RDPAC

中国外商投资企业协会药品研制和开发工作委员会
China Association of Enterprises with Foreign Investment
R&D-based Pharmaceutical Association Committee

CAEFI

Healthier China Through Innovation

Introduction to RDPAC

Established in 1999, the R&D-Based Pharmaceutical Association Committee (RDPAC), representing 47 leading multinational pharmaceutical companies with R&D capabilities, is a committee under the China Association of Enterprises with Foreign Investment (CAEFI), which in turn reports to the Ministry of Commerce of the People's Republic of China.

Through collaboration with key stakeholders to promote international cooperation and bridge communications between the government and the industry, RDPAC advocates sustainable policies that incentivize pharmaceutical innovation to ensure novel medicines benefit Chinese patients as early and as extensively as possible. It is dedicated to elevating China's pharmaceutical innovation ecosystem to foster higher-quality industry development, and to contributing to 'Healthy China' to improve the health and well-being of people in China.

RDPAC Member Companies in China

RDPAC member companies have established

40+ factories

30+ R&D centers

(As of 2023)

Total tax contribution

RMB 30 billion

(2023)

800+ new drugs introduced

(1999-2023)

"Healthier China Through Innovation"

RDPAC is committed to be a valued partner in delivering the "Healthy China" goal to improve the health and quality of life of people in China:

- ▹ Provide high-quality/ innovative healthcare products and services in a socially responsible and commercially viable manner
- ▹ Commit to securing patients timely access to innovative & high quality drugs
- ▹ Achieve the highest standard of integrity for ethical research and business practice
- ▹ Contribute to the growth of the biopharmaceutical sector in China
- ▹ Support the development of a sustainable healthcare system in China

RDPAC Vision

RDPAC's Positioning

Leader of innovative ideas

Based on sharing of pharmaceutical innovation and health information across the world, lead innovative ideas and visions

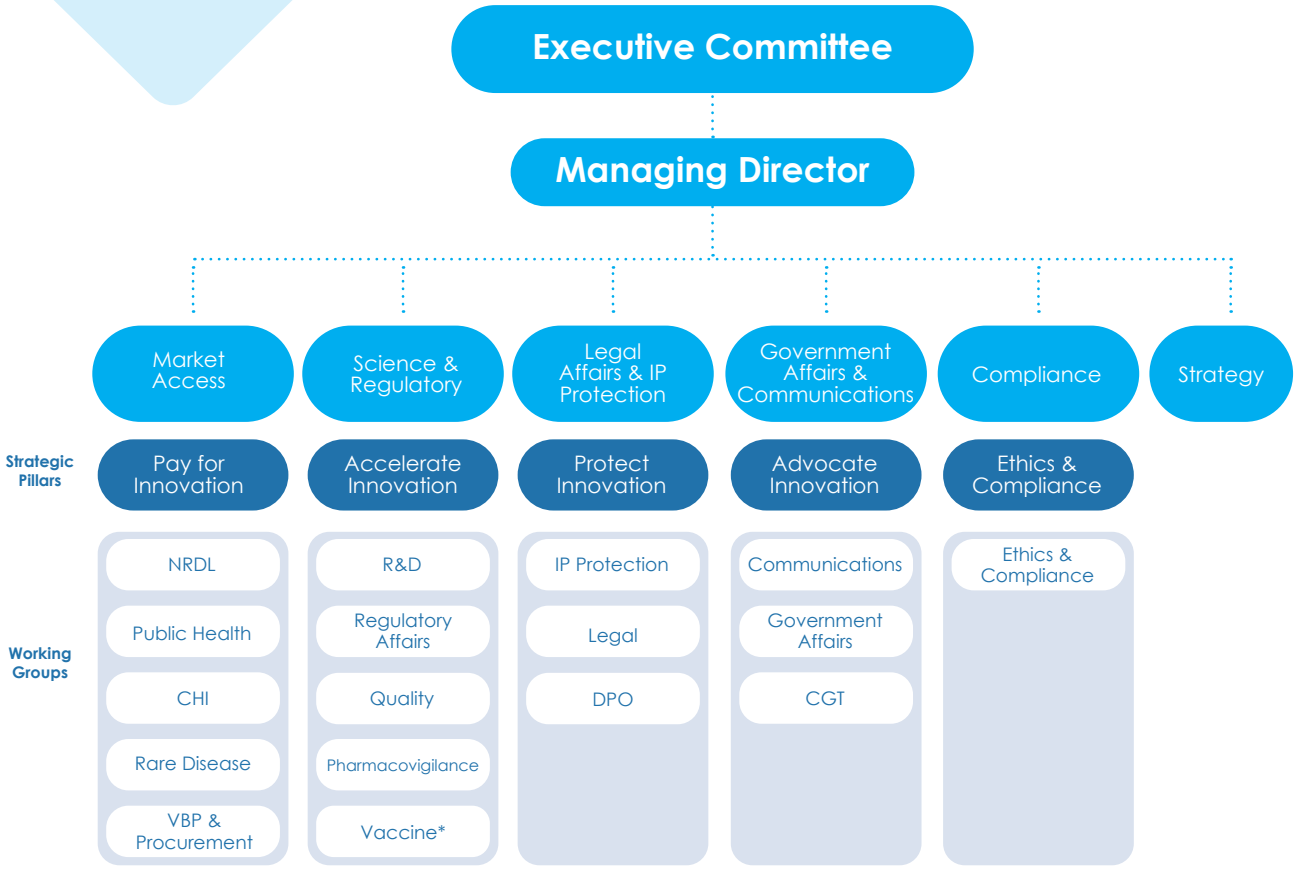
Solutions Provider

Unite member companies to face health challenges together and provide patients with affordable innovative drugs

Promoter of win-win cooperation

Build a bridge for communication and coordination between the government and the industry, and voice for the healthy and sustainable development of the pharmaceutical industry to achieve a win-win situation for all parties

RDPAC's Organizational Structure

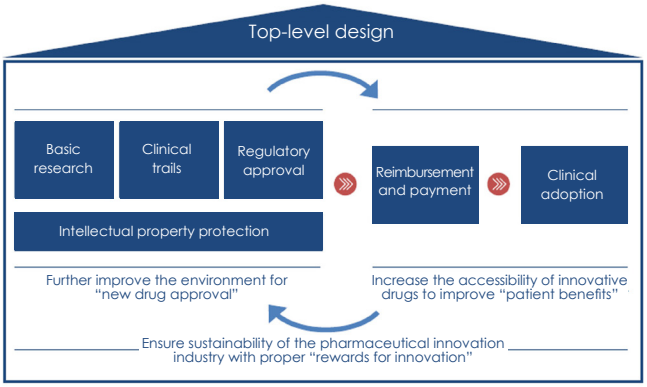


*The Vaccine Working Group is jointly driven by Market Access and Science & Regulatory.

What does RDPAC do?

1 Contribute to the sustainable development of China's pharmaceutical innovation ecosystem

RDPAC has been actively participated in the research and exploration of China's pharmaceutical innovation ecosystem. Since 2015, in cooperation with several industry associations, RDPAC has released a series of reports on the pharmaceutical innovation ecosystem, exploring innovative solutions with respect to concepts, policy mechanisms and capacity, listening to and communicating voices of the industry, and continuously advising government and relevant organizations. In this process, a number of reform results have been witnessed.



China's Pharmaceutical Innovation System (2021-2025)

Looking ahead, RDPAC will continue to focus on and promote the further development of China's pharmaceutical innovation ecosystem, with three key levers. The first lever is to further improve the environment for "new drug approval"; the second lever is to increase the accessibility of innovative drugs to improve "patient benefits"; and the third lever is to ensure sustainability of the pharmaceutical innovation industry with proper "rewards for innovation".

2 Accelerate the introduction of global innovative drugs into China

As a committed partner of the Chinese Government, RDPAC is committed to speeding up the entry of innovative drugs into the Chinese market and promoting simultaneous global R&D and registration to further meet the clinical needs of Chinese patients, working towards achieving the strategic goal of "Healthy China 2030".

Help optimize regulatory processes to promote accelerated review and approval.

Conduct research projects, provide recommendations on the reform of the review and approval system, and help establish an international-standard, scientific, transparent, and predictable regulatory system in China.

Support the improvement of clinical research capabilities to unleash the potential of China's pharmaceutical innovation.

Enhance the effective use of international clinical trial data and drive the development of clinical research and institutional capacity building in China to maximize the potential of innovation in China.

Facilitate the harmonization with international standards to achieve integration with international regulations.

Share international experience, communicate technical guidelines such as those issued by the International Council for Harmonization (ICH), and facilitate a transformation in regulatory thinking to achieve the international integration of China's regulatory system.

RDPAC has conducted several early-stage research projects looking into the introduction of innovative drugs, such as research globally into the marketing authorization holder (MAH) system, the construction of the clinical research system and the exploration of system design, in the process attracting the interest of China's regulatory authorities and pharmaceutical industry. In the future, RDPAC will continue to help China's drug regulation to match that of advanced countries, promote the participation of China's pharmaceutical industry in simultaneous global R&D, elevate China's global R&D status, and make Chinese innovative drugs available to global patients faster.

Support the establishment of quality management and safety supervision systems throughout the drug life cycle

3

As a partner of regulatory authorities, RDPAC actively supports the integration of drug quality management and safety supervision systems with systems globally:

Quality management: Help establish a drug quality supervision system that integrates with international standards and conforms to Chinese characteristics, and gradually improve the maturity of life cycle management capabilities in the pharmaceutical industry.

Safety supervision: Help establish a pharmacovigilance ecosystem, promote the establishment of a drug safety supervision system with risk-benefit balance at the core, facilitate the enhancement of drug safety and comprehensive risk management capabilities, and support linkage with regulatory authorities throughout the drug life cycle.

RDPAC member companies will play an exemplary role, actively sharing their experience in internationalization, helping launch and implement regulatory policies on drug quality and safety, and working with the entire industry to promote the establishment of quality management and safety supervision systems throughout the drug life cycle.

Improve the accessibility and affordability of innovative drugs for patients

4

RDPAC has always had a "patient-centric" focus and continues to play a leading role in improving the accessibility and affordability of innovative drugs by:

supporting the scientific assessment and efficient implementation of dynamic adjustments to the National Reimbursement Drug List (NRDL)

Improving the dynamic adjustment mechanism, establishing an independent review facility and an open and transparent review process, advocating value-oriented and evidence-based decision-making and improving the evaluation methods for inclusion of innovative drugs on the NRDL; and helping to accelerate the implementation of NRDL negotiations.

assisting the National Healthcare Security Administration (NHSA) in refined management to improve the efficient use and sustainability of basic medical insurance (BMI) funds.

Investigating an NRDL withdrawal mechanism to optimize the NRDL structure and ensure more valued drugs included in the NRDL, and enhancing awareness of medical institutions about the rational use of drugs to improve the efficient use and sustainability of BMI funds.

advancing continuous improvements to the multi-layered healthcare security (MLHS) system

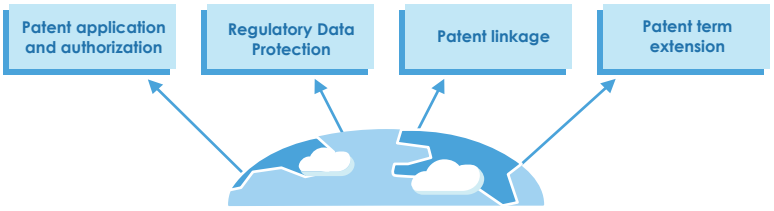
Exploring cooperation with commercial health insurance (CHI) and helping to develop a MLHS system that puts people's health at the center, advancing the establishment of a guarantee mechanism for drugs for rare diseases, and exploring the development of a diversified and sustainable payment ecosystem.

RDPAC will guide communication and cooperation between companies and government, conduct academic research based on international experience and local practice, and actively provide recommendations in key areas of health reform such as drug value assessment, procurement and supply, and payment reform, and team up with member companies and various sectors of the industry to assist the Government to establish a high-quality, multi-layered and sustainable healthcare security system with universal coverage and make world-class innovative drugs available and affordable for Chinese people.

5

Promote the full protection of intellectual property for pharmaceutical innovation to stimulate innovation

Fostering a sound legal framework and policy environment for intellectual property is key to supporting the development of pharmaceutical innovation. RDPAC is convinced that sustainable innovation in the biopharmaceutical industry depends on the incentives provided by intellectual property protection.



RDPAC is ready to provide the Government and relevant regulatory authorities with reference material for the development of policies and regulations, and to promote the development and continuous improvement of policies related to patent applications and authorization, regulatory data protection, patent linkage and patent term extension.

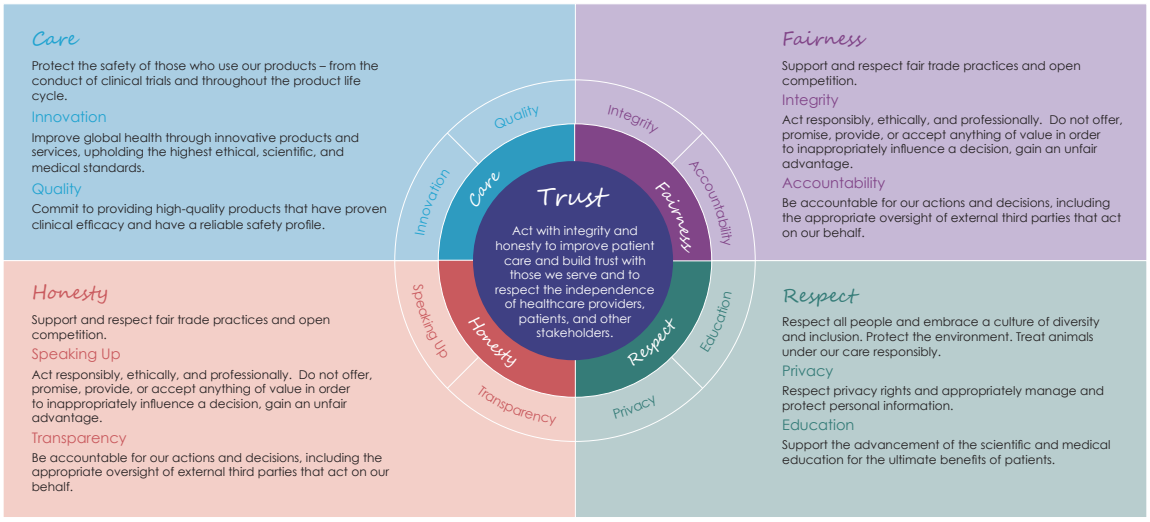
RDPAC will help improve the incentive mechanism for biopharmaceutical innovation in China to fuel sustainable innovation and cooperation in the biopharmaceutical industry, establishing an intellectual property protection system that strikes a balance between "generic drugs" and "innovative drugs" for the benefit of the general public.

6

Maintain high ethical standards to gain the trust of patients

Upon establishment, RDPAC developed its first Code of Practice based on the Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and in accordance with Chinese laws and regulations. As the first pharmaceutical industry organization in China to attach great importance to compliance, and as a member and an active player in the global pharmaceutical industry association system, RDPAC has continuously, on the basis of IFPMA Code of Practice, striven to reflect the latest standards of international pharmaceutical industry associations, the latest requirements of Chinese laws, regulations and policies, and the cutting-edge developments in business practices and compliance controls in China's pharmaceutical industry, providing member companies with the latest and highest standards of compliance based on best practice. Adherence to the RDPAC Code of Practice has been made a precondition for companies to join RDPAC. Furthermore, RDPAC is supportive of member companies developing and implementing even more stringent in-house codes of practice.

Our Ethos - *Building a culture of trust*



In order to promote patient-centric values to the wider Chinese healthcare industry, RDPAC has joined hands with several industry associations to issue the Chinese Consensus Framework for Ethical Collaboration in the Pharmaceutical and Medical Device Sectors, which aims to foster a favorable environment for all parties involved in the pharmaceutical industry to continuously enhance their credibility through its gradual implementation and the growing number of companies using it.

RDPAC Membership

(as of January 2025)

United States (12)	Abbott, Abbvie, Allergan, Amgen, Biogen, Bristol Myers Squibb, Eli Lilly, Gilead Sciences, Johnson and Johnson, MSD, Organon, Pfizer
Europe (24)	ALK, AstraZeneca, Bayer, Boehringer Ingelheim, Chiesi, Ethypharm, Ferring, Gedeon Richter, GSK, Helsinn, Ipsen, LEO Pharma, Lundbeck, Mayoly, Menarini, Merck, Mundipharma, Novartis, Novo Nordisk, Roche, Sanofi, Servier, UCB, Zambon
Asia (10)	Astellas, Chugai, Daiichi Sankyo, Eisai, Kyowa Kirin, Ping An-Shionogi, Santen, Sumitomo Pharma, Takeda, Teva
Africa (1)	Aspen

RDPAC International Partners

RDPAC and its member companies have established good communication and partnerships with many major international pharmaceutical industry institutions and organizations to jointly promote the sustainable development of China's pharmaceutical innovation ecosystem on important topics, contributing to the goal of "Healthy China 2030".

IFPMA (RDPAC is a member of IFPMA)

European Federation of Pharmaceutical Industries and Associations (EFPIA)

Pharmaceutical Research and Manufacturers of America (PhRMA)

Japan Pharmaceutical Manufacturers Association (JPMA)

Biotechnology Innovation Organization (BIO)

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