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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心
SERVIER
施维雅(天津)制药有限公司

SAMR Issued the *Measures for the Administration of Imported Medicinal Materials*

To strengthen the administration and guarantee the quality of imported medicinal materials, on May 16, 2019, the State Administration for Market Regulation (SAMR) issued the revised *Measures for the Administration of Imported Medicinal Materials* (SAMR Order No. 9, hereinafter referred to as the *Measures*).

The *Measures* has been adopted upon deliberation at the 8th SAMR Conference on April 28, 2019, and shall enter into force as from January 1, 2020. The *Measures for the Administration of Imported Medicinal Materials (Interim)*, promulgated by the former State Food and Drug Administration on November 24, 2005, shall be repealed simultaneously. The current *Measures* consists of 35 Articles in 7 Chapters. Regarding the administration of imported medicinal materials, the *Four Strictest* requirements and the standards for medicinal materials are strictly enforced, and traceability management is reinforced. Furthermore, the *Measures* embodies the reform requirements of *Streamlining Administration, Delegating More Powers to Lower-level Governments and Society, Improving Regulation and Optimizing Services*, requiring classified management on initial import and non-initial import of medicinal materials. Highlights include:

I. Encourage imports and reflect interconnection. Given that imported medicinal materials constitute an important part of China's medicinal materials resources, and most of their export sources are countries along the *Belt and Road*, to encourage import, the *Measures* abolished the former restrictive Article 4 that *A border port permitting the import of medicinal materials may only import medicinal materials produced in the neighboring countries or regions*, so as to honor the *Belt and Road* initiative, reflecting the spirit of *interconnection*.

II. Implement the *Four Strictest Requirements* and strictly enforce the standards for medicinal materials. The *Measures* stipulates that the medicinal materials applied for import shall comply with the national drug standards. Meanwhile, considering that traditional medicines such as Uygur medicine and Tibetan medicine are traditionally more dependent on import, to protect drug use in ethnic minority areas, the *Measures* stipulates that: in ethnic minority areas, the import of locally customarily used ethnic medicines shall, in the absence of national drug standards, conform to the medicinal materials standards of the corresponding province or autonomous region.

III. Deepen the reform of *Streamlining Administration*, *Delegating More Powers to Lower-level Governments and Society*, Improving Regulation and Optimizing Services, and implement classified management. The review and approval of initial import of medicinal materials shall be entrusted to the provincial-level drug administration departments in charge of the applicants. The sample inspection originally undertaken by the National Institutes for Food and Drug Control (NIFDC) shall be, accordingly, entrusted to the provincial drug control institutions. Furthermore, the import management of non-initial-import of medicinal materials has been simplified as per risk levels, whereby the Applicants can seek record filing directly at the competent drug administration department at the port or border port to file the

国家市场监督管理总局发布《进口药材管理办法》

为加强进口药材监督管理，保障进口药材质量，2019年5月16日，国家市场监督管理总局发布了修订后的《进口药材管理办法》（国家市场监督管理总局令第9号，以下简称《办法》）。

《办法》经2019年4月28日国家市场监督管理总局第8次局务会议审议通过，自2020年1月1日起实施。原国家食品药品监督管理局2005年11月24日公布的《进口药材管理办法（试行）》同时废止。《办法》共7章35条，在进口药材管理上，严格落实“四个最严”要求，严格药材执行的标准，加强溯源管理。同时，落实“放管服”改革要求，对首次进口和非首次进口药材实施分类管理。重点内容包括：

一是鼓励进口，体现互联互通。进口药材是我国药材资源的重要组成部分，且药材多数出口国为“一带一路”沿线国家。为鼓励药材进口，《办法》取消了“允许药材进口的边境口岸，只能进口该口岸周边国家或者地区所产药材”的限定，落实“一带一路”倡议，体现“互联互通”精神。

二是落实“四个最严”要求，严格药材执行标准。《办法》规定申请进口的药材应当符合国家药品标准。同时，考虑维药、藏药等少数民族药传统上多依赖进口药材，为保障少数民族地区用药，规定少数民族地区进口当地习用的少数民族药药材，尚无国家药品标准的，应当符合相应的省、自治区药材标准。

三是深化“放管服”改革，实施分类管理。将首次进口药材的审批委托至申请人所在地省级药品监督管理部门，原来由中国食品药品检定研究院承担的样品检验，相应地调整至省级药品检验机构。此外，根据风险级别，对非首次进口药材的进口管理进行了简化，申请人可直接到口岸或者边境口岸所在地负责药品监督管理的部门进行备案，办理进口药品通关单。

四是加强事中事后监管，强化溯源管理。

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Servier (Tianjin) Pharmaceutical Co., Ltd.

Customs Clearance Form for Imported Drugs.

IV. Reinforce concurrent and ex post regulation and traceability management. In view of the problems existing in the supervision practice, it is further clarified that and the imported medicinal materials shall not be marketed for sale and use unless they pass the port inspection; and the purchase of imported medicinal materials must be accompanied with the request of the supplier's relevant certification dossiers, as well as the strict compliance with the related provisions on drug traceability management. At the same time, it is stipulated that for the import of medicinal materials, the application & acceptance, the results of review and approval, the circumstances of violations of laws and regulations and the resulting penalties shall be disclosed on the websites of national drug administration departments.

(May 17, 2019)

针对监管实践中存在的问题，进一步明确进口药材须经口岸检验合格后，方可上市销售使用的要求；采购进口药材时，须向供货方索要相关证明资料，严格执行药品追溯管理的有关规定。同时，要求药材进口申请受理、审批结果、有关违法违规的情形及其处罚结果应当在国家药品监督管理部门网站公开。 (2019-05-17)

NMPA issued the *Announcement on Adjusting the Relevant Matters Concerning the Definition of the Attributes of Drug/Device Combination Products*

To further standardize the definition of the attributes of Drug/Device Combination Products, according to the *Three-Determinations (of posts, duties and staffing)* regulations for NMPA institutions, on May 31, 2019, NMPA announced the relevant matters as follows:

I. The NMPA Management Center for Medical Device Standards (hereinafter referred to as the Management Center for Standards) shall be responsible for organizing the attributes-definition.

II. The applicant submits an application for attributes-definition to the Management Center for Standards via the *Definition Information System for Attributes of Drug/Device Combination Products* (see Annex for details).

III. The Management Center for Standards conducts a preliminary review of the application dossier for attributes definition. If it meets the requirements, it shall be accepted; otherwise, the applicant shall be notified to make corrections, or the application shall be rejected.

IV. The Management Center for Standards shall review the accepted application, and give the opinions on attribute definition within 20 working days, and inform the applicant. Experts can be organized, where necessary, to study and proffer technical recommendations for product attributes. The time required for supplementary dossiers and expert discussions shall not be counted in the time limit.

V. Where additional information is required, the applicant shall make a one-time supplement within 60 working days as required. If the supplementary dossiers are not submitted within the time limit, or if the applicant fails to submit such dossiers as required, the application shall be rejected.

VI. Where the applicants disagree with the attribute-definition outcome, they may request for a re-review to the Management Center for Standards within 10 working days as from the date of being informed of the definition results. The Management Center for Standards shall organize a re-review, the opinions of which shall be final for attributes definition.

VII. The Management Center for Standards shall publish the results of attributes definition on its website in a timely manner.

VIII. Other registration issues of Drug/Device Combination Products shall be handled in accordance with the *Announcement on Matters Concerning the Definition of the Attributes of Drug/Device Combination Products* (SFDA Announcement No. 16 of 2009).

IX. This Announcement shall enter into force as from June 1, 2019.

(May 31, 2019)

国家药品监督管理局发布《关于调整药械组合产品属性界定有关事项的通告》

为进一步规范药械组合产品属性界定工作，根据国家药品监督管理局事业单位“三定”规定，2019年5月31日，国家药品监督管理局就调整药械组合产品属性界定有关事项通告如下：

一、国家药品监督管理局医疗器械标准管理中心（以下简称标管中心）负责组织开展药械组合产品属性界定工作。

二、申请人通过“药械组合产品属性界定信息系统”向标管中心提交药械组合产品属性界定申请（具体要求见附件）。

三、标管中心对收到的药械组合产品属性界定申请资料进行初审。对于符合要求的，予以受理；对于不符合要求的，通知申请人补正或者予以退回。

四、标管中心对受理的药械组合产品属性界定申请进行审查，20个工作日内提出属性界定意见，并告知申请人。必要时可组织专家研究提出产品属性的技术建议。补充资料和专家研讨所需时间不计算在时限内。

五、需补充资料的，申请人应当在60个工作日内按照要求一次性补充，逾期未提交补充资料的，或者申请人未按要求提交补充资料的，退回申请。

六、申请人若对药械组合产品属性界定结果有异议，可在界定结果告知之日起10个工作日内向标管中心提出复审。标管中心组织复审，复审意见作为最终属性界定结果。

七、标管中心及时在其网站对外公布药械组合产品属性界定结果。

八、其他药械组合产品注册事项按照《关于药械组合产品注册有关事宜的通告》（国家食品药品监督管理局通告2009年第16号）的规定执行。

九、本通告自2019年6月1日起实施。

(2019-05-31)

NMPA Issued the *Announcement on Issues Concerning the Import of Reference Drugs for Clinical Research of Biosimilar Drugs*

On November 30, 2018, NMPA issued the *Announcement on Issues Pertaining to the One-off Import of Reference Drugs for Biologicals in Clinical Trials* (Announcement No. 94 of 2018), clarifying that the applicant can apply for one-off import of brand-name drugs that meet certain conditions as reference drugs for clinical trials. To further implement the relevant policies set forth in the *Opinions on Deepening the Reform of the Review & Approval System to Encourage the Innovation of Drugs and Medical Devices* (General Office [2017] No. 42), and further promote the reform of *Streamlining Administration, Delegating More Powers to Lower-level Governments and Society, Improving Regulation and Optimizing Services,* in light of the domestic enterprises' actual demand of biosimilar R&D, NMPA decided to grant the one-off import of brand-name drugs as reference drugs for biosimilar clinical research that are produced by the same manufacturer in different places of origin, and have been approved for import registration or clinical trial in China. The Announcement was issued on May 28, 2019. The relevant issues are hereby announced as follows:

I. Applicants should select, as far as practicable, the brand-name drug that has been approved for import registration or clinical trial in China as reference drugs for biosimilar clinical trials.

II. Where the applicant intends to select brand-name drugs as reference drugs for biosimilar clinical research that are produced by the same manufacturer in different places of origin, and have been approved for import registration or clinical trial in China, in order to protect the safety of the subjects, prior to the clinical trials, comparable evidence of the brand-name drugs from differed places of origin must be furnished; or, according to the relevant technical guidelines for the research and evaluation of biosimilars in China's drug regulatory authorities, a comparative research shall be carried out on the brand-name drugs of different origins to prove that they are comparable (similar/consistent), and a pre-trial supplementary application must be filed with NMPA Center for Drug Evaluation for review and approval, only after which the applicant may use the brand-name drug that has not been approved in China for the clinical trial.

III. The reference drugs selected by the applicant at each stage of R&D for biosimilarity comparative research must be from the same place of origin.

(May 28, 2019)

国家药品监督管理局发布《关于生物类似药临床研究用原研参照药进口有关事宜的公告》

2018年11月30日，国家药品监督管理局发布了《关于临床试验用生物制品参照药品一次性进口有关事宜的公告》（2018年第94号），明确申请人可对符合一定条件的原研药申请一次性进口用于临床试验的参照药。为进一步落实《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号）要求，深入推进“放管服”改革，根据国内企业对生物类似药研发工作的实际需求，国家药品监督管理局决定对与在我国获批进口注册或临床试验的原研药品产地不一致的同一企业的原研药品作为生物类似药临床研究用参照药予以一次性进口。2019年5月28日发布公告，将有关事项通知如下：

一、申请人应尽可能选择已在我国获批进口注册或临床试验的原研药作为生物类似药临床试验用参照药。

二、为保护受试者安全，对申请人拟选择与在我国获批进口注册或临床试验产地不一致的同一企业的原研药品作为参照药的，在临床试验开始前，应提供不同产地原研药之间可比的证据或按照我国药品监管部门关于生物类似药研究与评价的相关技术指导原则要求，开展不同产地原研药品的比对研究并证明二者可比后，以补充申请方式提交国家药监局药品审评中心。待国家药监局药品审评中心审评认可后，申请人方可将未获批产地的原研药用于临床试验。

三、申请人在研发的各个阶段开展相似性比较研究所选择的参照药应为同一产地产品。

（2019-05-28）

Medical Devices

NMPA issued the *Announcement on Implementing Electronic Application of Medical Device Registration*

To implement the relevant policies set forth in the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of the Review & Approval System to Encourage the Innovation of Drugs and Medical Devices* (General Office [2017] No.

医疗器械

国家药品监督管理局发布《关于实施医疗器械注册电子申报的公告》

为落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号），实现医疗器械注册申请的电子申报，国家药品监督管理局组织开发了医疗器械注册电子申报信息化系统（eRPS），2019年5月31日

42), and to realize the electronic application of medical device registration, NMPA has organized the development of the electronic Regulated Product Submission (eRPS) system, and announced the relevant issues as follows on May 31, 2019:

I. Scope of application

At present, the eRPS system business scope covers the NMPA medical device registration affairs, including the registration, change in registration and registration renewal of domestic Class III medical devices, imported Class II and Class III medical devices; the examination and approval of clinical trials for Class III high-risk medical devices; notification for revising medical device instructions; re-review of registration of medical devices and change of licensing items; and special review of innovative medical devices, etc.

The record filing of imported Class I medical devices; the replacement, correction, self-deregistration, and self-revocation of registration certificates and change documents; and the designated test for medical device registration, etc., are not included in the scope of the eRPS system.

II. Time schedule

(I) CA application

Since May 2019, the applicants and registrants of medical device registration can apply for a Certificate Authority (CA) for use in the eRPS system. Please pay attention to the website of the NMPA Center for Medical Device Evaluation (www.cmde.org.cn) for specific notification of application.

(II) System startup

On June 24, 2019, the eRPS system was officially launched. Medical device registration applicants and registrants can apply for online electronic registration of medical devices without submitting paper dossiers. Meanwhile, NMPA reserves the means of submitting paper dossiers.

The submission of paper materials may follow the current requirements for registration of medical devices and in vitro diagnostic reagents prior to October 31, 2019;

From November 1, 2019, the submission of paper materials shall abide by the requirements of the *Technical Guidelines for Electronic Submission of Medical Device Registration Applications* (Interim) in alignment with the electronic filing form.

(May 31, 2019)

将实施医疗器械注册电子申报有关事项公告如下：

一、适用范围

目前，eRPS系统业务范围为国家药品监督管理局医疗器械注册事项，包括境内第三类和进口第二、三类医疗器械注册、注册变更、延续注册，第三类高风险医疗器械临床试验审批，以及医疗器械说明书更改告知、医疗器械注册及许可事项变更复审、创新医疗器械特别审查等。

进口第一类医疗器械备案，注册证及变更文件的补办、纠错、自行注销、自行撤回，医疗器械注册指定检验等事项暂不包含在eRPS系统业务范围之内。

二、时间安排

（一）CA申领

自2019年5月起，医疗器械注册申请人、注册人申领eRPS系统配套使用的数字认证证书（Certificate Authority，CA）。具体申领通知请关注国家药品监督管理局医疗器械技术审评中心网站（www.cmde.org.cn）。

（二）系统启用

2019年6月24日，正式启用eRPS系统。医疗器械注册申请人、注册人可进行线上医疗器械注册电子申报，无需提交纸质资料。同时，国家药品监督管理局保留纸质资料的提交途径。

2019年10月31日前，纸质资料提交按照现行医疗器械、体外诊断试剂注册申报资料要求进行。

2019年11月1日起，纸质资料提交应当按照《医疗器械注册申请电子提交技术指南（试行）》的要求，与电子申报目录形式一致。 (2019-05-31)

NMPA Issued 27 Medical Device Industry Standards (Covering YY 0096-2019 Co-60 Teletherapy Unit) and 1 Amendment Form

After review and approval, NMPA published the YY 0096-2019 *Co-60 Teletherapy Unit* and other 26 medical device industry standards, as well as the No. 1 amendment form for YY 0285.3-2017 *Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters* medical device industry standard on May 31, 2019. See Annex for the standard code, name, scope of application, date of implementation and contents of the amendment(Annex omitted). (May 31, 2019)

国家药品监督管理局发布YY 0096—2019《钴-60远距离治疗机》等27项医疗器械行业标准和1项修改单

YY 0096-2019《钴-60远距离治疗机》等27项医疗器械行业标准和YY0285.3-2017《血管内导管一次性使用无菌导管第3部分：中心静脉导管》医疗器械行业标准第1号修改单已经审定通过，国家药品监督管理局于2019年5月31日予以公布。标准编号、名称、适用范围、实施日期和修改单内容见附件 (附件略)。 (2019-05-31)

NMPA Issued 3 Guidelines for Technical Review of the Registration of Synthetic Resin Teeth and Others

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA organized the formulation of and published the *Guidelines for Technical Review of the Registration of Synthetic Resin Teeth, the Guidelines for Technical Review of the Registration of IUD*, and the *Guidelines for Technical Review of the Registration of Implantable Drug Delivery System* on May 22, 2019.

(May 22, 2019)

国家药品监督管理局发布合成树脂牙等3项注册技术审查指导原则

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药品监督管理局组织制定了《合成树脂牙注册技术审查指导原则》《宫内节育器注册技术审查指导原则》《植入式给药装置注册技术审查指导原则》，于2019年5月22日发布。

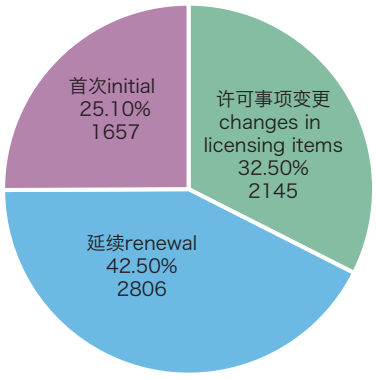
（2019-05-22）

Annual Report

2018 Annual Report for Medical Device Registration Released

On May 31, 2019, NMPA issued the *2018 Annual Report for Medical Device Registration*, which consists of five parts, namely, the situation of medical device registration; the acceptance of medical device registration applications; review and approval of medical device registration; review and approval of registration for innovative medical devices and other products; and management of other registration affairs. The statistics period of this Report spans from January 1, 2018 to December 31, 2018.

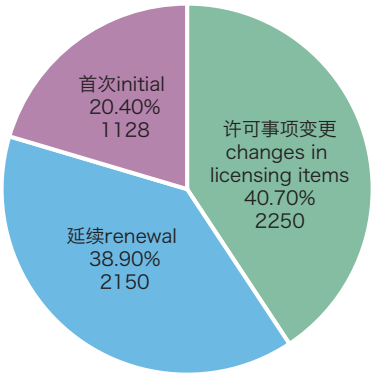
图：受理医疗器械注册形式比例图
Figure: Pie-chart of registration forms of medical device registration acceptance



Among them, in 2018, within its purview, NMPA accepted 6608 applications for initial registration, registration renewal and registration of changes in licensing items for medical devices, decreased by 3.3% as compared with that in 2017.

In 2018, NMPA approved a total of 5,528 items of medical device initial registrations, registration renewals and registration of changes. Compared with 2017, the total number of registration approvals is down by 38.0%. Among them, 1,128 were for initial registrations, 2,150 were for registration renewals, and 2,250 were for registration of changes in licensing items.

图：2018年度批注医疗器械注册形式比例图
Figure: Pie-chart of registration forms of approved medical device registrations in 2018



In 2018, NMPA has rejected a total of 118 medical device registration applications, while 238 applications were voluntarily withdrawn by the enterprises. (May 31, 2019)

年报

《2018年度医疗器械注册工作报告》发布

2019年5月31日，国家药品监督管理局发布《2018年度医疗器械注册工作报告》，报告共分五部分内容，即医疗器械注册工作情况、医疗器械注册申请受理情况、医疗器械注册审批情况、创新医疗器械等产品注册审批情况以及其他注册管理情况。报告数据统计期间为2018年1月1日至2018年12月31日。

其中，2018年国家药品监督管理局依职责共受理医疗器械首次注册、延续注册和许可事项变更注册申请6608项，与2017年相比注册受理项目减少3.3%。

2018年国家药品监督管理局共批准医疗器械首次注册、延续注册和变更注册5528项。与2017年相比注册批准总数量减少38.0%。其中，首次注册1128项，延续注册2150项，许可事项变更2250项。

2018年国家药品监督管理局共对118项医疗器械注册申请不予注册，企业自行撤回238项。（2019-05-31）

General Information

CDE Released the *List of the Second Batch of Overseas New Drugs Urgently Needed in Clinical Settings*

On May 29, 2019, NMPA Center for Drug Evaluation issued the *Notice on the Issuance of the List of the Second Batch of Overseas New Drugs Urgently Needed in Clinical Settings*, which reads as follows:

To implement the policies set forth in the State Council executive meetings and speed up the entry of overseas new drugs urgently needed in clinical practice to China, according to the *Announcement on Issues Pertaining to the Review and Approval of Overseas New Drugs Urgently Needed in Clinical Settings* (No. 79 of 2018), NMPA and the National Health Commission organized relevant experts to study, demonstrate and select the second batch of overseas new drugs urgently needed in clinical settings, the list of which has been published on the website of CDE. On May 29, 2019, the list of 26 uncontested varieties (such as Biopten Granules) as the second batch of urgently needed overseas new drugs in clinical practice, was officially announced to the public.

The application for marketing of varieties listed in the list of new overseas drugs urgently needed in clinical settings can be submitted directly in accordance with the *Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs*. CDE has established a special channel to speed up the review. For not-yet-declared product, you can contact us at any time to submit an application for marketing ASAP.

综合信息

药品审评中心发布第二批临床急需境外新药名单

2019年5月29日，药品审评中心发布《关于发布第二批临床急需境外新药名单的通知》，内容如下：

为落实国务院常务会议精神，加快临床急需境外新药进入我国，根据《关于临床急需境外新药审评审批相关事宜的公告》（2018年第79号）工作程序，国家药品监督管理局、国家卫生与健康委员会组织有关专家研究论证，遴选出了第二批临床急需境外新药，该名单前期已在药品我中心网站公示。2019年5月29日，现将Biopten Granules等26个无异议的品种作为第二批临床急需境外新药品种名单正式对外发布。

列入上述临床急需境外新药名单的品种，可按照《临床急需境外新药审评审批工作程序》提交相关资料，直接提出上市申请，药审中心建立专门通道加快审评。尚未申报的品种，可随时提出与中心进行沟通交流，尽快提出上市申请。

临床急需境外新药名单（第二批）
List of urgently needed overseas new drugs in clinical practice (second batch)

序号 Serial number	药品名称 （活性成分） Drug Name (active ingredient)	企业名称 （持证商） Company Name (certificate holder)	首次批准地 Place of first approval	欧美日首次批准日期 First approved date in Europe, America and Japan	治疗领域 Therapeutic areas
1	Biopten Granules 10%, 2.5% (sapropterin hydrochloride)	Daiichi Sankyo Co., Ltd.	日本 Japan	2013/8/20	内分泌和代谢病 Endocrine and metabolic diseases
2	NORDITROPIN (somatropin) injection	NOVO NORDISK INC	美国 United States	Noonan (2007) Prader-Willi (2018)	
3	Crysvita (Burosumab)	Kyowa Kirin Limited	欧盟 EU	2018/2/19	
4	Increlex (Mecasermin [rDNA origin]) Injection	IPSEN INC	美国 United States	2005/8/30	内分泌 Endocrine disease
5	Aldurazyme (laronidase)	BIOMARIN PHARMACEUTICAL INC.		2003/4/30	遗传代谢性疾病 Hereditary metabolic disease
6	Elaprase (Indursulfase) Injection	Shire Human Genetic Therapies, Inc.		2006/7/24	
7	Fabrazyme (Agalsidase Beta)	Genzyme Europe B.V.	欧盟 EU	2001/3/8	
8	Replagal (Agalsidase alfa)	Shire Human Genetic Therapies AB		2001/3/8	
9	Galafold (Migalastat hydrochloride)	Amicus Therapeutics UK Ltd		2016/5/25	

10	Erleada (apalutamide)	Janssen Biotech, Inc.	美国 United States	1970/7/8	肿瘤 Tumor
11	Lysodren (mitotane)	HRA Pharma		1970/7/8	
12	ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein]	Bioverativ Therapeutics Inc		2014/3/28	血液系统疾病 Blood system disease
13	Maviret (Glecaprevir/ Pibrentasvir)	AbbVie Deutschland GmbH Co. KG	欧盟 EU	2017/7/26	感染性疾病 Infectious disease
14	BIKTARVY (bictegravir, emtricitabine, and tenofovir alafenamide) Tablets	Gilead Sciences,Inc.	美国 United States	2018/2/7	
15	Tracleer 32 mg dispersible tablets	Janssen-Cilag International N V	欧盟 EU	2009/6/3	呼吸系统 Respiratory system
16	Revatio (Sildenafil Citrate)	Pfizer Inc.	美国 United States	2009/11/18	
17	Careload LA (Beraprost sodium)	レ株式会社	日本 Japan	2007/10/19	
18	Ruconest (Recombinant human C1-inhibitor)	Pharming Group N.V.	欧盟 EU	2010/10/28	皮肤疾病 Skin disease
19	STELARA (ustekinumab) Injection	Janssen Biotech, Inc.	美国 United States	2016/9/23	消化系统 Digestive system
20	Lokelma (sodium zirconium cyclosilicate)	AstraZenecaAB	欧盟 EU	2018/3/22	高钾血症 Hyperkalemia
21	Humira (adalimumab)	AbbVie Deutschland GmbH Co. KG		2016/6/24	眼部疾病 Eye disease
22	Lemtrada (Alemtuzumab)	Sanofi Belgium		2013/9/12	神经系统 Nervous system
23	Radicava (Edaravone)	Mitsubishi Tanabe Pharma Corporation	日本 Japan	2015/6/1	
24	Vigadrone (vigabatrin)	Lundbeck Inc.	美国 United States	2009/8/21	
25	DUPIXENT Injection	Regeneron Pharmaceuticals, Inc.		2017/3/28	皮肤疾病 Skin disease
26	Eucrisa (crisaborole) Ointment	Anacor Pharmaceuticals, Inc.		2016/12/14	

(May 29, 2019)　　(2019-05-29)

注：原表中“欧美日首次批准日期、治疗靶点、适应症、列为临床急需原因”项略

Note: “First approved date in Europe, America and Japan, therapeutic targets, indications, and reasons for listed as clinical imperative” in the original table: Omitted

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.

• For electronic version of the Newsletter please visit http://www.ccfdie.org

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。

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