上海市药品监督管理局

上海城市精神：海纳百川 追求卓越 开明睿智 大气谦和

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Introduction of Action Scheme for Promotion in the Development of Medical Robot Industry & Regulatory Measures in Shanghai

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Shanghai Medical Products Administration

2023-11-27

- Implemention of the National Action Plan for the High-Quality Development of the Medical Equipment Industry (2023-2025)
- 5 Departments jointly formulated the "Shanghai Action Scheme for Promotion in the Development of Medical Robot Industry (2023-2025)"

上海市经济和信息化委员会
上海市科学技术委员会
上海市卫生健康委员会 文件
上海市医疗保障局
上海市药品监督管理局

沪经信医〔2023〕935号

关于印发《上海市促进医疗机器人产业发展行动方案（2023–2025年）》的通知

有关单位：

为落实国家《医疗装备产业高质量发展行动计划（2023–2025年）》，进一步促进本市医疗机器人产业高质量发展，市经济信息化委、市科委、市卫生健康委、市医保局、市药品监管局联合制定了《上海市促进医疗机器人产业发展行动方案（2023–2025年）》，现印发给你们，请认真贯彻执行。

特此通知。

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General Requirements 01

Guiding Principles

- Aim at the Development Trend of Medical Robot's Miniaturization,Intelligence & Biomimetics
- Actively plan new products, new models & new formats for future technology & industrial transformation of medical robots
- Focus on Medical Robots modern engineering technology & key common technologies promote deep integration of Industrial chain, innovation chain & talent chain
- Construct a number of domestic leading & international advanced innovative medical robot products

- Build ~5 professional technical public service platforms
- Establish ≥3 medical robots application show case platforms
- Form ≥10 application scenarios can be promoted & replicated

Cutting-edge Achievement

Emerging ≥ 10 International advanced & innovative products

Main Objectives

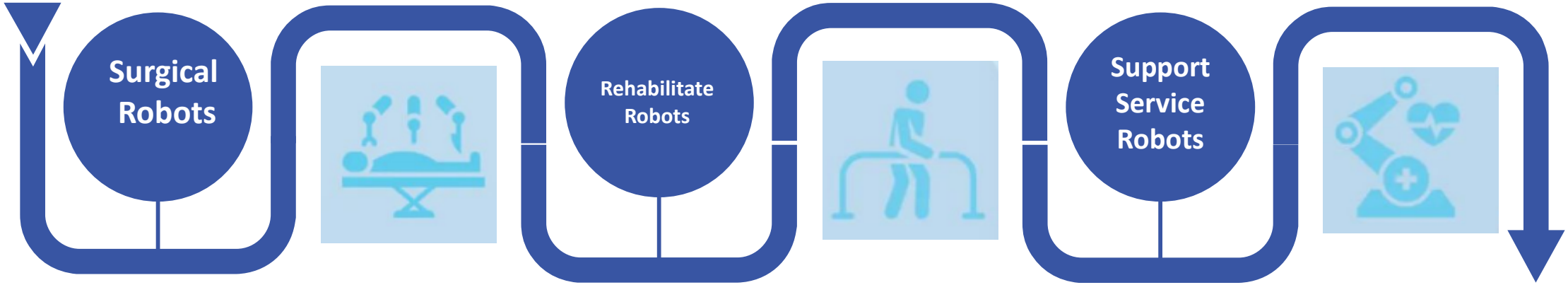
Innovation Ecosystem

Industry Energy level

- Create ≥ 2 characteristic industrial clusters
- Promote ~10 subdivision track leaders

By 2025, Wish scale of the industry reach 10 billion RMB

Development Focus 02



- Accelerate R&D of multi-channel vascular interventional robots
- Intraoperative three-dimensional fluoroscopy, integrated orthopedic robot, etc
- Support innovative development such as 5G remote surgical robots

- Accelerate R&D of multi-environment simulation & behavior quantitative analysis & TCM treatment rehabilitation robots, etc
- Support innovation & development of rehabilitation robots based on brain-computer interface technology

- Accelerate R&D of medical logistics robots with complex environment perception & navigation capabilities
- Support innovative developments such as companion care humanoid robots

Key Tasks 03

Build up industry Forward-looking plan

01

02 Achieve breakthroughs in key & core technologies

03 Reinforce R&D of key materials & devices

10 Tasks

04 Bring in, promote & strengthen high-quality enterprises

05 Construct "dual-core" industry space

Propel products application demonstration

Improve products go-to-market services

Fulfill professional service system

Deepen integrated development of industry & medicine

Promote overseas markets development

General Supporting Measures 04

- Fully strengthen the coordination role of Municipal Leading Group of Biomedical Industry Development
- Solve common demands & major problems

- Coordinate the use of various special funds to support project

- Strengthen service for high-level talents
- Speed up the Recruitment/Training for talents in urgent need

- Improve the price formation mechanism
- Promte the dynamic adjustment mechanism of medical services

Enhance effectiveness of innovative products post-market supervision

Precise formulation of Regulatory measures

- Develop targeted regulatory plans
- Establish the system of regular work meetings & risk consultations

Accurate tracibility of Product risk

- Assign special personnel for tracibility
- Strengthen unannounced inspections of innovative medical device manufacturers

lean assessment of Quality management System

- Actively social co-governance

Elaborately Implimentation A series of training

- Innovative corporate training
- MD Supervision Public Lecture

- Adhere to principle of "supervision must keep up"
- Adhere to principle of "supervision in one hand, service in the other"

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Thanks!