REGULATORY FOCUS

China Regulatory Reform: An Update on Review Timelines and Drug Lag

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This article provides three case studies with an assessment of the impact of the regulatory changes and insight into the importance of including China in a global strategy for clinical development and drug registration.

Introduction

China has implemented a series of regulatory changes and improvements through a comprehensive regulatory reform starting in August 2015. The largely shortened new drug review timeline provides one of the biggest impacts for the pharmaceutical industry. This article analyses 2017 new drug approvals for imported drugs in China comparing Investigational New Drug (IND) and New Drug Application (NDA) approval timelines for procedures started before the regulatory reform and after. Furthermore, the current drug lag for approvals in China (time gap between approval in China and approvals from US Food and Drug Administration (FDA) and European Medicines Agency (EMA) is determined. Three case studies provide an assessment of the impact of the regulatory changes and insight into the importance of including China in a global strategy for clinical development and drug registration.

Background

Major regulatory reform in China started in August 2015 with the backing of the China State Council.{1} The chief targets include improving the drug review process and shortening IND and NDA review timelines, encouraging new drug innovation, eliminating the existing backlog of registration applications and minimizing the drug lag. Drug lag is defined as the time it takes to have a new drug approved in a certain country after it has been approved by other jurisdictions. Drug lag, particularly in emerging markets, has long

been observed and is a major source of concern in respect to the availability of new therapies.{2,3} This article presents an analysis of the progress resulting from the regulatory reform in China for drug approval timelines.

Some actions taken by the China Food and Drug Administration (CFDA) and the Center for Drug Evaluation (CDE) already have shown a positive effect:

- Increase in drug review capacity in CDE: in 2015, around 70 reviewers were tasked with processing more than 7,000 drug applications that were received annually at the CDE. Through recent hiring activity, 600 drug reviewers were added by the end of 2016,{4} and there were more than 800 reviewers employed by CDE by the end of 2017, with more hiring planned for 2018.
- Priority review process in place since February 2016:{5} this newly installed review process helps encourage local and international new drug innovation to meet unmet medical needs. It also incentivizes overseas sponsors to plan and perform clinical development in China in parallel with the US, European Union (EU) and other countries. This is already effective, and the authors observe that the current IND and NDA review timelines are within six months for priority-reviewed projects, compared to a timeline of up to one to two years before the regulatory reform began in 2015.
- Clinical trial startup process changes: the CFDA proposed big changes to the startup process, although they are not effective yet. Some industry experts estimate it would become effective in the first quarter of 2018. The Ethics Committee (EC) submission for clinical trial approval is proposed to be conducted prior to IND submission to CFDA. The IND review timeline would be reduced to 60 days. Approval using the new process would implement silent approval. If CDE/CFDA issues no queries within 60 days (around two months) from submission, the application is regarded as approved. This proposed new startup process promises to be another significant improvement in the drug review timeline and is likely to encourage more drug development in China through shorter lead times.

IND and NDA Approval Timelines

The two tables below summarize the IND (**Table 1**) and NDA (**Table 2**) timelines for imported drugs approved by CFDA in 2017. **Table 2** also compares the time difference between CFDA approval and approval by FDA or EMA to determine drug lag and the effects of the reforms on the drug lag.

Table 1: Approval Timelines for Chinese INDs for Products Approved in China in 2017

Applicant	Product Name/ Strength	Application #	IND Submission Date	IND Approval Date	IND Timeline (Months)
Pfizer Manufacturing Deutschland GmbH	Tofacitinib citrate tablets	JXHL1400280	1 Sep 2014	12 Jan 2016	16.5
		JXHL1400229	11 Jul 2014	13 Oct 2015	15
		JXHL1300232	5 Jul 2011	2 Mar 2015	44
		JXHL1300046	18 Feb 2013	23 Nov 2015	33
		JXHL1200357	19 Nov 2012	4 Jul 2013	7.5
Celgene Europe Ltd	Azacitidine for injection	JXHL1500306	11 Dec 2015	In review	
		JXHL1500257	13 Oct 2015	15 Dec 2017	26
		JXHL1000071	1 Mar 2010	25 Nov 2010	9
		JXHL0900448	7 Jan 2010	15 Nov 2011	23
AbbVie Ltd	Adalimumab solution for injection	JXSL1600075*	28 Dec 2016*	20 Dec 2017*	12*
		JXSL1500008	14 Apr 2015	8 Aug 2016	16
Boehringer Ingelheim International GmbH	Dabigatran etexilate capsules	JXHL1400314	4 Jul 2014	29 Feb 2016	19.5
		JXHL1400225	4 Jul 2014	13 Oct 2015	15
Novo Nordisk A/S	Insulin degludec injection	JXSL1300028	17 Apr 2013	7 Aug 2015	27.5
Allergan Pharmaceuticals Ireland	Dexamethasone intravitreal implant	JXHL1200118	2 May 2012	25 Jan 2013	9
		JXHL1000059	12 Apr 2010	5 Jun 2012	26
Teva Pharmaceutical Industries Ltd	Rasagiline mesylate tablets	JXHL1000135	5 May 2010	27 Jul 2011	14.5
Bayer Pharma AG	Riociguat tablets	JXHL1400088	26 Mar 2014	12 Jan 2016	21.5

Actelion Pharmaceuticals Ltd	Macitentan tablets	JXHL1700023*	6 Mar 2017*	20 Sep 2017*	6.5*
		JXHL1400220	18 Jul 2014	6 Sep 2016	25.5
Novartis Pharma Schweiz AG	Sacubitril valsartan sodium tablets	JXHL1500271	28 Oct 2015	27 Sep 2016	11
MSD Ltd	Sugammadex sodium injection	JXHL1100467	28 Dec 2011	18 Sep 2015	45
Pharmacyclics LLC	Ibrutinib capsules	JXHL1700019*	15 Feb 2017*	8 Nov 2017*	9*
		JXHL1300519	9 Jan 2014	28 Oct 2016	33.5
Bayer Pharma AG	Regorafenib tablets	JXHL1700083*	20 Apr 2017*	29 Aug 2017*	4.5*
		JXHL1400377	25 Nov 2014	3 Dec 2015	12
		JXHL1300096	29 Mar 2013	17 Jun 2014	14.5
Novartis Europharm Ltd	Ruxolitinib phosphate tablets	JXHL1600052	14 Apr 2016	8 Nov 2016	7
BMS (Singapore) PTE Ltd	Asunaprevir soft capsules	JXHL1600016	4 Feb 2016	31 Oct 2016	9
Gilead Sciences International Ltd.	Sofosbuvir tablets	JXHL1500329	8 Jan 2016	13 Apr 2017	15
		JXHL1500145	23 Jun 2015	18 Oct 2016	16
Janssen-Cilag International NV	Simeprevir capsules	JXHL1500151	8 Jul 2015	28 Oct 2016	15.5
BMS (Singapore) PTE. Ltd	Daclatasvir hydrochloride tablets	JXHL1600015	4 Feb 2016	31 Oct 2016	9
AbbVie AG	Ombitasvir, paritaprevir and ritonavir tablets	JXHL1600143*	15 Dec 2016*	11 Oct 2017*	11*
		JXHL1500313	16 Dec 2015	29 Sep 2016	9.5

All the data in **Table 1** are sourced from CFDA database.{6}
*Approvals for IND submissions after December 2016

For foreign-imported products approved in 2017, the IND submission and approval dates are listed. The time required for approval is listed in the last column. Almost all the above mentioned foreign-developed drug clinical trial IND submissions and approvals were performed around 2010-2016 (i.e., before the impact of the China regulatory reform could be seen). At the time, CDE drug reviewer resources were limited and no priority review process was in place. Therefore, it took a long time (15 - 40 months) to receive IND approval. Approvals for INDs submitted before December 2016 took an average of 18.5 months, while approvals for IND submissions after December 2016 (indicated by * in **Table 1**) took an average of only 8.6 months. The data for submissions since the regulatory reform took effect is still limited at this stage, but current IND approval timelines for the chemical drug priority review process would be within six months.

Table 2: NDA Approval Timelines and Drug lag of Products Approved in China in 2017 Compared to Approvals in the US and EU

Applicant	Product Name	NDA Submission Date	NDA Approval Date	NDA Timeline Month	Date of Approval in the US	Date of Approval in the EU	Drug Lag (Months) US/EU
Boehringer Ingelheim International GmbH	Dabigatran etexilate capsules 110mg,150mg	8 Mar 2016	10 Mar 2017	12	75, 110, 150mg – Priority – 19 Oct 2010	75, 110, 150mg - 18 Mar 2008	77/108
Pfizer Manufacturing Deutschland GmbH	Tofacitinib citrate tablets 5mg	29 Dec 2015	14 Mar 2017	14.5	5mg – 6 Nov 2011 11mg Extended Release – 23 Feb 2016	5 mg - 22 Mar 2017	64/0
Roche Pharma (Schweiz) AG	Vemurafenib film-coated tablets 240mg	6 Apr 2016	17 Mar 2017	11.5	240mg – Priority/ Orphan – 17 Aug 2011	240 mg – 17 Feb 2012	67/61
Novartis Europharm Ltd	Ruxolitinib phosphate tablets 5, 10, 15, 20, 25mg	11 Nov 2015	20 Mar 2017	16.5	5, 10, 15, 20, 25mg – priority/orphan – 16 Nov 2011	5, 10, 15, 20mg – 23 Aug 2012	65/55

Celgene Europe Ltd	Azacitidine for injection 100mg	23 Dec 2014	4 May 2017	28	100mg – Priority Orphan – 19 May 2004 – also approved as 1/2mg vial by BMS in 1986	Orphan - 17 Dec 2008	156/100.5
MSD Ltd	Sugammadex sodium injection 200mg/2ml, 500mg/5ml	3 Mar 2016	4 May 2017	14	100mg/ml – priority – 15 Dec 2015	100mg/ml – 25 Jul 2008	17.5/106
AbbVie Ltd	Adalimumab solution for injection 40mg/0.8ml	3 Jun 2014	19 May 2017	35	40mg – Orphan – 31 Dec 2002 + two biosimilars available	8 Sep 2003	173/164
Teva Pharmaceutical Industries Ltd	Rasagiline mesylate tablets 1mg	6 Jan 2014	26 Jun 2017	41.5	0.5/1mg – 16 May 2005	1mg – 21 Feb 2005	145/148
Bayer Pharma AG	Riociguat tablets 0.5, 1, 1.5, 2, 2.5mg	29 Mar 2016	26 Sep 2017	18	0.5, 1, 1.5, 2, 2.5mg – orphan – 8 Oct 2013	0.5, 1, 1.5, 2, 2.5mg – orphan – 27 Mar 2014	48/42
Novo Nordisk A/S	Insulin degludec injection 300units/3ml	22 Sep 2015	27 Sep 2017	24	100/200 units/ml – 25 Sep 2015	100, 200 units/ml - 21 Jan 2013	24/56
Allergan Pharmaceuticals Ireland	Dexamethasone intravitreal implant 0.7mg	2 Jun 2016	26 Oct 2017	17	0.7mg – priority – 17 Jun 2009	0.7mg – 27 Jul 2010	100/87
Bayer Pharma AG	Regorafenib tablets 40mg	22 Sep 2017 for HCC	11 Dec 2017 for HCC	3	27 Apr 2017 for HCC	2 Aug 2017 for HCC	7/4
Note: the entries above (in Table 2) indicate approvals with NDA filings before the reform took place, while those below include NDAs filed after the reform took place.							
AstraZeneca AB	Osimertinib mesylate tablets 40mg, 80mg	25 Jan 2017	24 Mar 2017	2	40/80mg – Priority/ Orphan – 13 Nov 2015	40, 80 mg – 2 Feb 2016	16.5/13.5
BMS (Singapore) PTE. Ltd	Daclatasvir hydrochloride tablets 60mg	10 Nov 2016	27 Apr 2017	5.5	30, 60, 90mg – priority – 24 Jul 2015	30, 60, 90mg – 22 Aug 2014	21/32
Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations)	Dolutegravir sodium, abacavir sulfate and lamivudine tablets 50mg+ 600mg+ 300mg	19 Jan 2017	1 Aug 2017	6.5	VIIV Healthcare – 600mg – 22 Aug 2014	1 Sep 2014	35/34.5
Pharmacyclics LLC	Ibrutinib capsules 140mg	4 Nov 2016	28 Aug 2017	9.5	140mg – priority/ orphan – 13 Nov 2013	140mg – orphan – 21 Oct 2014	45.5/34
Janssen-Cilag International NV	Simeprevir capsules 150mg	7 Nov 2016	28 Aug 2017	9.5	150mg – priority – 22 Nov 2013	150mg – 14 May 2014	45/39.5
AbbVie AG	Ombitasvir, paritaprevir and ritonavir tablets 12.5mg+ 50mg+ 75mg	21 Mar 2017	22 Sep 2017	6	12.5 + 50 + 75mg – priority – 24 Jul 2015	12.5 + 50 + 75mg – 15 Jan 2015	26/32
Gilead Sciences International Ltd	Sofosbuvir tablets 400mg	13 Mar 2017	25 Sep 2017	6.5	400mg – priority – 6 Dec 2013	400mg – 16 Jan 2014	46.5/44
Boehringer Ingelheim International GmbH	Nintedanib esilate soft capsules 100mg, 150mg	17 Apr 2017	26 Sep 2017	5.5	100mg – Priority/Orphan 15 Oct 2014	100, 150 mg – 21 Nov 2014	35.5/34.5
Novartis Pharma Schweiz AG	Sacubitril valsartan sodium tablets 24mg, 49mg	9 Jan 2017	26 Sep 2017	8.5	24, 49, 97mg – Priority – 7 Jul 2015	24, 49, 97mg – 19 Nov 2015	26.5/22
Actelion Pharmaceuticals Ltd	Macitentan tablets 10mg	30 Nov 2016	12 Oct 2017	11.5	10mg – orphan – 18 Oct 2013	10mg – orphan – 20 Dec 2013	48/46
Data in Table 2 are sourced from databases for drug approvals by the CFDA, FDA and EMA.{7-9}							

Approvals by FDA and EMA indicate the strength approved, whether the product had orphan designation (orphan) and/or underwent priority review (priority). All applications are sorted according to approval dates and the first half of the table includes NDAs before the reform took effect while the second half includes those filed after the reform was in place. Drug lag data for approval in China compared to the US and EU is noted in the last column.

For foreign imported products approved in 2017, the dates of NDA submission and approval are listed in conjunction with approval dates for the US and EU. The drug lag (i.e., time required for approval in China from the approval in the US and EU) is listed in the last column in months. Drug lag for NDA submissions submitted before October 2016 was an average of 85.1 months compared to FDA approvals and 84.3 months compared to EMA approvals. However, the average drug lag for approvals for NDAs submitted after October 2016 was only 28.3 months compared to FDA approvals and 30.5 months compared to EMA approvals, providing a significant reduction in drug lag. For the US, the drug lag was reduced by 66.7%, while the EU drug lag reduction was 63.8%.

A significant drug lag (up to 48+ months to approval) was observed for some drugs because sponsors did not conduct any clinical trials in China until after the product was approved by FDA and/or EMA. The hesitance to conduct clinical trials in advance of approvals in other jurisdictions is explained by the time required to go through the whole registration process: CTA for registration trial in China; conduct of the registration trial in China (Phase III plus Pharmacokinetics (PK)) and then finally the NDA. This whole process would take at least four years before regulatory reform beginning in mid-2015.

Case Studies

The CFDA has recognized the importance of certain drugs and the regulatory reforms are ensuring these drugs are approved more swiftly. To illustrate the post-reform drug approval timelines, three case studies are presented.

AstraZeneca—Tagrisso® (Osimertinib)

AstraZeneca (AZ) announced that its drug product Tagrisso (Osimertinib, AZD9291) was approved by CFDA for Non-Small Cell Lung Cancer (NSCLC) on 24 March 2017.{10,11}

The development history in China was as follows:{12,13}

- AZ submitted a global Phase III trial IND application to CFDA in June 2014.
- After the trial was completed in China and the NDA approved by FDA on 13 November 2015, AZ submitted an IND to CFDA in September 2016 to request a clinical trial waiver for an exemption to conduct a local clinical trial in China.
- This IND application was granted priority review by CFDA due to the drug's indication for a serious condition in oncology. Therefore, it sped through the review and the trial waiver was approved by the end of January 2017.
- AZ subsequently submitted the NDA to CFDA on 25 January 2017. This application also received priority review status, again due to the indication.
- The NDA was approved by CFDA on 24 March 2017.
- Considering that FDA approval occurred on 13 November 2015, the drug lag was only 16 months. The CFDA approval timeframe was much shorter than for other products.

Bayer—Regorafenib

Bayer China announced that its Regorafenib was approved by CFDA on 11 December 2017 for the new indication to treat Hepatocellular Cancer (HCC). This followed the earlier approval by CFDA for two indications: metastatic Colorectal Cancer (mCRC) and advanced Gastrointestinal Stromal Tumors (GIST) on 27 March 2017.{14}

The approval for HCC as a new indication occurred only about four months after the product's approval for this indication by the EMA (2 August 2017), and about seven months after approval by FDA (27 April 2017). This demonstrates a significant shortening of drug lag.

Background History{15,16}

Bayer conducted an extensive development program for Regorafenib in China. Beginning in 2014, there were three global trials for these three indications, including sites in China.

- By 11 December 2015, Bayer's NDA had been accepted by CFDA for the two initial indications mCRC and GIST.
- After strict clinical trial data self-inspection in 2016, these two indications were approved on 27 March 2017.
- Bayer applied for a clinical trial to request a clinical trial waiver for HCC in April 2017. This application was approved by CFDA in August 2017. The clinical trial assessing the HCC indication already had been completed in China.
- The application for the HCC indication was granted priority review by CFDA because it is a global trial for this new indication, and it had potentially significant clinical advantages.
- A supplemental application was submitted to CFDA (on 22 September 2017) to add HCC as a new indication. The application was approved by CFDA on 11 December 2017. This is also under priority review for the same reason.
- This represents only four months for IND approval and only three months for the approval of adding a new indication.

The whole program above shows CFDA's desire to accelerate drug review to meet patients' needs. It is also based on global information and knowledge on Regorafenib and it highlights the unmet medical needs in China in HCC area.

Chinese Academy of Military Medical Science—Ebola Vaccine

Another example is for a locally developed Ebola vaccine under specially accelerated process: CFDA approved the first vaccine for the Ebola virus on 19 October 2017. The vaccine was developed by the government-owned Chinese Academy of Military Medical Sciences.{17}

The development history in China was as follows:

- Only 10 days for IND approval (in February 2015) and 79 days for NDA approval (in October 2017).
- The approvals were based on data from only three trials: Phase I trial in China with 120 Chinese subjects; Phase I trial in China with 61 African subjects; and Phase II trial in Sierra Leone with 500 subjects.
- It is a conditional approval with the commitment to complete a Phase III trial later.
- The development program was supported by close communication between the CFDA/CDE and the sponsor (government-owned Chinese Academy and government-invested project).

All the above mentioned foreign-developed drug approvals by CFDA in 2017 have been under an NDA priority review process, which started in February 2016. Some products qualifying for priority review are indicated for serious oncology indication, HIV or HCV infection; as well as some for pediatric usage or others have an obvious advantage over current treatment(s).

Conclusion

Although the data is still limited, a clear trend emerges indicating that the reforms in China have had a positive impact on drug development by reducing approval timelines and processes for INDs and NDAs, as well as reducing drug lag compared to approvals in the US and/or EU. The addition of more drug reviewers within the CDE since 2016 has had a significant impact: for NDAs submitted in 2014, 2015 or early 2016, it still took a long time to obtain approval (about 15 to 40 months with an average of 21.4 months). However, for NDAs submitted at the end of 2016 or early in 2017, the timeline has been much shorter with a range from two to 10 months (average 6.8 months).

Insight-China Pharma Data has a very detailed analysis on all the priority-reviewed IND and NDA projects submitted in 2016 and 2017{18} and the approval timeline tendency is very promising. According to this analysis, it took an average of 305 days (10 months) from

CDE accepting the dossier to approval of INDs and NDAs submitted in 2016, whereas INDs and NDAs submitted in 2017 were turned around in 176 days (less than six months). A significant improvement in the efficiency of CDE can be observed in these two years.

Drug development programs seem to benefit from the regulatory reform, which has resulted in a reduction in drug lag compared to FDA approvals from 85.1 months before the reform to 28.3 months after the reform. The lag time in approval in China from EMA is similarly changing with an average lag time of 84.3 months prior to the reform and 30.5 months after the reform.

Approval timelines are benefiting from the CFDA implementation of the conditional approval policy. For drugs and medical devices indicated for serious life-threatening conditions or for significant unmet medical needs, or for rare disease, where early- or mid-stage clinical data can predict clinical benefits, CFDA intends to grant a conditional approval to allow early marketing in China, provided a defined risk management plan is provided and commitment by the sponsor to complete the clinical trial(s) based on CFDA's review and conclusion. The Ebola vaccine is a good example. Additionally, the CFDA also created a new policy specific on foreign-developed new drug registration in 2016. This policy opened first-in-human Phase I trials to foreign-developed new drugs, also has simplified and shortened the clinical trial and drug registration process. And foreign sponsors can submit an NDA in China without the condition of drug approval in the US or another foreign country.

In late 2017, CFDA issued a new policy proposing the acceptance of clinical trial data from trials conducted in foreign countries, which would further support a significant improvement in the approval process.{19} According to the draft policy, a sponsor can use certain data generated in foreign clinical trials for the drug registration process in China after CFDA's audit. Due to the newness of this option, the potential benefit on approval timelines remains to be seen.

As the IND and NDA review timelines have been greatly shortened and new policies further supporting efficient drug development, sponsors should consider including China in their global regulatory strategy. The potential acceptance of foreign-generated clinical trial data, changes in the imported drug registration, and simplified submission processes and programs—such as conditional approval and priority review—promise continuing improvements in the approval and drug registration process supporting a global clinical development program including China from the start. Bottom line, sponsors should consider including development in China in parallel with the US and EU—beginning at the Phase I stage—rather than at a later point in time to take the greatest advantage of the benefits the Chinese market now has to offer.

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