



China adds 30 drugs to its "urgently needed" list

Faster review periods and waiver of requirement for Chinese clinical trials are intended to encourage marketing applications

2 April 2019

On 28 March China's National Medical Products Administration (NMPA) published a list of an additional 30 drugs that are "urgently needed" in China, and for which NMPA seeks to encourage the submission of marketing applications.

To that end, the agency has:

- Waived the requirement to conduct clinical trials in China, if the sponsor has data demonstrating that racial or ethnic differences between the study population and Chinese patients would not affect the product's efficacy.
- Established an expedited six-month review period (three months for orphan drugs) for the identified drugs.

Each of the drugs identified by NMPA meets at least one of the following criteria: (1) an orphan drug; (2) a drug intended to treat a life-threatening disease for which there is currently no approved product; or (3) a drug intended to treat a life-threatening disease and offering a substantial clinical advantage over existing approved therapies.

This is the second time NMPA has taken this step to encourage pharmaceutical companies to bring to China new treatments approved in the United States, European Union, or Japan, but unavailable in China. See our previous [blog](#) for the list of 48 "urgently needed" drugs published in August 2018. Reportedly, 11 of the drugs on that first list have been approved in the months since then.

Although comments disagreeing with the listing of any of the 30 drugs as "urgently needed" may be submitted to NMPA by 4 April, the list seems unlikely to change. We will continue to monitor the status of any regulatory changes and reforms by NMPA. With offices in Washington, D.C., Beijing, and Shanghai and a team of Life Sciences lawyers well-versed in both Food and Drug Administration (FDA) and NMPA regulations, we are well-positioned to assist pharmaceutical companies with regulatory and legal issues in China. Please contact one of the authors of this alert if you have any questions or if we can be of further assistance.

Appendix:

Second list of drugs urgently needed in China (unofficial translation by Hogan Lovells)

(Source: [Center for Drug Evaluation, NMPA](#))

| Serial no. | New drug | Manufacturer/sponsor | First approval date outside of China (jurisdiction) | Indication |
|------------|--|------------------------------------|---|--|
| 1 | Biopten Granules 10 percent, 2.5 percent (sapropterin hydrochloride) | Daiichi Sankyo Co. Ltd. | 2013/8/20 (Japan) | Type A hyperphenylalaninemia; BH4 reactive hyperphenylalaninemia |
| 2 | Levemir Insulin Detemir [rDNA origin] Injection | Novo Nordisk Inc. | 2007 for Noonan, 2018 for Prader-Willi (U.S.) | Noonan; Prader-Willi |
| 3 | Crysvita (Burosumab) | Kyowa Kirin Ltd. | 2018/2/19 (EU) | X-linked hypophosphatemia |
| 4 | Increlex (Mecasermin [rDNA origin]) Injection | Tercica Inc. | 2005/8/30 (U.S.) | Severe primary insulin-like factor 1 deficiency in children; defective growth hormone receptor gene; growth-deficient and antibody-induced undergrowth in children |
| 5 | Aldurazyme (laronidase) | BioMarin Pharmaceutical Inc. | 2003/4/30 (U.S.) | Mucopolysaccharidosis type I |
| 6 | Elaprase (Indursulfase) Injection | Shire Human Genetic Therapies Inc. | 2006/7/24 (U.S.) | Mucopolysaccharidosis type II |
| 7 | Fabrazyme (Agalsidase Beta) | Genzyme Europe B.V. | 2001/3/8 (EU) | Fabry disease |
| 8 | Replagal (Agalsidase alfa) | Shire Human Genetic Therapies AB | 2001/3/8 (EU) | Fabry disease |
| 9 | Galafold (Migalastat hydrochloride) | Amicus Therapeutics UK Ltd. | 2016/5/25 (EU) | Fabry disease |
| 10 | Erleada (apalutamide) | Janssen Biotech Inc. | 2018/2/14 (U.S.) | Non-metastatic castration resistant prostate cancer |

| | | | | |
|----|--|--------------------------------|-----------------------|--|
| 11 | Lysodren(mitotane) | Bristol-Myers Squibb Co. | 1970/7/8 (U.S.) | Adrenal cortical carcinoma |
| 12 | ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein] | Bioverativ Therapeutics Inc. | 2014/3/28 (U.S.) | Hemophilia B |
| 13 | Inavir (laninamivir octanoate hydrate) | Daiichi Sankyo Co. Ltd. | 2010/9/10 (Japan) | Influenza A and B infections |
| 14 | Xofluza (Baloxavir marboxil) | Shionogi & Co. Ltd. | 2018/2/23 (Japan) | Influenza A and B |
| 15 | Maviret (Glecaprevir/Pibrentasvir) | AbbVie Deutschland GmbH Co. KG | 2017/7/26 (EU) | Hepatitis C |
| 16 | BIKTARVY (bictegravir, emtricitabine, and tenofovir alafenamide) Tablets | Gilead Sciences Inc. | 2018/2/7 (U.S.) | AIDS |
| 17 | Tracleer 32 mg dispersible tablets | Janssen-Cilag International NV | 2009/6/3 (EU) | Pulmonary hypertension |
| 18 | Revatio (Sildenafil Citrate) | Pfizer Inc. | 2009/11/18 (U.S.) | Pulmonary hypertension |
| 19 | Careload LA (Beraprost sodium) | Toray Industries Inc. | 2007/10/19 (Japan) | Pulmonary hypertension |
| 20 | Praluent Alirocumab | Sanofi-Aventis U.S. Inc. | 2015/7/24 (U.S.) | Hypercholesterolemia |
| 21 | Ruconest (Recombinant human C1-inhibitor) | Pharming Group N.V. | 2010/10/28 (EU) | Hereditary angioedema |
| 22 | STELARA (ustekinumab) Injection | Janssen Biotech Inc. | 2016/9/23 (U.S.) | Crohn's disease |
| 23 | Lokelma (sodium zirconium cyclosilicate) | AstraZeneca AB | 2018/3/22 (EU) | Hyperkalemia |
| 24 | Verkazia (ciclosporin) | Santen OY | 2018/7/6 (EU) | Severe spring keratoconjunctivitis |
| 25 | Humira (adalimumab) | AbbVie Deutschland GmbH Co. KG | 2016/6/24 (EU) | Non-infectious intermediate uveitis, posterior uveitis and total uveitis |
| 26 | Lemtrada | Sanofi Belgium | 2013/9/12 | Multiple sclerosis |

| | (Alemtuzumab) | | (EU) | |
|----|--------------------------------|--------------------------------|-------------------|--|
| 27 | Radicava (Edaravone) | Mitsubishi Tanabe Pharma Corp. | 2015/6/1 (Japan) | Amyotrophic lateral sclerosis |
| 28 | Vigadrone(vigabatrin) | Aucta Pharmaceuticals | 2018/6/21 (U.S.) | Infantile spasm (IS) for infants from 1 month to 2 years of age; together with other therapies for the treatment of refractory complex partial seizures (CPS) in adults and children aged 10 years and older |
| 29 | DUPIXENT Injection | Regeneron Pharmaceuticals Inc. | 2017/3/28 (U.S.) | Moderate to severe atopic dermatitis |
| 30 | Eucrisa (crisaborole) Ointment | Anacor Pharmaceuticals Inc. | 2016/12/14 (U.S.) | Mild to moderate atopic dermatitis 2 years and older |

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