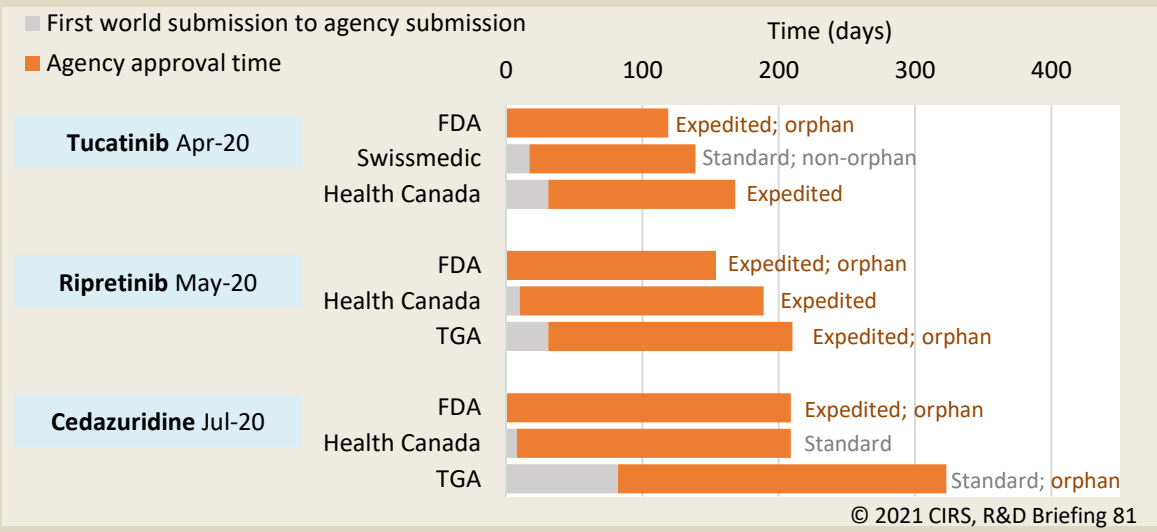
**Health Canada** median approval time for **3 NASs: 179 days**

**Swissmedic** median approval time for **1 NAS: 122 days**

**TGA** median approval time for **2 NASs: 210 days**

**In 2020, 3 NASs were approved through Project Orbis by FDA, Health Canada and TGA (Fig. 15)**. The initial collaboration for the first NAS approved was between FDA, Swissmedic and Health Canada, whereas for the other two between FDA, Health Canada and TGA. Interestingly, the NASs differed in terms of the orphan designation as well as the type of review undertaken (expedited vs. standard), which highlights differences in agency criteria to obtain expedited review or orphan designation, processes available (Health Canada does not currently have an orphan policy) as well as company strategy to apply for the pathway or designation. Project Orbis has demonstrated that global regulatory collaboration is attainable and can deliver faster access to new therapies for patients with cancer. Furthermore, it could facilitate the development of therapies more broadly, especially in settings where global collaboration would be critically important to public health, such as the ongoing COVID-19 pandemic.

Figure 15: Project Orbis; submission lag and approval times for NASs approved in 2020 (by month-year of approval by FDA)






*Submission gap is calculated as the time from date of submission at the first regulatory agency to the date of regulatory submission to the target agency. 'Expedited review' refers to FDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast Track'. Health Canada does not currently have an orphan policy. Approval time is calculated from the date of submission to the date of approval by the agency.*

## Summary of NAS approved in 2020 by the 6 agencies

This table summarises approval times for NAS approved in 2020 by the 6 agencies, broken down by product type, review type and major therapeutic area.

| Agency median time in calendar days | EMA  p.12 | FDA  p.13 | PMDA  p.14 | Health Canada  p.15 | Swissmedic  p.16 | TGA  p.17 |
|---|---|---|---|---|---|---|
| **Number of NAS approved** | 35 | 50 | 31 | 33 | 36 | 27 |
| **NAS overall Approval time (days)** | 426 | 244 | 313 | 306 | 470 | 315 |
| **By Biologics (days)** | 405 | 244 | 311 | 306 | 303 | 315 |
| **By Chemicals (days)** | 431 | 244 | 318 | 310 | 490 | 301 |
| **By Standard review (days)** | 431 | 365 | 335 | 344 | 490 | 330 |
| **By Expedited review (days)** | 248 | 226 | 190 | 208 | 280 | 203 |
| **By Orphans (days)** | 425 | 234 | 200 | 276* | 280 | 255 |
| **By Anticancer and Immuno-modulators (days)** | 428 | 212 | 273 | 318 | 467 | 311 |

** Health Canada does not have an orphan policy; however, 19 NASs that were classified as orphan by either FDA, EMA or TGA were approved by Health Canada in 2020, with a median approval time of 276 days.*

# Approval at EMA 2020



EMA **APPROVED A TOTAL OF 35 NASs IN 2020,** WITH A MEDIAN APPROVAL TIME OF **426 DAYS (TIME TO END OF SCIENTIFIC ASSESSMENT: 370 DAYS)**

THE MEDIAN EU COMMISSION TIME WAS 57 DAYS, THE AGENCY TIME 240 DAYS AND COMPANY TIME 128 DAYS

## Type of Medicine

**11 BIOLOGIC NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **405 DAYS**

**24 CHEMICAL NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **431 DAYS**

**13 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **428 DAYS**

**22 NASs IN OTHER THERAPY AREAS APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **426 DAYS**

## Designation and Review Type

**3 EXPEDITED NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **248 DAYS;** THIS IS **183 DAYS FASTER** THAN THE MEDIAN OF THE **32 STANDARD NAS APPROVALS IN 2020**

**16 ORPHAN NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **425 DAYS;** THIS IS **9 DAYS FASTER** THAN THE MEDIAN OF THE **19 NON-ORPHAN NAS APPROVALS IN 2020**

## Availability by EMA

**23% OF THE NASs APPROVED IN 2020 BY EMA** WERE APPROVED BY EMA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY FDA, PMDA, HEALTH CANADA , SWISSMEDIC OR TGA**

**77% OF THE NASs APPROVED IN 2020 BY EMA** WERE APPROVED BY FDA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY EMA**

THE MEDIAN **SUBMISSION GAP** TO EMA FOR THESE NASs WAS **24 DAYS**

EMA approval time includes the EU Commission time.
'Expedited review' refers to EMA 'Accelerated Assessment.
Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

# Approval at FDA 2020



FDA (CDER AND CBER) **APPROVED A TOTAL OF 50 NASs IN 2020,** WITH A MEDIAN APPROVAL TIME OF **244 DAYS**

**FOR THE NASs APPROVED 94% WERE 1-CYCLE REVIEWS, 6% 2-CYCLE REVIEWS**

## Type of Medicine

**15 BIOLOGIC NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **244 DAYS**

**35 CHEMICAL NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **244 DAYS**

**22 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **212 DAYS**

**28 NASs IN OTHER THERAPY AREAS APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **327 DAYS**

## Designation and Review Type

**31 EXPEDITED NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **226 DAYS;** THIS IS **139 DAYS FASTER** THAN THE MEDIAN OF THE **19 STANDARD NAS APPROVALS IN 2020**

**31 ORPHAN NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **234 DAYS;** THIS IS **131 DAYS FASTER** THAN THE MEDIAN OF THE **19 NON-ORPHAN NAS APPROVALS IN 2020**

## Availability by FDA

**86% OF THE NASs APPROVED IN 2020 BY FDA** WERE APPROVED BY FDA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY EMA, PMDA, HEALTH CANADA , SWISSMEDIC OR TGA**

**14% OF THE NASs APPROVED IN 2020 BY FDA** WERE APPROVED BY EMA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY FDA**

THE MEDIAN **SUBMISSION GAP** TO FDA FOR THESE NASs WAS **118 DAYS**

'Expedited review' refers to FDA 'Priority Review'.
Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

# Approval at PMDA 2020



PMDA **APPROVED A TOTAL OF 31 NASs IN 2020,** WITH A MEDIAN APPROVAL TIME OF **313 DAYS (TIME TO END OF SCIENTIFIC ASSESSMENT: 272 DAYS)**

## Type of Medicine

**5 BIOLOGIC NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **311 DAYS**

**26 CHEMICAL NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **318 DAYS**

**14 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **273 DAYS**

**17 NASs IN OTHER THERAPY AREAS APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **322 DAYS**

## Designation and Review Type

**10 EXPEDITED NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **190 DAYS;** THIS IS **145 DAYS FASTER** THAN THE MEDIAN OF THE **21 STANDARD NAS APPROVALS IN 2020**

**7 ORPHAN NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **200 DAYS;** THIS IS **128 DAYS FASTER** THAN THE MEDIAN OF THE **24 NON-ORPHAN NAS APPROVALS IN 2020**

## Availability by PMDA

**45% OF THE NASs APPROVED IN 2020 BY PMDA** WERE APPROVED BY PMDA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY EMA, FDA, HEALTH CANADA , SWISSMEDIC OR TGA**

**55% OF THE NASs APPROVED IN 2020 BY PMDA** WERE APPROVED BY EMA, FDA, HEALTH CANADA, SWISSMEDIC OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY PMDA**

THE MEDIAN **SUBMISSION GAP** TO PMDA FOR THESE NASs WAS **689 DAYS**

'Expedited review' refers to PMDA 'Priority Review'.
Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

# Approval at Health Canada 2020



HEALTH CANADA **APPROVED A TOTAL OF 33 NASs IN 2020,** WITH A MEDIAN APPROVAL TIME OF **306 DAYS (TIME TO END OF SCIENTIFIC ASSESSMENT: 305 DAYS)**

## Type of Medicine

**11 BIOLOGIC NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **306 DAYS**

**22 CHEMICAL NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **310 DAYS**

**14 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **318 DAYS**

**19 NASs IN OTHER THERAPY AREAS APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **295 DAYS**

## Designation and Review Type

**11 EXPEDITED NAS APPROVALS IN 2020** WITH A MEDIAN APPROVAL TIME OF **208 DAYS;** THIS IS **136 DAYS FASTER** THAN THE MEDIAN OF THE **22 STANDARD NAS APPROVALS IN 2020**

HEALTH CANADA DOES NOT HAVE AN ORPHAN POLICY; HOWEVER, **19 NASs THAT WERE CLASSIFIED AS ORPHAN BY EITHER FDA, EMA OR TGA WERE APPROVED BY HEALTH CANADA IN 2020,** WITH A MEDIAN APPROVAL TIME OF **276 DAYS**

## Availability by Health Canada

**9% OF THE NASs APPROVED IN 2020 BY HEALTH CANADA** WERE APPROVED BY HEALTH CANADA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY EMA, FDA, PMDA, SWISSMEDIC OR TGA**

**91% OF THE NASs APPROVED IN 2020 BY HEALTH CANADA** WERE APPROVED BY EMA, FDA, PMDA, SWISSMEDIC OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY HEALTH CANADA**

THE MEDIAN **SUBMISSION GAP** TO HEALTH CANADA FOR THESE NASs WAS **307 DAYS**

'Expedited review' refers to Health Canada 'Priority Review'.
Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

# Approval at Swissmedic 2020



SWISSMEDIC **APPROVED A TOTAL OF 36 NASs IN 2020** ,WITH A MEDIAN APPROVAL TIME OF **470 DAYS (TIME TO SCIENTIFIC ASSESSMENT: 297 DAYS)**

## Type of Medicine

**10 BIOLOGIC NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **303 DAYS**

**26 CHEMICAL NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **490 DAYS**

**17 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **467 DAYS**

**19 NASs IN OTHER THERAPY AREAS APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **472 DAYS**

## Designation and Review Type

**7 EXPEDITED NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **280 DAYS;** THIS IS **210 DAYS FASTER** THAN THE MEDIAN OF THE **29 STANDARD NAS APPROVALS IN 2020**

**7 ORPHAN NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **280 DAYS;** THIS IS **210 DAYS FASTER** THAN THE MEDIAN OF THE **29 NON-ORPHAN NAS APPROVALS IN 2020**

## Availability by Swissmedic

**8% OF THE NASs APPROVED IN 2020 BY SWISSMEDIC** WERE APPROVED BY SWISSMEDIC **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY FDA, EMA, PMDA, HEALTH CANADA OR TGA**

**92% OF THE NASs APPROVED IN 2020 BY SWISSMEDIC** WERE APPROVED BY FDA, EMA, PMDA, HEALTH CANADA OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY SWISSMEDIC**

THE MEDIAN **SUBMISSION GAP** TO SWISSMEDIC FOR THESE NASs WAS **270 DAYS**

'Expedited review' refers to Swissmedic 'Fast-Track procedure'.
Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

# Approval at TGA 2020



TGA **APPROVED A TOTAL OF 27 NASs IN 2020**, WITH A MEDIAN APPROVAL TIME OF **315 DAYS**

## Type of Medicine

**5 BIOLOGIC NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **315 DAYS**

**22 CHEMICAL NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **301 DAYS**

**16 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **311 DAYS**

**11 NASs IN OTHER THERAPY AREAS APPROVED IN 2020,** WITH A MEDIAN APPROVAL TIME OF **315 DAYS**

## Designation and Review Type

**5 EXPEDITED NAS APPROVALS IN 2020** WITH A MEDIAN APPROVAL TIME OF **203 DAYS;** THIS IS **127 DAYS FASTER** THAN THE MEDIAN OF THE **22 STANDARD NAS APPROVALS IN 2020**

**12 ORPHAN NAS APPROVALS IN 2020,** WITH A MEDIAN APPROVAL TIME OF **255 DAYS;** THIS IS **67 DAYS FASTER** THAN THE MEDIAN OF THE **15 NON-ORPHAN NAS APPROVALS IN 2020**

## Availability in TGA

**4% OF THE NASs APPROVED IN 2020 BY TGA** WERE APPROVED BY TGA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY FDA, EMA, PMDA, HEALTH CANADA OR SWISSMEDIC**

**96% OF THE NASs APPROVED IN 2020 BY TGA** WERE APPROVED BY FDA, EMA, PMDA, HEALTH CANADA OR SWISSMEDIC **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY TGA**

THE MEDIAN **SUBMISSION GAP** TO TGA FOR THESE NASs WAS **484 DAYS**

'Expedited review' refers to TGA 'Priority Review' introduced in 2017.
Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

# Definitions: Facilitated Regulatory Pathways

| | What is it? | Advantage |
|---|---|---|
| **FDA Priority Review** | A process that directs resources to the evaluation of drugs that represent significant improvements in safety or effectiveness compared with standard applications | • Review time shortened from 10 to 6 months |
| **FDA Accelerated Approval** | Regulation allowing drugs for serious conditions that fulfil an unmet medical need to be approved based on a surrogate endpoint | • Conditional approval granted using surrogate endpoint(s) from phase 2 trials or interim phase 3 data; confirmatory trials with hard clinical endpoints required |
| **FDA Fast Track** | A process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fulfil an unmet medical need | • More frequent meetings with FDA to discuss drug development plan<br>• More frequent communication on clinical trials design<br>• Option for rolling data submission |
| **FDA Breakthrough Therapy** | A process designed to expedite the development and review of drugs that may demonstrate substantial improvement over available therapy | • All Fast Track designation features<br>• Intensive guidance on an efficient drug development program from phase 1<br>• Organisational commitment with senior managers<br>• Option for priority review |
| **Real-Time Oncology Review** | A program launched by the FDA Oncology Center of Excellence (OCE), it allows FDA to access and review key data ahead of time, prior to official submission | • RTOR allows the FDA to review much of the data earlier, before the applicant formally submits the complete application. |
| **EMA Accelerated Assessment** | A process designed to expedite products of major interest in terms of public health and therapeutic innovation | • CHMP opinion shortened from 210 days to 150 days |
| **EMA Conditional Approval** | Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved with limited clinical safety or efficacy data, provided a positive benefit-risk balance | • Conditional approval is granted before all data are available (valid for one year, on a renewable basis; once pending studies are provided, it can become a "normal" marketing authorisation) |
| **EMA Exceptional Circum-stances** | Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved without comprehensive efficacy and safety data | • Conditional approval is granted before all data are available (reviewed annually to re-assess the risk-benefit balance) |
| **EMA PRIME (Priority Medicines)** | A scheme to enhance support for the development of medicines that target an unmet medical need. It is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development and speed evaluation. | • Early dialogue with EMA (appointed rapporteur)<br>• Provision of scientific advice, involving additional stakeholders (e.g. HTA)<br>• Dedicated point of contact from EMA<br>• Option of Accelerated Assessment |
| **PMDA Priority Review** | A process that provides faster access to new therapies responding to high medical needs; includes products such as orphans, HIV medicines | • Review time shortened from 9 to 6 months |
| **PMDA Conditional Early Approval** | A system to put highly useful and effective drugs for treating serious diseases into practical use as early as possible | • Early application through confirmation of a certain degree of efficacy and safety<br>• Shorten overall review times for priority review products |
| **PMDA Sakigake (pioneer)** | A system to put highly useful and effective drugs for treating serious diseases into practical use as early as possible | • All Priority Review designation features<br>• Prioritised clinical trial and pre-application consultation<br>• Assigned PMDA manager as a concierge<br>• Post-marketing safety measures |

# Definitions Facilitated Regulatory Pathways

| | What is it? | Advantage |
|---|---|---|
| **Health Canada Priority** | A fast-track status for medicines for severe, debilitating or life-threatening disease; to address unmet medical need and where a high therapeutic benefit can be expected | • Review time shortened from 300 to 180 days |
| **Health Canada Conditional (NOC/c)** | Authorisation to market a new promising drug with the condition that the sponsor undertakes additional studies to verify the clinical benefit | • Earlier marketing of promising drugs for serious conditions before the drugs have definitively demonstrated clinical efficacy |
| **Swissmedic Fast-Track** | A rapid review of applications for severe, debilitating or life-threatening disease; to address unmet medical need and where a high therapeutic benefit can be expected | • Review time shortened from 330 to 140 days |
| **Swissmedic Prior Notification** | A process to enable applicants to notify their submission date at an early stage, so that Swissmedic can draw up a streamlined and precise schedule for the review | • 20% faster processing time and fixed planning offered by this procedure are subject to a fee surcharge of 100% |
| **Art.13 TPA** | A process to authorise medicinal products that have already been approved in a country with a comparable medicinal product control system, taking account of the results of the trials conducted for this purpose provided that some requirements are satisfied | • In justified cases Swissmedic may reduce the scale of scientific assessments, either on request or ex officio, based on the result of the corresponding assessment by the foreign authority (e.g. USA FDA or EMA) |
| **Art.14 TPA** | An authorisation procedure for medicinal products with active substances that has been authorised in an EU or EFTA country for at least 10 years | • A simplified procedure where a review of original clinical documentation is generally only admissible for bioequivalence studies, e.g. where the pharmaceutical forms differ |
| **TGA Priority** | A formal mechanism for faster assessment of vital and life-saving medicines for severe, debilitating or life-threatening disease, to address unmet medical need and where a high therapeutic benefit can be expected | • Review time shortened from 220 to 150 working days<br>• Dynamic process with rolling questions and more flexible arrangements for accessing advice |
| **TGA Provisional Approval** | Time-limited provisional registration for certain promising new medicines where the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data are still required | • Conditional approval is granted based on preliminary clinical data (valid for a maximum of 6 years) |
| **Access Worksharing** | Medium-sized coalition to promote greater regulatory collaboration and alignment of regulatory requirements between Australia-Canada-Singapore-Switzerland-UK | • Maximises international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products.<br>• Maximises the use of up-to-date technical expertise, and ensures a consistent, contemporary approach to assessing the benefits and risks associated with the use of therapeutic products |
| **Project Orbis** | An initiative of the FDA Oncology Center of Excellence (OCE), provides a framework for concurrent submission and review of oncology products among international partners – Australia-Brazil-Canada-Singapore-Switzerland-UK-US | |

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

### Biological/Biotechnology product
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.

### Chemical entity
An entity produced by chemical synthesis.

### Expedited review
Refers to EMA 'Accelerated Assessment' and FDA/PMDA/Health Canada/Swissmedic/TGA 'Priority Review'.

### Facilitated regulatory pathway
Regulatory pathway designed to facilitate availability, review and/or approval of medicines where there is an unmet medical need by providing alternatives to standard regulatory review routes.

### New active substances (NASs)*
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 through changes to the 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
- Biosimilars
- 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).

### Submission gap
Date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

### Time from submission to the end of Scientific Assessment

Time from submission to the end of Scientific Assessment has been defined as follows for the 6 agencies. It includes agency and company time and is calculated as time from acceptance of the submission for evaluation submission until:

• EMA: The CHMP issues an opinion for granting a marketing authorisation. Excluded is the time from CHMP opinion to final decision by the European Commission.

• FDA: The FDA action letter to approve is signed (FDA action date). This is equivalent to the regulatory approval, and therefore for FDA, time from acceptance of submission to end scientific assessment and time from acceptance of submission to approval are the same.

• PMDA: The First/Second Committee on New Drugs' meeting, when it is concluded that a marketing authorisation can be granted. Excluded is the time from New Drugs meeting to MHLW final decision.

Continued: see next page

*The full list of NASs approved by each jurisdiction in 2020 is available on the CIRS website.

• Health Canada: The last review stream is completed and the outcome letter is sent. Excluded is further time to ensure the information on file is complete and properly filed, generate drug identification numbers, prepare an executive summary and prepare the Notice of Compliance (NOC) package for routing and sign off as well as time to check that requirements are met with respect to the Patented Medicines (NOC) Regulations and the data protection provisions .

• Swissmedic: The advisory committee review and decision is made and the outcome letter (preliminary decision) is sent. Excluded is the negotiation time with the sponsor regarding the label following the end of the scientific review.

• TGA: The delegate decision is made and the decision (outcome letter) is sent to the sponsor. This is equivalent to the regulatory approval, and therefore for TGA, time from acceptance of submission to end scientific assessment and time from acceptance of submission to approval are the same.

### Top company

Pharmaceutical company with R&D spending >3 billion USD in 2020.

### 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
- B – Blood and blood forming organs: antithrombotic agents, antihemorrhagics, antianemic preparations, blood substitutes and perfusion solutions, other hematological 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.

# R&D Briefing 81

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**About CIRS**

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

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