Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Introduction of Innovative Medical Devices Review in CHINA

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Special Review Procedure for Innovative Medical Devices

2014 *Special Review and Approval Procedure for Innovative Medical Devices (Interim)*

2016 *Guidance for the Preparation of Registration Application Dossiers for Special Review and Approval for Innovative Medical Devices*

Operation Specification of Special Review and Approval for Innovative Medical Devices

2018 *Special Review Procedure for Innovative Medical Devices*

Preparation of Registration Application Dossiers for Special Review of Innovative Medical Devices

Operation Specification of Special Review of Innovative Medical Devices

Purposes of the Procedure

- To ensure the safety and effectiveness of MD
- To encourage MD research and innovation
- To promote the promotion and application of new MD technology
- To drive the development of the MD industry

Requirements of Innovative Medical Devices Review

The review of medical devices that meet the following circumstances applies to the *Special Review Procedure for Innovative Medical Devices* :

Intellectual Property

The product shall obtain the invention patent of the core technology of the product in China in accordance with the law.

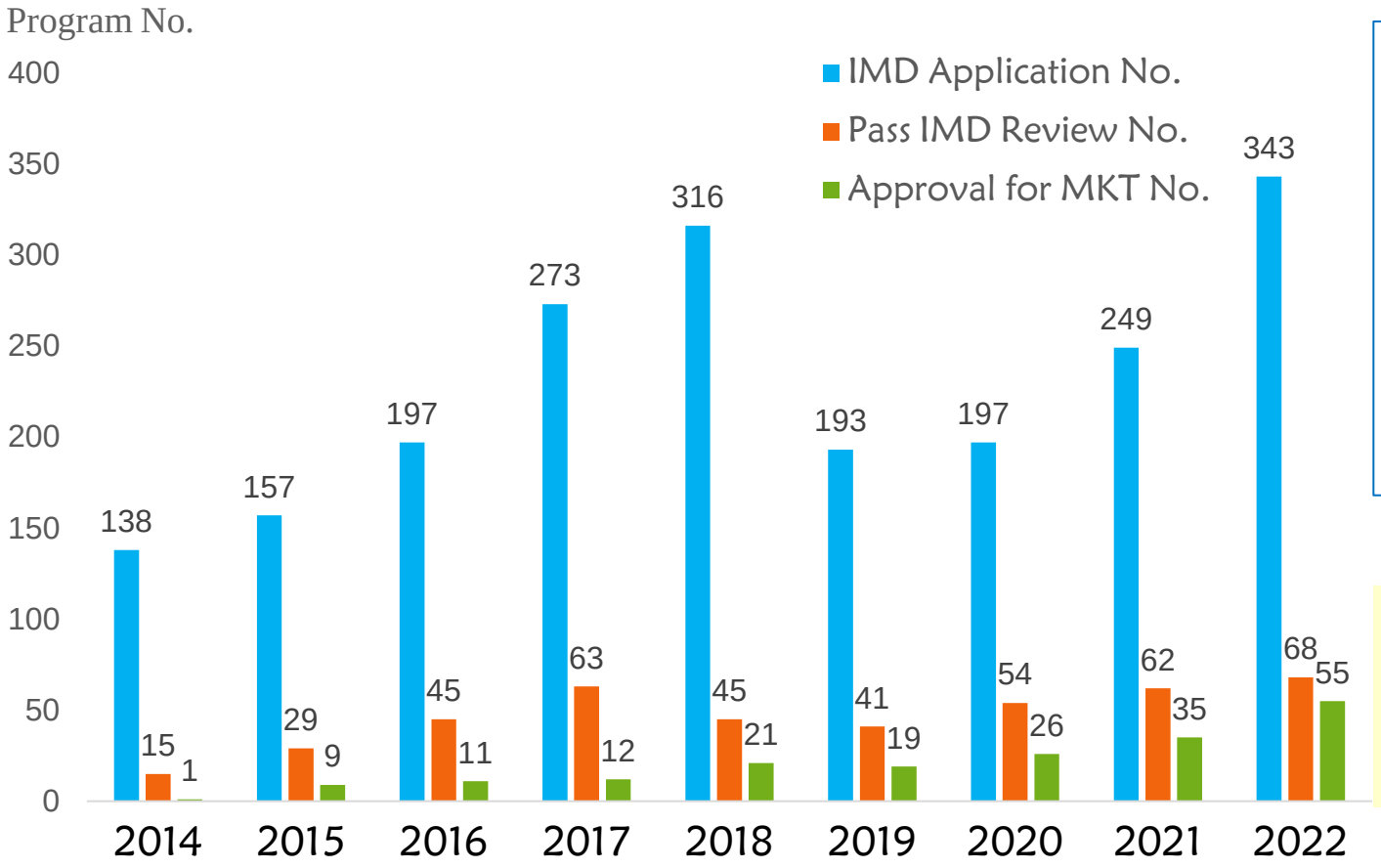
Basically Finalize the Design

The product shall basically finalize its product design.

Initiative MD with Significant Value

The main working principle or mechanism of the product shall be initiative domestically and have significant clinical value.

Introduction of Innovative Medical Devices Review & Registration



In 2014, the former CFDA issued *Special Review and Approval Procedure for Innovative Medical Devices(Interim)*. Early intervention, special responsibility and priority approval shall be given to the innovative medical devices with China's independent intellectual property rights and significant clinical application value, under the condition that the standards are not lowered and the procedures are not reduced.


国家药品监督管理局
National Medical Products Administration

食品药品监管总局关于印发创新医疗器械特别审批程序（试行）的通知

食药监械管〔2014〕13号

各省、自治区、直辖市食品药品监督管理局：

为了保障医疗器械的安全、有效，鼓励医疗器械的研究与创新，促进医疗器械新技术的推广和应用，推动医疗器械产业发展，总局组织制定了《创新医疗器械特别审批程序（试行）》，现印发给你们，请遵照执行。

国家食品药品监督管理总局
2014年2月7日

创新医疗器械特别审批程序（试行）

第一条 为了保障医疗器械的安全、有效，鼓励医疗器械的研究与创新，促进医疗器械新技术的推广和应用，推动医疗器械产业发展，根据《医疗器械监督管理条例》、《医疗器械注册管理办法》等法规和规章，制定本程序。

第二条 食品药品监督管理部门对同时符合下列情形的医疗器械按本程序实施审评审批：

（一）申请人经过其技术创新活动，在中国依法拥有产品核心技术发明专利权，或者依法通过受让取得在中国发明专利权或其使用权；或者核心技术发明专利的申请已由国务院专利行政部门公开。

（二）产品主要工作原理/作用机理为国内首创，产品性能或者安全性与同类产品比较有根本性改进，技术上处于国际领先水平，并且具有显著的临床应用价值。

By the end of Oct. 2023, **2,451** items of innovation applications had been received. During which, **483** items had passed the innovative MD channel review, **234** products had been approved for market.

Support to Innovative Medical Devices

- Give Priority to the Whole Process from Acceptance to Review
- Senior Reviewers Are Responsible to Strengthen Communication
- Conduct Panel Review
- Make the Review Report Public
- Small Enterprises Are Exempt from Registration Fees
- Carry out On-site Review for Domestic Innovative MD
- Give Priority to Quality Management System(QMS) Verification
- Give priority to the Approval Matter Changes of Innovative MD

2 Priority Review and Approval for Medical Devices

Priority Review and Approval Procedure for Medical Devices

- In order to ensure the clinical needs of medical devices, the former China Food and Drug Administration issued the *Priority Review and Approval Procedure for Medical Devices*
- Issued on October 26th, 2016(No. 168, 2016)
- Implemented on January 1st, 2017

国家药品监督管理局
National Medical Products Administration

中国药品监管 中国药闻 中国药监APP 邮箱 政务信息报送
请输入关键字

总局关于发布医疗器械优先审批程序的公告（2016年第168号）

2016年10月26日 发布

为保障医疗器械临床使用需求，根据《医疗器械监督管理条例》（国务院令第650号）、《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号）等有关规定，国家食品药品监督管理总局组织制定了《医疗器械优先审批程序》，现予发布，自2017年1月1日起施行。

特此公告。

附件：医疗器械优先审批程序

食品药品监管总局
2016年10月25日

2016年第168号公告附件.docx

Requirements of Priority Review and Approval

Priority review and approval shall be given to the registration applications for domestic Class III and imported Class II and Class III MD that meet any of the following circumstances:

Situation 1: Clinical emergency, etc.

- 1. Diagnose or treat rare diseases with obvious clinical advantages
- 2. Diagnose or treat malignant tumors with obvious clinical advantages
- 3. Diagnose or treat diseases specific to and frequent in the elderly with no effective diagnosis or treatment currently
- 4. Specially used in children with obvious clinical advantages
- 5. Clinical emergency without the same variety products approved in China

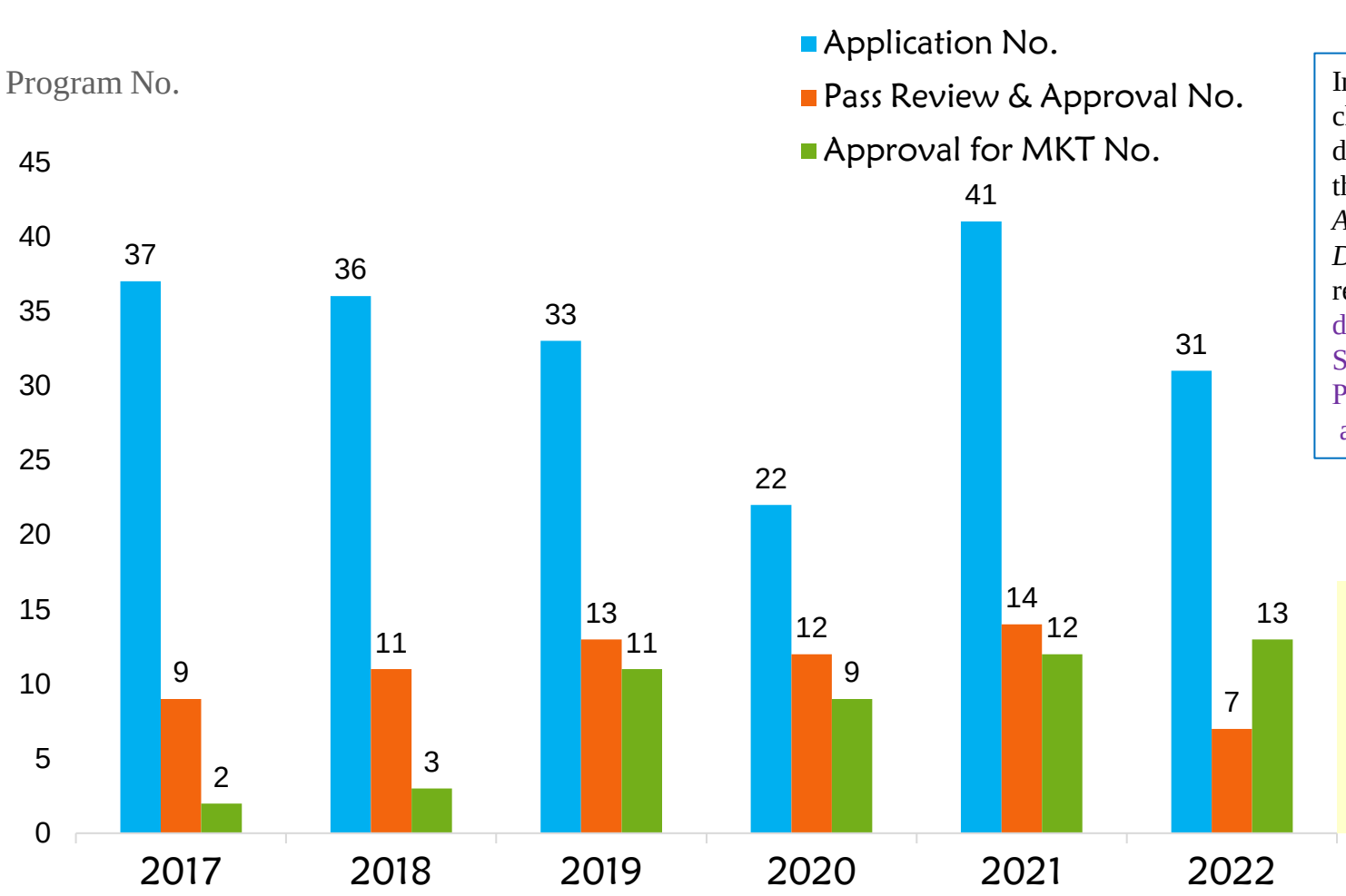
Conditional approval is allowed to be applied at the same time.

Situation 2: Key projects supported by Ministry of Science and Technology of the People's Republic of China

- Medical devices included in national major science and technology projects or national key research and development plans.

Situation 3: Others

Introduction of Priority Review and Approval Procedure Review & Approval



In 2017, on the basis of the green channel for innovative medical devices, the former CFDA issued the *Priority Review and Approval Procedure for Medical Devices*, giving priority to the review and approval of medical devices supported by Ministry of Science and Technology of the People's Republic of China and in urgent clinical needs.


国家药品监督管理局
National Medical Products Administration

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食品药品监管总局
2016年10月25日

2016年第168号公告附件.docx

By the end of Oct. 2023, **223** items of priority review & approval applications had been received. During which, **73** items had passed the priority review & approval, **57** products had been approved for market.

Support to Priority Review and Approval Medical Devices

- Give Priority to the Whole Process from Acceptance to Review
- Senior Reviewers Are Responsible to Strengthen Communication
- Conduct Panel Review
- Give Priority to Quality Management System(QMS) Verification
- Make the Review Report Public

3 Other Measures to Encourage Innovative MD Development

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Construction of Expert Database for Medical Device Technical Evaluation Consultation

17 expert advisory committees, involving 116 specialties and 242 research directions, cover most of the fields related to medical devices.

1. Active Equipment Engineering Expert Advisory Committee
2. Medical Materials Engineering Expert Advisory Committee
3. Biological Evaluation of Medical Devices Expert Advisory Committee
4. In vitro Diagnostic Reagents Expert Advisory Committee
5. Internal Medicine Medical Devices Expert Advisory Committee
6. Surgical Medical Devices Expert Advisory Committee
7. Orthopedic Medical Devices Expert Advisory Committee
8. Obstetrics and Gynecology Medical Devices Expert Advisory Committee
9. Pediatric Medical Devices Expert Advisory Committee
10. Ophthalmic Medical Devices Expert Advisory Committee
11. ENT Medical Devices Expert Advisory Committee
12. Stomatology Medical Devices Expert Advisory Committee
13. Plastic and Aesthetic Medical Devices Expert Advisory Committee
14. Oncology Medical Devices Expert Advisory Committee
15. Anesthesiology Medical Devices Expert Advisory Committee
16. Medical Imaging Medical Devices Expert Advisory Committee
17. Other Medical Devices Expert Advisory Committee

Promote Research on Supervision Science

Three key R&D projects of Ministry of Science and Technology of the People's Republic of China

- Research on development and application of scientific and technological innovation service platform for intelligent medical device industry
- Basic research on product standards and evaluation science of new medical metal materials and implantable devices
- Research on safety and effectiveness system and standard system of active health products and human health state evaluation

Four NMPA scientific supervision research

- Safety and effectiveness evaluation of artificial intelligence medical devices
- Research on technical evaluation of pharmaceutical and mechanical combination products
- Research on supervision science of new materials for medical devices
- Methodological research on real-world data for clinical evaluation of medical devices

Many ministerial key or major scientific research projects

Promote Research on Supervision Science

Artificial Intelligence Medical Device Innovation and Cooperation Platform (established in 2019)

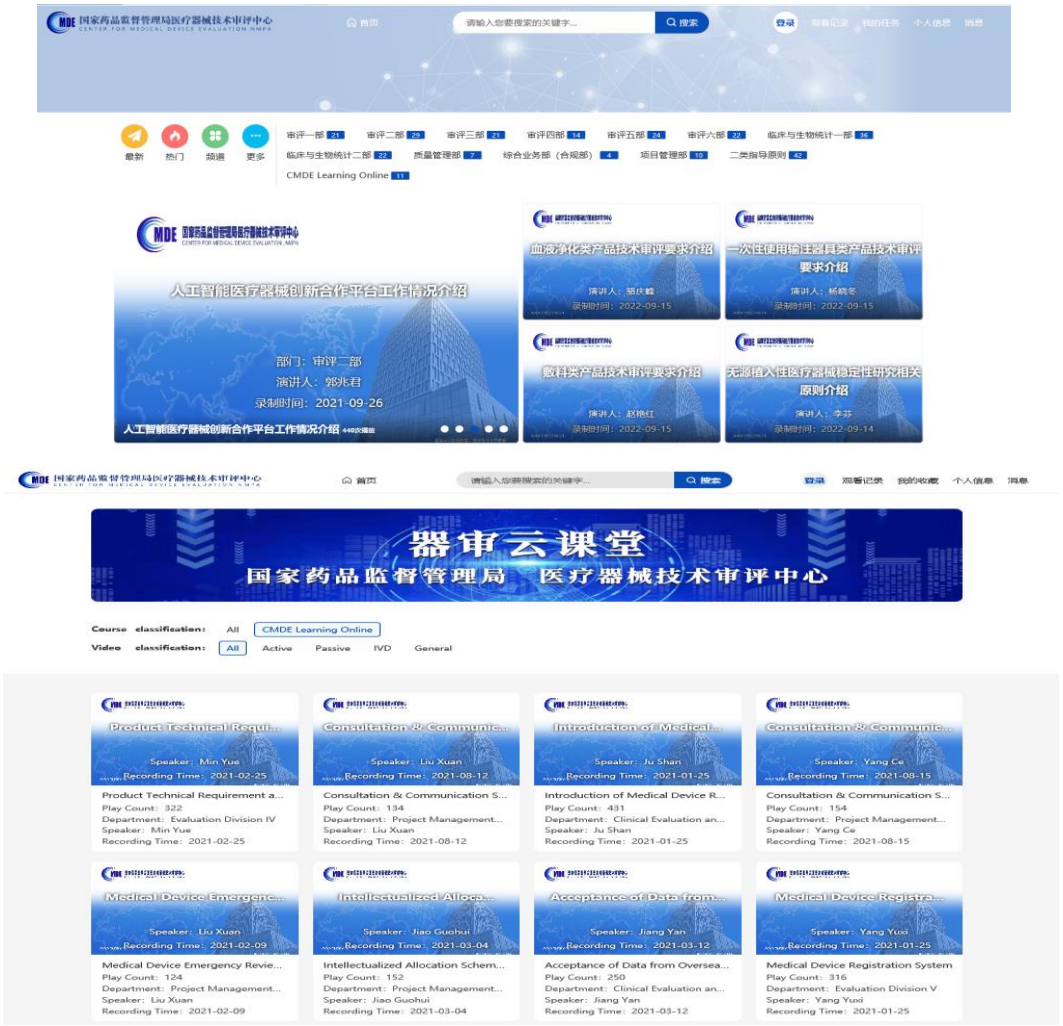
- To actively respond to new risks and challenges brought by the rapid development of artificial intelligence to regulation and MD industry;
- To coordinate forces and all related parties in data management, standard formulation, clinical evaluation, testing and other links, and strive to establish a scientific evaluation system for artificial intelligence medical devices in China;
- To encourage innovation and accelerate the transformation and application of artificial intelligence scientific and technological achievements in the field of medical devices.

Biomaterials Innovation and Cooperation Platform (established in 2021)

- To provide support for the key work of relevant national ministries and agencies in related fields;
- To promote key core technology research, and help China seize the international commanding heights in the field of biological materials by giving full play to professional advantages, focusing on the key technologies problems in the field of biological materials and guiding the transformation and application of raw materials and technology.

Conduct MD Technical Examination Training

Support the organizer to carry out online or on-site training for relevant personnel engaged in the R&D, production and registration of medical devices on medical devices technical examination introduction, involving active medical devices, non-active medical devices, in vitro diagnostic reagents, clinical evaluation, etc.



Build the “CMDE On-line Learning" Network Training Platform

Provide various courses related to examination process introduction, rules and regulations interpretation, examination requirements explanations to R&D registrants, supervisors, researchers, etc.

CMDE Homepage Column Try to Meet the Individual Needs of MD Industry!

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

MDE 国家药品监督管理局医疗器械技术审评中心
CENTER FOR MEDICAL DEVICE EVALUATION, NMPA

中国器审

Thank You for Your Attention!