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Legal Updates

1. Top 10 Traps to Avoid: Navigating China's HGR Applications
2. Overview: 2022–2023 China Drug & Medical Device Annual Report

1. Top 10 Traps to Avoid: Navigating China's HGR Applications[1]

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In recent years, the regulatory framework for human genetic resources ("**HGR**") in China has become increasingly mature. Regulatory authorities have issued and updated a series of laws and regulations, including the *Regulations on the Administration of Human Genetic Resources* (the "***HGR Regulations***"), the *Implementation Rules on the Administrative Regulations on Human Genetic Resources* (the "***Implementation Rules***"), the corresponding administrative guidelines, as well as the *Answers for Frequently Asked Questions on Human Genetic Resource Administration.* The regulatory system for HGR in China has been thereby established and refined (For our insights on the regulations of HGR in China, please refer to: *Highlights on HGR Regulation Implementation Rules*; *Key Takeaways of the New HGR Guidelines*; *Key Takeaways on the New HGR FAQs issued by the MOST of China*).

Meanwhile, significant progresses have been made for the review and approval process of HGR applications. According to the approval results for HGR projects publicly disclosed on the HGR Management System, 105 collection projects and 704 international scientific research collaboration projects have obtained approval to date this year. The rate of approval is high, and the average time for approval ranges between 16 to 20 working days[3].

Since May 1, 2024, the regulatory authority of HGR in China has been transferred from the Ministry of Science and Technology (the "**MOST**") to the National Health Commission (the "**NHC**"). (For our insights on the changes of HGR regulatory authority, please refer to: *汉坤·快评 | 《人类遗传资源管理条例》再次修订*). On April 25, 2024, the MOST issued an announcement that the application process and management system for HGR projects will remain unchanged. Furthermore, there are reports indicating that the NHC has thereafter commenced the revision of the *Implementation Rules*, where the NHC may consider further widening the scope of the "Chinese entities" and streamlining the application process for HGR projects to reduce the burden on industry in the future[4]. Such relaxation of the future standards and requirements for the applications of HGR projects may facilitate the ongoing and future research projects. However, we have also observed that due to a lack of understanding of compliance requirements, a number of common traps in HGR applications have emerged across various projects in recent years, resulting in failure to obtain the approval. Regardless of any future revision, foreseeably China's current regulatory system for HGR will not undergo any fundamental changes unless any amendments to the *Biosecurity Law of the PRC*. Therefore, failure to avoid these traps may still pose significant obstacles to the process of HGR projects, whether there will be any relaxation to the specific requirements. In light of

[1] For the Chinese version, please click *十大雷区：中国人类遗传资源项目申报避坑指南*.

[2] Shuwen Sun have contributions to this article.

[3] HGR Management System: https://apply.hgrg.net/.

[4] Moting Jiang, Xiaotian Cui (2024, May 13), 独家 | "人类遗传资源管理条例实施细则"修订提上日程, *Caixin*, https://m.caixin.com/red/2024-05-13/102195539.html?s=6d1d82d074b45ff0376cf93f789cba1b813014478d3b719ab1fc919d78206db00c0be4674434d5b0.

this, in accordance with the latest regulations, policies and regulatory practices, this article specifies ten common traps in the application of HGR projects in China. We also hope that this article could help the industry better understand regulatory requirements, mitigate risks, improve efficiency in obtaining approvals and facilitate smooth process of HGR projects.

Trap one: inappropriate pathway for the application

Choosing an appropriate application pathway is the initial step for a compliant and smooth HGR application. Current HGR pathways include procedures of the collection approval, the biobanking approval, the material exportation approval and the international scientific research collaboration approval of HGR, as well as the international clinical trial collaboration filing and data sharing reporting of HGRs. Based on the specific characteristics of the projects, applicants shall select the right pathway and complete the application process in accordance with the laws and regulations. Failure to choose the right pathway may lead to the failure to obtain approvals for the projects or result in potential legal risks for the projects.

For instance, if a foreign entity plans to utilize Chinese HGR information for scientific research, the procedures of the international scientific research collaboration approval, the international clinical trial collaboration filing, or the data sharing reporting may be applied based on the project's collaboration arrangements and specific circumstances. If the foreign entity merely intends to provide investigational drugs or funding for such HGR-related scientific research without any substantial involvement in the research, no application procedures are required. However, if the foreign entity intends to substantially participate in the project, obtain the HGR and the related research data, share the project's intellectual property rights ("**IPR**"), or share or jointly publish research findings, it is necessary to complete the applicable application procedures.

Trap two: safety risks and inadequate risk mitigation methods in the projects

The safety risks associated with the projects have always been a significant concern in the regulation of HGR in China. The legislative intent of the *HGR Regulations* is the effective protection and reasonable utilization of the HGR, as well as to safeguard public health, national security and public interests[5].

Therefore, whether a project poses potential safety risks, including risks to public health, national security, or public interests, is a key focus of the regulatory authority in the review. To manage such safety risks, applicants shall make proper arrangements for the biobanking, use, and mitigation measures of the involved HGR in the project and provide specific explanations of such arrangements in the application materials. For instance, it shall be provided that no personally identifiable information of subjects/patients shall be uploaded to public platforms. Key data generated in the project, such as raw data from whole-exome sequencing or whole-genome sequencing, shall be stored on domestic platforms. If no reasonable and effective risk mitigation measures is implemented in the project, it is highly likely that the application will not be approved.

[5] Article 1 of the *HGR Regulations*.

Trap three: insufficient research capabilities of the collaborating parties

Another key focus during the review and approval of HGR projects is the foundation and capability of the collaborating parties to conduct relevant research. If the necessity and reasons for the collaboration are not sufficient, or if the collaborating parties do not have sufficient personnel, technologies, equipment, or HGR materials and information related to the proposed research project, it may be difficult for the corresponding project to obtain an approval.

For example, if a Chinese research institution wants to collaborate with a foreign pharmaceutical company specializing in cardiovascular drugs to conduct a study on mental illness, but the Chinese institution fails to provide sufficient explanation of the foreign partner's research capabilities in the field of mental illness, the regulatory authority is likely to consider whether the collaboration is unreasonable. Therefore, the research capabilities of the collaborating parties and the provision of relevant basic information are crucial for the project to be approved. The collaborating parties shall be able to demonstrate their research strength and resources in the relevant field to increase the chances of the project being approved smoothly.

Trap four: questionable source of the HGR

The legitimacy of the source of the HGR is also an important consideration in the review of HGR projects. If the source of the HGR to be used in the project is not legal, it is likely that the project will fail the review.

The applicant shall provide an explanation of the source of the HGR involved and the administrative procedures already completed (if applicable). If the applicant cannot prove the legitimacy of the source of the HGR, the project is likely to be denied by the regulatory authority.

Trap five: unreasonable HGR utilization plan, or the mismatch between the proposed utilization plan and the types and quantities of the HGR applied

During the review process of HGR projects, the regulatory authority will review the proposed utilization plans of the HGR involved, such as the international collaboration research plans, HGR collection plans, and HGR material export plans, to ensure that the utilization of the HGR is both reasonable and legitimate. The applicants must ensure the legitimacy, reasonableness, and consistency of the proposed plans to smoothly pass the review. Meanwhile, the applicants shall also ensure that the types and quantities of the HGR applied are consistent with the proposed plans when submitting their applications.

Specifically, the following issues regarding the utilization plans of HGR are likely to result in the project application being denied:

- Unclear or unreasonable description in the HGR utilization plan, or the inconsistency between the utilization plan and other project materials (such as the collaboration agreements).
- Unreasonable specifications, quantities, etc., of the HGR materials or information involved.
- Unclear, unreasonable, or even illegal research purposes reflected in the plan.
- Failure of the plan/solution to adhere to the established standards and guidelines set forth by the relevant professional field or industry.

In addition, the types and quantities of the HGR applied shall match the research plan. Otherwise, it may raise doubts from the regulatory authority regarding the scientificalness, reasonableness, and even the authenticity of the research plan. If the types of the HGR applied do not match the research plan, or if the quantities of the HGR applied are excessive or insufficient, it may lead to delays in the review process or even the rejection of the applications.

Trap six: unclear or unreasonable disposal arrangements for the remaining HGR

The regulatory authority pays special attention to the entire lifecycle of HGR utilization to maximize the safety of the HGR, ensuring the implementation of research ethics, subject rights, and social responsibility.

Therefore, the proper arrangement and disposal of the remaining HGR is crucial. If the disposal arrangements for the remaining HGR are not clearly and reasonably outlined in the plan, or if there are inconsistencies in the disposal arrangements for the remaining HGR in the application materials, the project may fail to get an approval. For the applicants, it is crucial to develop a clear and reasonable plan for the disposal of the remaining HGR in advance, and to clearly describe such plan in the application materials for the smooth approval of the project.

Trap seven: unclear or incomplete arrangements in the collaboration agreements

The application materials also include the agreements between the collaborating parties, which may include international collaboration agreements as well as agreements related to the collection, transportation, testing, and disposal of the HGR. In the collaboration agreements, the clarity of the relationship between the collaborating parties and their division of work, and the completeness of the agreement are all key points of the review.

In practice, if there are disagreements between the collaborating parties regarding their division of work, the parties need to reach a consensus on the solution to such disagreements before the final submission of the application, and such consensus shall be clearly reflected in the submitted agreements. For example, a university biotechnology research institute plans to collaborate with a US pharmaceutical company on an international scientific research project involving Chinese HGR. During the drafting of the collaboration agreement, the two parties disagreed on the selection of the sample transportation provider and testing site. After negotiation, the two parties reached an agreement on the specific division of work for sample transportation and testing, and this agreement was clearly recorded in the collaboration agreement, providing a solid foundation for the smooth application and approval of the project.

Trap eight: failure to obtain compliant informed consent according to law

According to Chinese laws and regulations, a written informed consent of the individual shall be obtained for the collection, biobanking, utilization, and external provision of HGR of China to protect the individual's legal rights and interests[6]. Applicants shall ensure that the informed consent form, a common and important document in project ethics review and regulatory procedures, fully complies with the relevant

[6] Article 9 of the *HGR Regulations*, Article 9 of the *Implementation Rules*.

regulations. If necessary, the informed consent forms may need to be modified and the informed consent of the individual shall be obtained again.

In practice, the utilization of an informed consent form (ICF) that does not fully comply with the relevant regulations poses significant risks to the overall application process. In certain projects, for example, the individuals are simply informed that their genetic resources will be used for clinical diagnosis, yet not informed that the same may be used for research activities other than clinical diagnosis. Similarly, some informed consent forms fail to disclose that the genetic materials or data may be sent abroad for testing or research, resulting in failure for the project to pass ethics review and regulatory procedures.

Trap nine: lack of legal and valid ethics review approval, or inconsistency between application materials and ethics review approval

The collection, biobanking, utilization, and external provision of HGR shall comply with ethical principles and undergo ethics review[7]. Ethics review is usually conducted by the ethics (review) committee of the medical institution involved in the project. Obtaining an ethics review approval is a prerequisite "checkpoint" for HGR projects and is also an important document to be reviewed by regulatory authority.

In practice, there are situations where the project may be rejected in obtaining ethics review approvals, causing delays in the progress of HGR project. For example, the ethics review approval may be expired or invalid at the time of application; the composition and number of the ethics committee may fail to meet the required standards; the information in the ethics review approval may be inconsistent with that of other project materials such as protocols or informed consent forms; the version of the ethics review approval submitted is not be the final version.

Trap ten: incompliance with legal requirements regarding IP ownership

In terms of HGR international scientific research collaboration projects, the ownership of IPR have always drawn close attention from and have been scrutinized by the regulatory authority. The laws and regulations clearly stipulate that, the corresponding patent rights shall be jointly owned by the collaborating parties if any Chinese HGR is used in the international scientific research collaboration; and the right to use, transfer rights, and arrangements for sharing the benefits of other scientific and technological outcomes shall be agreed upon by the collaborating parties through a collaboration agreement[8]. Furthermore, provincial regulatory authorities are specifically required to supervise and inspect the arrangements of IPR and benefit-sharing of these projects[9].

Therefore, it is necessary to stipulate that any patent right generated from HGR international scientific research collaboration projects shall be jointly owned by the collaborating parties; otherwise, the projects may not be approved. However, in practice, there are different approaches regarding the specific distribution of benefits of patent rights and other project outcomes. Based on our experience, many projects that consider multiple factors and make separate arrangements for economic benefits have also

[7] Article 9 of the *HGR Regulations*.

[8] Article 24 of the *HGR Regulations*.

[9] Article 56 of the *Implementation Rules*.

been approved by the regulatory authorities. During the application process, it is important to pay special attention to the rationality of the allocation plan of IPR and ensure consistency between the provisions in the collaboration agreement and the application materials regarding IPR ownership and distribution.

Conclusion

In terms of HGR regulation, the companies always find it of challenges as well as opportunities, and it is crucial to understand and address various issues concerning the review procedures. This article aims to summarize common issues the companies may encounter in the regulatory authorities' review procedures of HGR projects, facilitating practitioners better comply with regulatory requirements. In addition, with shift in HGR regulatory authorities and the buildup of regulatory experience, regulatory requirements may also be adapted through amending HGR rules such as the *Implementation Rules*. We will closely monitor the latest regulatory trends and share our latest insights with the industry to facilitate the review progress of HGR projects in China and promote the development of life sciences.

2. Overview: 2022–2023 China Drug & Medical Device Annual Report[10]

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China's National Medical Products Administration (NMPA) released the 2023 Drug Review Annual Report on its official website on February 4, 2024, closely followed by the 2023 Medical Device Registration Annual Report on February 5. According to the public information, more than 60 innovative drugs have been approved by NMPA from 2022 to 2023, and a total of 61 innovative medical devices have been approved in 2023. China has been making steady progress in research and development of innovative drugs and medical devices.

By observing each year's drug review reports and medical device registration reports, we can visualize the outstanding achievements of China's regulatory authorities on medical products, which may help us to take a closer look at the development dynamics of China's pharmaceutical industry.

In previous articles, we have made a comprehensive analysis of the drug review annual reports from 2015 to 2021 (See *Overview of China Drug Review Annual Report (2015–2021)*). In this article, we will analyze the following 2022–2023 drug review reports and the 2023 medical device registration report and select some of the highlights of these reports to observe the major development and achievements of China's drug and medical device regulation activities in the past two years.

The number of registration applications has increased from year to year

I. Drugs

From 2022 to 2023, the number of drug registration applications filed in China has increased year by year. In 2022, the Center for Drug Evaluation (CDE) accepted 12,368 applications. In 2023, the total number of applications has reached 18,503, increasing by 35.84% compared to that in 2022.

Among all drug registration applications, chemical drugs have always been the category at the largest proportion, reaching 74.66% in 2023. However, the number of registration applications for Class 5.1 chemical drugs (i.e., innovator drugs and modified drugs that have been approved to market overseas and are under application to be marketed in China) in 2023 has decreased compared to that of previous years.

The number of registration applications for biological products experienced a slight decrease in 2022 but rebounded in 2023, reflecting the overall trend of continuous development and innovation in China's biological products industry. With the rapid development of modern biotechnology, biological products are consistently achieving innovative breakthroughs. In recent years, the vigorous development of ADC drugs, RDC drugs, mRNA drugs, as well as cellular and gene therapy (CGT)

[10] For the Chinese version, please click *60 余款创新药获批：2022–2023 年度中国药品审评报告亮点解读* and *61 款创新医疗器械获批：2023 年度中国医疗器械注册工作报告亮点解读*.

[11] Shuwen Sun have contributions to this article.

products such as CAR-T/NK/TIL, among others, has brought forth optimism within the pharmaceutical industry.

II. Medical devices

In 2023, the total number of registration applications for medical devices has increased by 25.4% compared to that in 2022. Among them, in terms of medical device classification, NMPA accepted 7,106 domestic Class III medical device registration applications and 6,154 imported medical device registration applications (including 3,036 Class II medical devices and 3,118 Class III medical devices). In terms of product varieties, there were 9,968 medical device registration applications and 3,292 in vitro diagnostic reagents (IVD reagents) registration applications. Registration applications for IVD reagents constituted 24.80% of all applications in 2023, marking a significant growth in both quantity and percentage compared to those in 2022.

The completion of application review is rising steadily

I. Drugs

According to the 2022 Drug Review Annual Report, there was a decline in the number of completed application reviews in 2022 compared to those of previous years. This decrease was mainly attributed to the widespread disruption of drug research and development activities resulting from the COVID-19 pandemic, which also led to the impact on the progress of the review and approval of the drugs.

Fortunately, the year 2023 witnessed a rebound in the number of completed application reviews, with a total of 15,713 completed applications, reaching the highest among recent years.

II. Medical devices

In 2023, NMPA approved a total of 12,213 applications for medical device registrations, marking a 2.3% rise from 2022. Among the approved registrations, in terms of medical device classification, 6,151 were domestic Class III medical devices and 6,062 were imported medical devices (comprising 2,947 Class II medical devices and 3,115 Class III medical devices). The approval rate for imported medical devices witnessed a 3% decrease compared to that of 2022. In terms of product varieties, 9,130 medical device registration applications were approved, and 3,083 IVD reagent registration applications were approved. Approvals of IVD reagents have increased in both quantity and percentage compared to those in 2022.

Various pathways accelerate the marketing of innovative and high-quality products

I. Drugs

In 2022–2023, CDE continued to shorten the time for drug development and review by implementing various accelerated procedures for drug registration, facilitating the marketing of more innovative and high-quality products while broadening treatment options available to patients. It is worth mentioning that the accelerated procedures have played an obvious role in the marketing of innovative drugs:

among the 40 innovative drugs approved in 2023, 9 of them were approved through the priority review and approval procedure, 13 obtained conditional marketing approval, and 8 were incorporated into the breakthrough therapy drug procedure during the clinical research stage. The drugs registered and approved through the above pathways are mainly antitumor drugs.

In China, various accelerated pathways for drug marketing registration include:

Pathway	Legal basis	Applicable scope
Breakthrough therapy drug procedure	Articles 59–62 of the *Provisions for Drug Registration* The *Working Procedures for Review of Breakthrough Therapy Drugs (Interim)*	During clinical trials, the applicant may apply for the breakthrough therapy drug procedure for innovative drugs or modified new drugs used for the prevention and treatment of serious life-threatening diseases or diseases that seriously affect the quality of life but without effective means of prevention and treatment available, or that have significant clinical advantage over current treatments with sufficient evidence demonstrated.
Conditional approval procedure	Articles 63–67 of the *Provisions for Drug Registration* The *Working Procedures for Review and Approval of Applications for Conditional Approval of Drug Marketing (Interim)*	■ Drugs used for treating serious life-threatening diseases but without effective treatment available, whose efficacy has been verified by data in drug clinical trials and whose clinical values can be predicted; ■ Drugs that are urgently needed for public health, whose efficacy has been demonstrated by data in drug clinical trials and whose clinical values can be predicted; ■ Vaccines urgently needed in response to critical public health emergencies or urgently needed as identified by the National Health Commission, whose benefits outweigh risks as evaluated.
Priority review and approval procedure	Articles 68–71 of the *Provisions for Drug Registration* The *Working Procedures for Priority Review and Approval of Drug Marketing Authorization (Interim)*	■ Drugs in short supply with urgent clinical needs, innovative drugs and modified new drugs for the prevention and treatment of major infectious diseases or rare diseases; ■ New product types, dosage forms and specifications of pediatric drugs complying with the pediatric physiological characteristics; ■ Vaccines and innovative vaccines urgently needed for disease prevention and control; ■ Drugs included in the breakthrough therapy drug procedure; ■ Drugs complying with the criteria of the conditional approval procedure; ■ Other circumstances of priority review and

Pathway	Legal basis	Applicable scope
		approval specified by the NMPA.

II. Medical devices

In 2023, NMPA received 466 applications for the special review procedure for innovative medical devices, marking an increase of 35.9% compared to the number in 2022. Among them, 69 applications were accepted by the special procedures.

China has set up a number of accelerated pathways for various medical device products, such as the special review procedure for innovative medical devices, the priority registration procedure and the emergency registration procedure. These pathways have played an important role in accelerating the marketing of innovative and high-quality products to meet the multifaceted needs of patients.

Pathway	Legal basis	Applicable scope
Special review procedure for innovative medical devices	Articles 68–72 of the *Provisions for Medical Device Registration and Filing* Articles 67–71 of the *Provisions for In-vitro Diagnostic Reagent Registration and Filing* *Special Review Procedures of Innovative Medical Devices*	■ The applicant, through technological innovation activities led by him/her, holds the patent right to the invention of the core technology of the product in China in accordance with laws, or has obtained the patent right to or the license to use the invention in China through transfer in accordance with laws, and the application for special review procedure for innovative medical devices is within five years from the date of announcement of the patent grant; or the application for the patent of the invention of the core technology has been made public by the patent administration department of the State Council, and a patent search report has been issued by the State Intellectual Property Office Patent Search and Consultation Center stating that the core technical solution of the product has novelty and inventiveness; ■ The applicant has completed preliminary research on the product and has a basic finalized product, the research process is authentic and controllable, and the research data are complete and traceable; ■ The main working principle or functional mechanism of a product is the first of its kind in China, and the product performance or safety has radical improvement compared with similar products, the product is in the international leading level technically, and has significant value in clinical application.
Priority	Articles 73–75 of the	■ Medical devices that can diagnose or treat rare

Pathway	Legal basis	Applicable scope
registration procedure	*Provisions for Medical Device Registration and Filing* Articles 72–74 of the *Provisions for In-vitro Diagnostic Reagent Registration and Filing* The *Priority Registration Procedure of Medical Devices*	diseases and malignant tumors and have obvious clinical advantages; medical devices that can diagnose or treat unique and multiple diseases of the elderly without effective diagnosis or treatment method at present; medical devices used for children with obvious clinical advantages; or are in urgent clinical need and for which no registration has been approved for products of the same kind in China; ■ Medical devices that have been listed in the National Major Science and Technology Project or National Key Research and Development Plan; ■ Other medical devices subject to priority registration procedures as stipulated by the NMPA.
Emergency registration procedure	Articles 76–78 of the *Provisions for Medical Device Registration and Filing* Articles 75–77 of the *Provisions for In-vitro Diagnostic Reagent Registration and Filing* The *Emergency Registration Procedure of Medical Devices*	Medical devices that are required for public health emergencies and for which no similar products of the same kind have been marketed in China, or for which similar products of the same kind have been marketed in China but its supply cannot meet the needs for emergency treatment of public health emergencies.

The development and marketing of innovative products are supported and encouraged

I. Drugs

Since the reform of the review and approval system for drugs and medical devices, China has been attaching great importance to encouraging innovative development in the field of pharmaceuticals and has formulated numerous policies to support and encourage more innovative drugs to be developed and registered. Due to the support from regulatory policies, the research and development of innovative drugs in China has been very active in recent years. From 2022 to 2023, the number of applications and approvals for innovative drugs including traditional Chinese medicines, chemical drugs, and biological products has increased by varying degrees. For example, the number of NDA applications and approvals for innovative chemical drugs has increased by 172.41% and 123.53% respectively, while the number of NDA applications and approvals for innovative therapeutic biological products has increased by 136.84% and 111.11% respectively.

II. Medical devices

In 2023, China's innovative medical devices have made significant progress in terms of both quantity and quality. As mentioned above, NMPA received 466 applications for the special review procedure for innovative medical devices in 2023, and 69 applications were accepted to enter the special review procedure. It has also been mentioned in the annual report that a total of 6l innovative medical devices were approved by the NMPA in 2023, increasing by nearly 11% from 2022. High-end medical devices such as active surgical devices, passive implantable devices, medical software, medical imaging devices, and radiation therapy devices are among the top five category in number of approved innovative medical devices.

While the quantity is increasing, the quality of China's innovative medical devices is also improving. A number of innovative medical devices have reached the international leading level, effectively meeting the public's demand for high-end medical devices.

NMPA is striving to meet the patients' multifaceted medication needs

In each year's drug review annual reports, NMPA has consistently paid great attention to special products such as drugs for pediatric use and orphan drugs, of which China has made significant progress in the review and approval procedures in recent years.

I. Drugs in short supply

In 2020, China issued the National List of Drugs in Short Supply for the purpose of solving the problem of shortages on the supply side of drugs and guarantee a more stable supply of drugs. It is provided in the 2023 Drug Review Annual Report that CDE recommended the approval of a total of 82 drugs on the National List of Drugs in Short Supply in 2023, an increase of 310% compared with that of 2022.

II. Drugs for pediatric use

From 2019 to 2023, the number of approvals for drugs for pediatric use has been increasing year by year. In 2023, 92 drug varieties were approved, including 72 for marketing authorization and 20 with extended indications for children.

Since 2016, China has formulated four batches of lists of drugs for children to promote the development and registration of the varieties, dosage forms and specifications suitable for children. From 2022 to 2023, CDE has together recommended the approval of 22 generic drugs on the above-mentioned list. In the past five years, China has cumulatively recommended the approval of 45 generic drugs on the list, fulfilling the needs of pediatric patients in various aspects.

III. Orphan drugs

In 2023, a total of 45 drug varieties for rare diseases were approved for marketing in China, of which 15 varieties (33.3%) were accelerated through the priority review and approval procedure and one product was approved for marketing through the conditional approval procedure. CDE's priority review resources have been tilted towards the registration applications of orphan drugs year by year.

IV. CGT products

In recent years, China's biomedical technology has experienced rapid growth with new breakthroughs. The new generation of therapies represented by cell therapy and gene therapy is maturing. In 2023, China approved three CAR-T cell therapy products, including the conditional market approval of the Equecabtagene Autoleucel Injection and the Inaticabtagene Autoleucel Injection, and the conditional approval for the addition of new indications to Axicabtagene Ciloleucel Injection.

CDE also issued a number of guidelines and documents related to the development of the CGT products in 2023 in order to better guide the research and registration of the CGT products.

It is worth noting that China's National Health Commission has also been actively exploring the regulatory models for CAR-T/NK and other somatic cell therapies in recent years. On August 18, 2023, the China Medicinal Biotech Association (CMBA), commissioned by the National Health Commission, issued the *Guidelines for the Somatic Cell Clinical Research (for Trial Implementation)*, which provides the industry with compliance guidelines to continuously explore and develop cell therapy technology.

Policies and applications of real-world research have further developed

In recent years, in order to accelerate the marketing of innovative drugs and medical devices, China has been exploring the policy of applying real-world data in the market registration of drugs and medical devices. A number of related guidelines have been issued and implemented.

In 2019, China launched a pilot project on the application of clinical real-world data in the Hainan Boao Lecheng International Medical Tourism Pilot Zone, demonstrating China's attempts in the field of drug and medical device regulation. The pilot project has achieved remarkable results. To date, four drugs and nine medical devices have been approved through the pilot project, benefiting more and more patients.

Regulatory guideline system becomes more mature

I. Drugs

In the process of drug development and registration application, the applicants often need to communicate and discuss with CDE on the specific requirements of the development of the products. Conducting communication meetings with the applicants is an important measure for CDE to guide and serve the applicants.

In 2023, CDE received a total of 5,912 requests for communication meetings, increasing by 20.06% compared to that of 2022, and CDE cumulatively provided communication services to l,607 enterprises. Communication meetings are becoming more and more common as a bridge of communication between the applicants and the regulatory authorities, and the services provided by the regulatory authorities are becoming increasingly adequate.

In addition, to better guide the development and registration activities of the applicants, CDE has formulated and issued respectively 61 and 60 new technical guidelines in 2022 and 2023. Up to now,

the cumulative number of drug-related technical guidelines issued by CDE has reached 482. The guidelines issued in recent years cover a wide range of contents, including the evaluation system of CGT technology, the policies regarding real-world research, and other aspects, focusing on international cutting-edge technology areas to promote the integration of China's guideline system with the international advanced technology standards.

II. Medical devices

In 2023, CMDE issued a total of 67 guidelines and 6 review points, bringing the number of active guidelines to 613. The issuance of a large number of guidelines helps to continuously promote the standardization of the research and development activities and the review activities.

Summary

Looking back at the drug and medical device review and approval activities in China in 2022–2023, it can be found that over the years China's reform of the review and approval system has achieved remarkable results. From the perspective of product development, the quantity and quality of products for market registration have been substantially improved in recent years. From the perspective of product regulation, the review and approval activities by the regulatory authorities have become more standardized, organized and efficient, better catering to the needs of applicants. A mature regulatory system will escort the development and marketing of more innovative, high-quality products, and the common progress of technology and regulatory system will combine to promote the vigorous development of China's pharmaceutical industry, so that more patients can enjoy more products with better quality.

Important Announcement

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