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Release and impact of China's "Second List of Rare Diseases"

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SUMMARY On September 18, 2023, the National Health Commission of China officially announced the "Second List of Rare Diseases". This list of 86 rare diseases, drafted in accordance with the "Working Procedures for Drafting the List of Rare Diseases", marks the second release of a rare disease list since the initial list was issued in May 2018. Following the release of the first batch, the Chinese Government introduced various policies to enhance the diagnosis and treatment of rare diseases, to promote the research on, development of, production of, and availability of rare disease medications in China, and to improve medication access for patients with rare diseases. Consequently, this has elevated the level of rare disease diagnosis and treatment, ensuring greater accessibility to treatment for affected individuals. The expansion of the rare disease list through the release of the "Second List of Rare Diseases" will further enhance rare disease management, increase awareness, improve diagnosis and treatment, facilitate the development and availability of more rare disease medications, establish a comprehensive support system for patients with rare diseases, and ultimately benefit a larger number of individuals affected by rare diseases. The definition of rare diseases in China should be refined by explicitly establishing corresponding criteria based on incidence, prevalence, or the number of affected individuals. Additionally, the mechanism for removal of diseases from rare disease lists should be enhanced, and prompt adjustments should be made regarding diseases that do not align with the selection principles of the list, taking into consideration environmental changes.

Keywords rare diseases, China, disease list, health policy, definition

1. Introduction

On September 18, 2023, six departments in China, including the National Health Commission, the Ministry of Science and Technology, the Ministry of Industry and Information Technology, the National Medical Products Administration, the National Administration of Traditional Chinese Medicine, and the Logistics Support Department of the Central Military Commission, jointly released the "Second List of Rare Diseases". This list includes a total of 86 rare diseases (*1*), such as acromegaly, narcolepsy, beta-thalassemia major, neuroblastoma, and clear cell sarcoma of the kidney. It covers 17 medical specialties, primarily including hematology, dermatology, rheumatology and immunology, pediatrics, neurology, and endocrinology. Combined with the 121 rare diseases listed in the "First List of Rare Diseases" released in May 2018, the current list of rare diseases in China now has 207 rare diseases (*2*) (Tables 1 and 2). In comparison to the "First List of Rare Diseases", the diseases included in the "Second List of Rare Diseases" are associated with either marketed or investigational drugs, thus emphasizing the significant principle of "treatable with medicine". Moreover, a point worth noting is that, similar to the first list, the National Healthcare Security Administration is still not identified as the issuing body in the second list. Internationally, rare diseases are typically defined based on their prevalence or the number of affected individuals. China's efforts in rare disease-related work have been relatively delayed, and there is a scarcity of epidemiological data on rare diseases. Given this context, the approach of recognizing and managing rare diseases through a list aligns with the country's specific circumstances.

2. Procedures for the drafting of the "Second List of Rare Diseases"

The drafting of the "Second List of Rare Diseases" takes into account national conditions in China, including economic development, population dynamics, and social security levels. It also draws upon the management

Table 1. "First List of Rare Diseases" in China (2018)

No.	Diseases	No.	Diseases
1	21-Hydroxyulase deficiency	61	Laron syndrome
2	Albinism	62	Leber hereditary optic neuropathy
3	Alport syndrome	63	Long chain 3-hydroxyacyl-CoA dehydrogenase deficiency
4	Amyotrophic lateral sclerosis	64	Lymphangioleiomyomatosis (LAM)
5	Angelman syndrome	65	Lysine urinary protein intolerance
6	Arginase deficiency	66	Lysosomal acid lipase deficiency
7	Asphyxiating thoracic dystrophy (Jeune syndrome)	67	Maple syrup urine disease
8	Atypical hemolytic uremic syndrome	68	Marfan syndrome
9	Autoimmune encephalitis	69	McCune-Albright syndrome
10	Autoimmune hypophysitis	70	Medium chain Acyl-CoA dehydrogenase deficiency
11	Autoimmune insulin receptopathy (type B insulin resistance)	71	Methylmalonic acidemia
12	Beta-ketothiolase deficiency	72	Mitochondrial encephalomyopathy
13	Biotinidase deficiency	73	Mucopolysaccharidosis
14	Cardiac ion channelopathies	74	Multi-focal motor neuropathy
15	Carnitine deficiency	75	Multiple Acyl-CoA dehydrogenase deficiency
16	Castleman disease	76	Multiple sclerosis
17	Charcot-Marie-Tooth disease	77	Multiple system atrophy
18	Citrullinemia	78	Myotonic dystrophy
19	Congenital adrenal hypoplasia	79	NAGS deficiency
20	Congenital hyperinsulinemic hypoglycemia	80	Neonatal diabetes mellitus
21	Congenital myasthenic syndrome	81	Neuromyelitis optica
22	Congenital myotonia syndrome (non-dystrophic myotonia, NDM)	82	Niemann-Pick disease
23	Congenital scoliosis	83	Non-syndromic deafness
24	Coronary artery ectasia	84	Noonan syndrome
25	Diamond-Blackfan anemia	85	Ornithine transcarbamylase deficiency
26	Erdheim-Chester disease	86	Osteogenesis imperfecta (brittle bone disease)
27	Fabry disease	87	Parkinson disease (young-onset, early-onset)
28	Familial Mediterranean fever	88	Paroxysmal nocturnal hemoglobinuria
29	Fanconi anemia	89	Peutz-Jeghers syndrome
30	Galactosemia	90	Phenylketonuria
31	Gaucher's disease	91	POEMS syndrome
32	General myasthenia gravis	92	Porphyria
33	Gitelman syndrome	93	Prader-Willi syndrome
34	Glutaric acidemia type I	94	Primary combined immune deficiency
35	Glycogen storage disease (type I, II)	95	Primary hereditary dystonia
36	Hemophilia	96	Primary light chain amyloidosis
37	Hepatolenticular degeneration (Wilson disease)	97	Progressive familial intrahepatic cholestasis
38	Hereditary angioedema (HAE)	98	Progressive muscular dystrophies
39	Hereditary epidermolysis bullosa	99	Propionic acidemia
40	Hereditary fructose intolerance	100	Pulmonary alveolar proteinosis
41	Hereditary hypomagnesemia	101	Pulmonary cystic fibrosis
42	Hereditary multi-infarct dementia (cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy, CADASIL)	102	Retinitis pigmentosa
		103	Retinoblastoma
		104	Severe congenital neutropenia
43	Hereditary spastic paraplegia	105	Severe myoclonic epilepsy in infancy (Dravet syndrome)
44	Holocarboxylase synthetase deficiency	106	Sickle cell disease
45	Homocysteinemia	107	Silver-Russell syndrome
46	Homozygous hypercholesterolemia	108	Sitosterolemia
47	Huntington disease	109	Spinal and bulbar muscular atrophy (Kennedy disease)
48	Hyperornithinaemia-hyperammoniaemia-homocitrullinuria syndrome	110	Spinal muscular atrophy
49	Hyperphenylalaninemia	111	Spinocerebellar ataxia
50	Hypophosphatasia	112	Systemic sclerosis
51	Hypophosphatemia rickets	113	Tetrahydrobiopterin deficiency
52	Idiopathic cardiomyopathy	114	Tuberous sclerosis complex
53	Idiopathic hypogonadotropic hypogonadism	115	Tyrosinemia
54	Idiopathic pulmonary arterial hypertension	116	Very long chain Acyl-CoA dehydrogenase deficiency
55	Idiopathic pulmonary fibrosis	117	Williams syndrome
56	IgG4-related disease	118	Wiskott-Aldrich syndrome
57	Inborn errors of bile acid synthesis	119	X-linked agammaglobulinemia
58	Isovaleric acidemia	120	X-linked adrenoleukodystrophy
59	Kallmann syndrome	121	X-linked lymphoproliferative disease
60	Langerhans cell histiocytosis		

experience of countries or regions with similar levels of social development. Spearheaded by the National Health Commission of China, the drafting of the List follows the guidelines outlined in the "Working Procedures for Drafting the List of Rare Diseases" issued by the National Health Commission in 2018. The National Health Commission oversees the Expert Committee on Diagnosis and Treatment of and Ensured Care for Rare Diseases (hereinafter referred to as the Expert Committee) and its corresponding office. The Expert Committee provides technical support and policy recommendations, while the office is responsible for day-to-day tasks such as receiving, collating, and organizing application materials for rare diseases.

Table 2. "Second List of Rare Diseases" in China (2023)

No.	Diseases	No.	Diseases
1	Achondroplasia	44	Lennox-Gastaut syndrome
2	Acquired hemophilia	45	Limbal stem cell deficiency
3	Acromegaly	46	Malignant hyperthermia
4	Adult-onset Still disease	47	Malignant pleural mesothelioma
5	Alagille syndrome	48	Melanoma
6	Alpha-1-antitrypsin deficiency	49	Metachromatic leukodystrophy
7	ANCA-associated vasculitis	50	Monogenic non-syndromic obesity
8	Bardet-Biedl syndrome	51	Multiple endocrine neoplasia
9	Behçet's disease	52	Narcolepsy
10	Blue rubber bleb nevus	53	Neuroblastoma
11	CDKL5 deficiency disorder	54	Neurofibromatosis
12	Choroideremia	55	Neuronal ceroid lipofuscinosis
13	Chronic inflammatory demyelinating polyneuropathy	56	Neurotrophic keratitis
14	Clear cell sarcoma of kidney	57	Osteosarcoma
15	Cold agglutinin disease	58	Pemphigus
16	Congenital biliary atresia	59	Persistent pulmonary hypertension of the newborn
17	Congenital factor VII deficiency	60	Pheochromocytoma
18	Cryopyrin-associated periodic syndrome/NLRP3-associated systemic autoinflammatory disease	61	PIK3CA-related overgrowth syndrome
		62	Polycythaemia vera
19	Cutaneous neuroendocrine carcinoma (Merkel cell carcinoma)	63	Primary biliary cholangitis
20	Cutaneous T-cell lymphomas	64	Primary growth hormone deficiency
21	Cystinosis	65	Primary IGF1 deficiency
22	Dermatofibrosarcoma protuberans	66	Primary immunodeficiency
23	Eosinophilic gastroenteritis	67	Primary myelofibrosis
24	Epithelioid sarcoma	68	Primary sclerosing cholangitis
25	Facioscapulohumeral muscular dystrophy	69	Progressive fibrosing interstitial lung disease
26	Familial hemophagocytic lymphohistiocytosis	70	Recurrent pericarditis
27	Familial adenomatous polyposis	71	Retinopathy of prematurity
28	Fibrodysplasia ossificans progressiva	72	Rett syndrome
29	Fragile X syndrome	73	Short bowel syndrome
30	Gangliosidosis	74	Systemic juvenile idiopathic arthritis
31	Gastroenteropancreatic neuroendocrine neoplasm	75	Systemic mastocytosis
32	Gastrointestinal stromal tumor	76	Takayasu arteritis
33	Generalized pustular psoriasis	77	Tenosynovial giant cell tumor/Pigmented villonodular synovitis
34	Genetic hypoparathyroidism	78	Thalassemia major
35	Giant cell arteritis	79	Thrombotic thrombocytopenic purpura
36	Giant cell tumor of bone	80	Transthyretin amyloidosis
37	Glanzmann thrombasthenia	81	Tumor necrosis factor receptor associated periodic syndrome
38	Glioblastoma	82	Tumor-induced osteomalacia
39	Gorlin syndrome	83	Von Hippel-Lindau syndrome
40	Hidradenitis suppurativa	84	Von Willebrand disease type3
41	Hutchinson-Gilford progeria syndrome	85	Waldenström macroglobulinemia/ Lymphoplasmacytic lymphoma
42	Inflammatory myofibroblastic tumor	86	West syndrome/Infantile spasms syndrome
43	Leber congenital amaurosis		

The application process for adding categories encompasses six stages: preparation of application materials, submission of materials, verification of information, research and demonstrations, solicitation of opinions, and final determination and publication of the list (see Figure 1 for a detailed overview). Applications to include disease categories in the list are made by provincial health administrative departments, national industry associations or societies, and registered civil organizations under the Ministry of Civil Affairs. The selection principle is based on evidence from both domestic and international sources, indicating a low incidence or prevalence, significant harm to patients and their families, clear methods of diagnosis, affordability of treatment or intervention measures, or the absence of an effective treatment or intervention measures, but inclusion in national research projects. Following deliberations by the Expert Committee, a preliminary list is drafted and widely circulated for public input. After considering the feedback, the final list is determined and subsequently issued by the National Health Commission (*3*). In accordance with the requirements outlined in the "Working Procedures for Drafting the List of Rare Diseases" the update cycle for the "List of Rare Diseases" in China is generally set at a minimum of two years. Five years have passed since the release of the first list of rare diseases in China, and the second batch is now being issued.

3. The impact of the list of rare diseases

The publication of the "First List of Rare Diseases" has provided a crucial reference for relevant departments to undertake rare disease-related work. With the release of this list, numerous complementary policies have been introduced by the National Health Commission, the National Medical Products Administration, the National Medical Insurance Administration, and other pertinent agencies. These policies aim to enhance the diagnostic and treatment of rare diseases in China, safeguard the

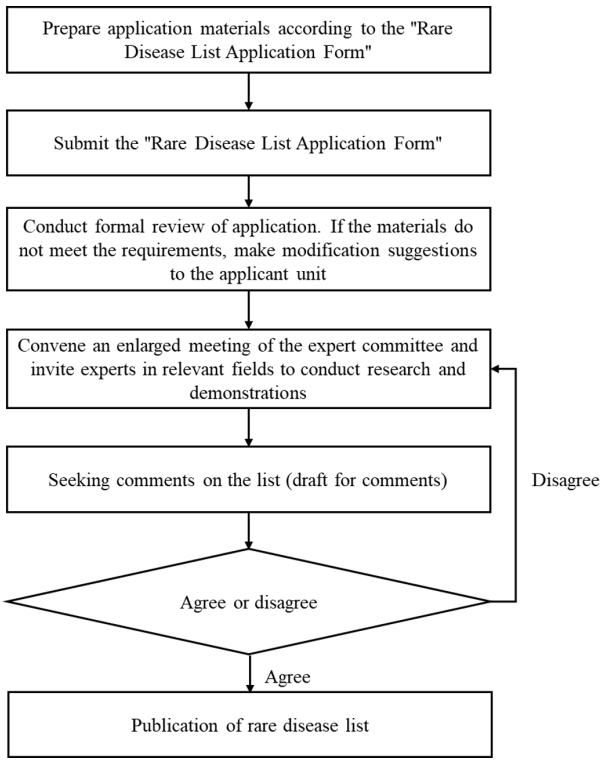

Figure 1. Application process for adding rare disease categories to the list

rights and interests of patients, improve the accessibility of treatment options, and foster the comprehensive development of the rare disease field.

3.1. Driving the enhancement of rare disease diagnosis and treatment capacity in China

In terms of promoting the improvement of diagnosis and treatment capabilities for rare diseases in China, in 2019, the release of the "First List of Rare Diseases" in China led to the release of the "Rare Disease Diagnosis and Treatment Guidelines (2019 Edition)", providing a solid foundation for rare disease diagnosis and treatment (*4*). In February 2019, the National Health Commission issued a notice to establish a national rare disease diagnosis and treatment collaboration network. This initiative involved the selection of 324 hospitals (1 national leading hospital, 32 provincial leading hospitals, and 291 member hospitals in the collaborative network) across the country with strong capabilities in rare disease diagnosis and treatment and a substantial number of cases, forming a collaborative network (*5*). The primary objective of this network is to provide concentrated diagnosis and treatment for patients with rare diseases and facilitate two-way referrals. The aim is to enhance the comprehensive diagnosis and treatment capabilities for rare diseases in China using quality medical resources. In October 2019, Peking Union Medical College Hospital was entrusted by the National Health Commission to develop the "China Rare Disease Diagnosis and Treatment Service Information System". This system requires hospitals in the collaborative network to promptly report information on patients they see with rare diseases from the first list of rare diseases (*6*). By collecting data on the diagnosis, distribution, and other relevant information regarding rare diseases in China, this system aims to provide scientific evidence for the formulation of population intervention strategies, improvement of the diagnosis and treatment system, and enhancement of drug accessibility. In February 2020, The National Rare Disease Diagnosis and Treatment Collaboration Network Office was officially established at Peking Union Medical College Hospital in Beijing (*7*). Additionally, in November 2020, the National Health Commission entrusted Peking Union Medical College Hospital to establish a national-level rare disease quality control center. The center focuses on implementing standardized diagnosis and treatment quality control measures for rare diseases, with the goal of improving the level of rare disease care. The implementation of a series of policies has resulted in continuous improvements in the level and standardization of rare disease diagnosis and treatment in China. Nevertheless, the rare disease diagnosis and treatment system in China is still in its early stages.

3.2. Encouraging the development and market approval of rare disease drugs in China

In terms of encouraging the research, production, and market launch of rare disease drugs in China, promoting the development and availability of drugs for rare diseases in China has been a priority for various government departments, including the National Medical Products Administration, the Ministry of Science and Technology, and the Ministry of Finance. These departments have implemented measures to expedite the evaluation and approval of rare disease drugs, enhance research and development efficiency, increase funding for research, and provide tax incentives (*8*). In October 2018, the National Medical Products Administration and the National Health Commission jointly established a special pathway for the evaluation and approval of urgently needed new drugs from overseas. This pathway focuses on new drugs for the treatment of rare diseases that have been approved in the United States, the European Union, or Japan but are not yet available in China, as well as drugs for severe life-threatening or life-impairing diseases without effective treatment options or with significant clinical advantages. A total of 40 rare disease drugs have been included in the three batches of lists issued through this pathway, and 26 of them have been approved for market (*9*). In January 2020, the revised "Drug Registration Management Measures" introduced a priority evaluation and approval process for innovative drugs and improved new drugs for the prevention and treatment of rare diseases with clear clinical value (*10*).

The evaluation and approval time limit for rare disease drugs within this priority scope is 130 days, with a shorter time limit of 70 days for urgently needed rare disease drugs that are already available overseas but not yet in China. This has expedited the evaluation process. In December 2020, the National Medical Products Administration issued the "Management Measures for Communication and Exchange during Drug Research and Technical Evaluation", which established a communication mechanism to improve research and development efficiency and accelerate the progress of rare disease drug development and availability. In May 2022, the "Regulations Implementing the Drug Administration Law of the People's Republic of China (Draft for Solicitation of Comments)" proposed a policy recommendation of a maximum market exclusivity period of 7 years to support the research and development of rare disease drugs. Additionally, the Ministry of Science and Technology has provided financial support through national research programs to advance rare disease research and development, with an investment of approximately 120 million yuan from the central government. The notice on the value-added tax policy for rare disease drugs, jointly issued by the National Medical Products Administration, the Ministry of Finance, the General Administration of Customs, and the State Taxation Administration, provides tax exemptions for these drugs (*11*). Over the past two years, the National Medical Products Administration has issued "Guiding Principles for Clinical Development of Orphan Drugs" and "Guiding Principles for Disease Natural History Study in the Development of Orphan Drugs" in order to better guide the research and development of orphan drugs. They have also sought opinions on "Guiding Principles for Statistical Guidance in Clinical Research of Orphan Drugs", "Guiding Principles for Clinical Trials of Gene Therapy Products for Rare Diseases", and "Guiding Principles for Non-clinical Research of Enzyme Replacement Therapy Drugs for Rare Diseases". As a result of these policy incentives, China has successfully launched 75 rare disease drugs (*12*) in accordance with the "First List of Rare Diseases", and at least 41 drugs have been launched domestically for the treatment of 29 rare diseases listed in the "Second List of Rare Diseases". These efforts have improved the accessibility of rare disease drugs for patients in China and addressed the challenges of accessing medication for patients with rare diseases.

3.3. Ensuring medical care for patients with rare diseases in China

In terms of ensuring medical care for patients with rare diseases, China has established a comprehensive medical insurance system that includes employee medical insurance, urban and rural resident medical insurance, supplementary enterprise medical insurance, and urban and rural medical assistance. The "First List of Rare Diseases" has already included over 50 out of the 75 rare disease drugs available in China, in the "National Basic Medical Insurance, Work-related Injury Insurance, and Maternity Insurance Drug List" (referred to as the "Medical Insurance Drug List") (*12*). Twenty-six drugs were included through a negotiation process, with an average price reduction of over 50%. This significantly lowered the prices of drugs for rare diseases, and especially some extremely expensive ones. It effectively alleviated the financial burden on patients, such as for the treatment of Fabry disease with agalsidase-α, spinal muscular atrophy (SMA) with nusinersen, and risdiplam. Moreover, the "Second List of Rare Diseases" has included three drugs in the medical insurance drug list, and multiple drugs have been submitted to the National Healthcare Security Administration for inclusion in the list. Additionally, the government has implemented a centralized procurement policy to include rare disease drugs, significantly reducing their prices. The drug Ambrisentan, used to treat idiopathic pulmonary arterial hypertension, has experienced a price drop from 115.97 yuan per tablet to 20 yuan per tablet through the national centralized procurement program. In provinces and cities where rare disease drugs are not covered by the medical insurance drug list, local models of coverage have been introduced, such as the rare disease drug special fund model in Zhejiang and Jiangsu provinces, and the "Hui Min Bao" commercial insurance model in many regions (*13*). China is also exploring the establishment of a multi-level insurance system, led by national medical insurance and shared with commercial insurance, charity, and medical assistance, to continuously improve the level of medical care for patients with rare diseases in the country.

4. Conclusion

The release of the "Second List of Rare Diseases" has expanded the scope of the rare disease list in China, providing a foundation for the implementation of future rare disease-related policies. This development will contribute to the strengthening of rare disease management in China, promoting greater awareness and enhancing the diagnosis and treatment of rare diseases. Additionally, it will facilitate the research on, development of, and availability of more rare disease drugs while establishing a robust system to safeguard the needs of patients with rare diseases and extend benefits to a larger population. An important point worth noting that while the procedures for drafting the list of rare diseases have outlined clear selection principles for rare diseases, the term "low incidence or prevalence" remains too ambiguous. The definition of rare diseases in China needs to be refined and specific criteria need to be established based on factors such as incidence, prevalence, or the number of affected individuals. The

definition of rare diseases and the list of rare diseases can coexist, with the former serving as a long-term strategic plan and the latter focusing on specific rare disease types and objectives within a defined timeframe. Additionally, a crucial step is to establish a mechanism for removing diseases from the list of rare diseases and promptly adjusting diseases that do not meet the list's selection principles based on changing circumstances.

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