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Review Article

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Analysis on the registration and review system of emergency medical devices in China and abroad in the context of COVID-19

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Abstract

Objective

In the context of COVID-19, the domestic and foreign demand for emergency medical devices, such as medical masks and protective suits, is surging, and it is urgent to complete the registration and review of emergency medical devices with high efficiency and quality, which requires a mature and perfect registration and review system as the support. This paper aims to compare and analyze the domestic and foreign registration and review system of emergency medical device, summarize the good experience, and provide feasible suggestions for improving China's emergency medical device registration and review system.

Method

USA, Canada, Japan and the European Union were selected to make a comparative analysis with China from the aspects of legal system and emergency registration and review procedure by literature research, comparative analysis and other theoretical methods.

Results

The legal system and review mechanism of emergency medical device registration in China have been relatively perfect, but the safety and risk balance mechanism and the comprehensiveness of emergency management measures need to be further improved.

Conclusion

On the basis of maintaining its own institutional advantages, China should learn from foreign experience to further optimize the registration and review system of emergency medical devices, so as to improve the ability of response and implementation of China in public health emergencies.

Keywords: COVID-19, emergency medical devices, Center for Medical Device Evaluation (CMDE), National Medical Products Administration (NMPA), PAHPA, FDA, Emergency Use Authorization (EUA).

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1. Introduction

At the end of 2019, COVID-19 broke out in China, and now it spreads in more than 200 countries or regions around the world. This pandemic not only poses a great threat to the human lives and health, but also brings a tough test to the coping system of all countries. Medical devices are the most important prevention materials in this pandemic. In China, under the correct leadership of the government, the relevant departments responded quickly and made some achievements. On January 21, 2020, Center for Medical Device Evaluation (CMDE) was notified by National Medical Products Administration (NMPA) to start the emergency review process. By September 9, 2021, NMPA has completed the emergency review of 64 COVID-19 detection kits, 30 instruments and equipment, 3 software and 3 dressing products. (1) Efficient review and approval process has greatly demonstrated China's executive ability and governance ability in this pandemic, but there is still a certain gap between China and developed countries in some aspects. Based on this, this paper selects China, USA, Canada, Japan and the European Union as the research objects, analyzes the registration and review

system of emergency medical devices in five countries or regions, from the aspects of legal system and emergency registration review procedure, learns advanced experience, and puts forward suggestions for optimizing the registration and review system of emergency medical devices in China, so as to improve the prevention and control ability of public health emergencies in China and further optimize the national emergency management system.

2. China

2.1 Legal system

China's legal system for dealing with public health emergencies is relatively mature, there are laws such as the *Law of the People's Republic of China on the Prevention and Control of Infectious Diseases*, the *Emergency Regulations for Public Health Emergencies* and the *National Emergency Plan for Public Health Emergencies*, and the legal system for medical devices is also relatively well-rounded, such as the *Regulations on the Supervision and Administration of Medical Devices*, the *Administrative Measures for the Registration and Filing of Medical Devices* and the *Administrative Measures for the Supervision and Administration of Medical Device Production*, etc. On the basis of these laws, in order to better cope with the COVID-19 pandemic situation and further improve the registration and review of emergency medical devices, NMPA issued the *Emergency Medical Device Approval Procedure* on December 30, 2021, (2) which comprehensively stipulated the scope and procedures for the emergency medical devices review and approval process during public health emergencies. In addition, on March 30, 2020, NMPA issued the *Announcement of China's Regulatory Requirements and Standards for COVID-19 Detection Reagents and Protective Products*, (3) which included a series of guiding documents such as *Technical Review Key Points of COVID-19 Nucleic Acid Detection Reagents Registration* and *Guiding Principles for Technical Review of Medical Mask Products Registration*.

2.2 Emergency Approval Procedure

According to the *Classification Catalogue of Medical Devices*, medical devices are classified into Class I, II and III in ascending order of risk level. (4) Class I medical devices are managed by filing on the record, and the municipal market supervision administration bureau is responsible for it; Class II and Class III medical devices are applied by registration, which is undertaken by the provincial drug administration bureau and NMPA. (5)

For the Class I emergency medical devices, the filing on the record process is consistent with the routine. For the Class II and Class III emergency medical devices, unlike the conventional registration process, the applicant should first apply for the emergency confirmation. And the registration application can only be carried out, after it is confirmed with the emergency registration condition, by relevant drug administration bureau. According to the *Emergency Medical Device Approval Procedure* and the regulations of provincial drug administration bureau, the emergency registration and review process of Class II and Class III medical devices is summarized (Figure 1), which can be roughly divided into several stages, such as emergency confirmation, registration inspection, quality management system evaluation, technical review and administrative approval.

Specifically, for the Class II medical devices, the emergency registration process and time limit shall be determined by each province, which is roughly the same, but there are still slight differences. Take the quality management system verification as an example, Shanghai stipulates that it should be carried out before the emergency confirmation, but Zhejiang Province stipulates that it should be carried out after the emergency confirmation; as for the time limit of quality management system verification, Zhejiang Province sets a duration of 3 days, while Jiangsu Province stipulates that the verification should be completed within 2 days. For the Class III emergency medical devices, it should be registered in accordance with the unified process throughout the country, similar with the routine. But the time limit for registration and review process is shortened to a certain extent during public health emergencies. For example, the provincial drug administration bureau should carry out the quality management system verification within 2 days (routine 10 days) after receiving the NMPA notification, with a technical review time limit of 10 days (routine 90 days) and an administrative approval time limit of 3 days (routine 20 days).

The above all belong to the emergency approval procedure, but if the applicant is unable to submit registration documents within 90 days after emergency confirmation, the application will no longer be handled in accordance with emergency approval procedure, but in accordance with the priority review and approval procedure. In addition, NMPA implements conditional approval procedure for some Class III emergency medical devices. In this case, the validity period of registration certificate should be consistent with the completion duration of the attached conditions, and in principle, it should not exceed one year. If the applicant completes the attached conditions within the specified duration, the registration renewal based on the former certificate will be encouraged, instead of applying for a new registration program.

3. US

3.1 Legal system

According to Article 564 of the *Federal Food, Drug, and Cosmetic Act (FD&C Act)*, (6) when the Department of Health and Human Services (HHS) Secretary determines (or largely believes) that there is or will be a potentially significant public health emergency, the Emergency Use Authorization (EUA) procedure should be announced and initiated. And during the emergency period, FDA can authorize the use of unlisted medical devices or the unexpected use of listed medical devices through each specific EUA. Combined with the *FD&C Act*, the *Pandemic and All-Hazards Preparedness Act (PAHPA)* and the *21st Century Cures Act (Cures Act)*, FDA promulgated the *Emergency Use Authorization of*

Medical Products and Related Authorities in 2017, (7) which comprehensively stipulated the announcement and application procedures of medical products' EUA during public health emergencies.

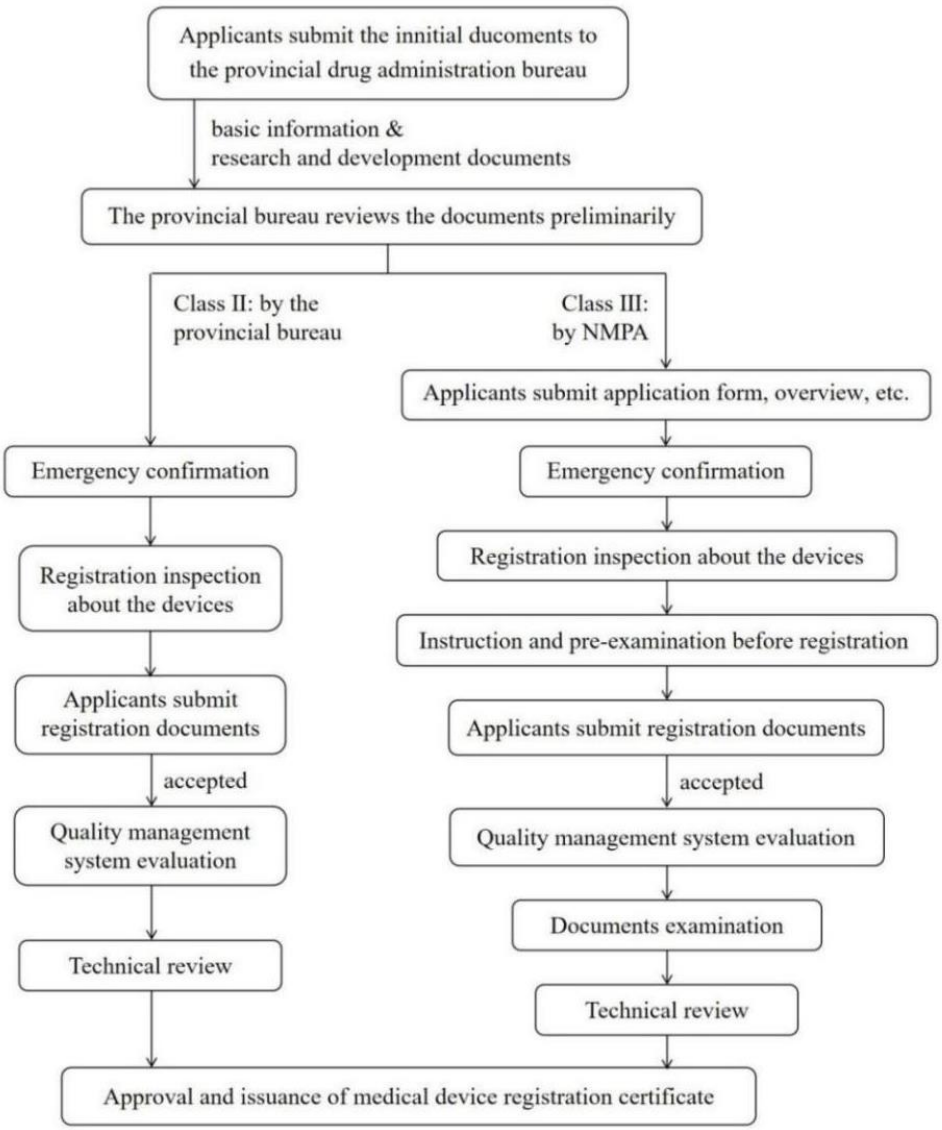

Figure 1. Emergency medical device registration procedure in China

On the basis of these laws, on February 4, 2020, HHS Minister issued *Determination of Public Health Emergency*, (8) which authorized FDA to grant the emergency use of unlisted medical devices (or the unexpected use of listed medical devices). In order to ensure that the EUA declaration can be carried out more accurately and efficiently, based on the Emergency Use Authorization of Medical Products and Related Authorities, FDA has developed the EUA registration document templates for each emergency medical device by category. (9) For the industry, FDA staff and other stakeholders, FDA has formulated and issued COVID-19-related guidance documents, (10) such as *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency*, *FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency* and so on.

3.2 EUA registration review procedure

Before formally submitting the EUA application or HHS minister's EUA statement, applicants (especially enterprises whose products are in the final stage of research and development) can communicate with the Center for Devices and Radiological Health (CDRH) when necessary, and ask them about the specific application requirements, which is called pre-EUA. Applicants can prepare the application documents according to the *Emergency Use Authorization of Medical Products and Related Authorities* and the EUA registration document templates.

After the EUA application is formally submitted and accepted, FDA will sort EUA application by priority in view of severity and incidence of diseases, and then CDRH will organize experts to review. CDRH will coordinate internal and external experts to jointly conduct EUA review of emergency medical devices, and give feedback to FDA. Finally, FDA commissioner will issue EUA authorization letter or decide not to authorize it. In addition, when HHS Minister announces that the

applicable circumstances of EUA are terminated or the authorized EUA no longer meets the authorization requirements, conditions or other circumstances, EUA will be terminated or revoked (Figure 2). Generally speaking, FDA has a certain degree of relaxation on the document and on-site review of EUA products compared with the routine. For example, in principle, enterprises should meet the requirements of cGMP, but for emergency EUA review, FDA will restrict or exempt cGMP inspection according to the actual situation.

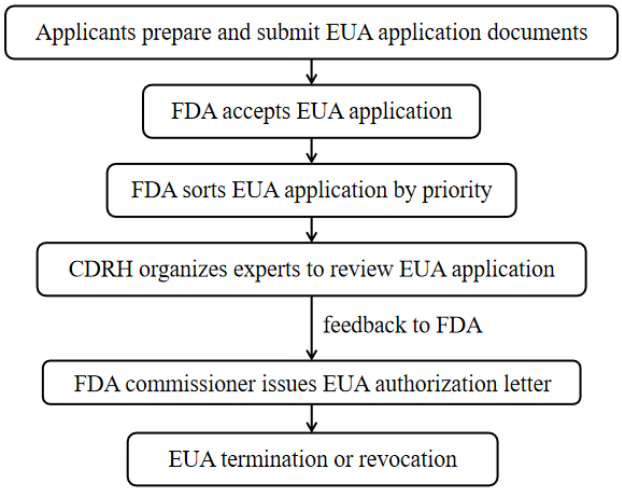

Figure 2. Emergency Medical Device EUA registration procedure in USA

4. Canada

4.1 Legal system

In order to deal with the situation with significant health risks, the *Food and Drugs Act* stipulates that the Health Canada Minister can issue Interim Order (IO) and take timely and effective actions; *Medical Devices Regulations* states that in case of emergency, (11, 12) health care professionals can apply to the Health Canada through special access to obtain and use specific medical devices. On the basis of these laws, Health Canada issued *Interim Order No.1 (abolished)* on March 18, 2020, *Interim Order No.2 (abolished)* on March 1, 2021 and *Interim Order No.3 (current)* on February 21, 2022, respectively. (13-15) Based on this, it established and carried out three expedited authorization pathways and the Special Access Program (SAP) to speed up the listing of COVID-19 medical devices. (16)

4.2 Expedited authorization pathways and SAP

Among the three expedited authorization pathways, pathway 1 aims at speeding up the import, sale and IO authorization number issuance of COVID-19 medical devices, allowing Health Canada to quickly review the application of emergency medical devices, which are applicable to Class I~IV (in ascending order of risk level) medical devices. As for the application of Class II~IV medical devices, enterprises must obtain Medical Device Establishment Licence (MDEL) before they import or sell products in Canada. Therefore, Health Canada set up pathway 2 to speed up the review and issuance of MDEL during COVID-19 period. Pathway 3 is a special import and sale channel designed to introduce COVID-19 medical devices, which do not fully comply with current regulatory requirements but are manufactured according to comparable standards. It is applicable to designated medical devices that are included in the list of special import and sale medical devices, and such enterprises must have the MDEL or medical device license (MDL). Different from the above three expedited authorization pathways, SAP aims to improve the accessibility of specific COVID-19 medical devices. When conventional therapy fails, is unavailable, is not suitable for treating patients or in an emergency, health care professionals can apply for obtaining and using customized and unlicensed medical devices through this program, such as Class III or IV devices customized for specific patients. (17)

4.3 IO authorization application procedure

Manufacturers, importers and distributors of COVID-19 medical devices should choose the applicable expedited authorization pathway, and after consulting the *"Applications for medical devices under the Interim Order for use in relation to COVID-19: Guidance document"* and COVID-19 medical device authorization application process, (18, 19) they should fill in the necessary application documents and submit them to the Medical Devices Director (MDD) under the Health Products and Food Branch (HPFB) of Health Canada. MDD is responsible for reviewing the application documents to evaluate the safety, effectiveness and quality of medical devices, (20) as well as the potential risks and benefits, and authorizing qualified medical devices. This authorization is only valid during the IO effective period (Figure 3).

In addition, in terms of clinical trials, Health Canada issued *Interim Order No.1 Respecting Clinical Trials (abolished)* on May 23, 2020, *Interim Order No.2 Respecting Clinical Trials (abolished)* on May 3, 2021, and *"Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations: SOR/2022-18"* on February 11, 2022, respectively. (21, 22) The current regulations stipulate that COVID-19-related clinical trials of medical devices should be reviewed and approved in priority, and the process must be completed within 14 days. The specific application steps are stipulated in *"Medical devices for COVID-19: Conducting a clinical trial"*. (23)

For the emergency medical device registration and review system analysis of the above three major research countries, this paper makes a comparison from several aspects (Table 1), such as organization, review procedure, review characteristic, etc. There are some notable differences. For example, China has specialized regulation in law on the registration and review procedure for emergency medical devices, which is valid within the legal validity period, and the procedure can be followed in the next emergency. USA and Canada have made general regulation in law about EUA and IO, respectively. However, this kind of regulation is not only for emergency medical devices. The EUAs and IOs for emergency medical devices are generally granted temporarily and will expire, and needs to be re-issued in the next emergency. Such differences are based on the disparate organizations and legal systems in three countries, so it is unlikely to make hasty judgments about which one is better. This paper will continue to introduce other countries' emergency registration systems in Part 5, and then discuss further in more details in Part 6

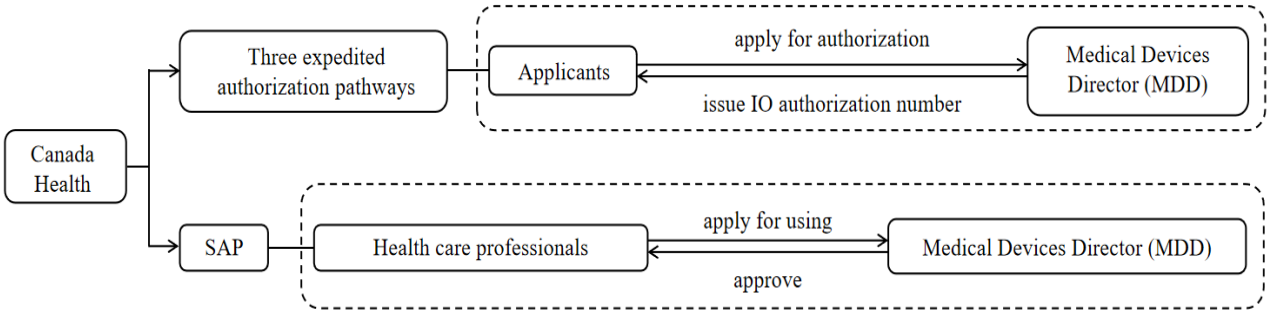

Figure 3. Emergency medical device management procedure in Canada

5. Other countries

Different from the above countries, Japan and EU don't have a specialized registration and review system for emergency medical devices during public health emergencies. Instead, on the basis of the conventional registration and review system, they adopt methods such as shortening the time limit and expert consultation to accelerate the review and promote the rapid listing of medical devices.

5.1 Japan

5.1.1 Legal system

Pharmaceuticals and Medical Devices Act is the general guide for medical device regulation in Japan, article 14-3 stipulates that certain medical products can obtain special approval under the following circumstances: (1)require the use of unapproved medical products in emergency situations to prevent the spread of disease and damage to public health; (2)such emergencies cannot be properly managed by any means other than the use of unapproved products; (3)such kind of products are legally available in a country with a regulatory system comparable to Japan's for medical products. (24) In addition, in response to the COVID-19 outbreak, Japan also issued the *PMDA pledge to tackle COVID-19 Pandemic, PMDA Takes Further Steps to Speed up Clinical Development of COVID-19 Products* and other notification documents. (25)

5.1.2 Emergency registration review measures

In Japan, medical devices are classified into general medical devices, management medical devices and advanced management medical devices according to their risk levels from low to high, adopting the registration review methods of product filing, third-party organization certification and acknowledged by MHLW respectively. On this basis, in the face of COVID-19, Japan has taken a series of targeted registration review measures to ensure that emergency medical devices can be put on the market as soon as possible. Such as there is no need for COVID-19 related medical products to apply in accordance with the priority review procedure, and priority review can be carried out directly; (26) if data on safety and efficacy, for example, clinical trial data ,is insufficient, it can be approved for listing with conditions; (27) for innovative medical devices, four systems are established to expedite approval: SAKIGAKE medical device designation system, designation system for medical devices for specific applications, conditional early approval system and IDATEN; (28) during the specific product development process and prior to application acceptance, the applicant may consult and discuss with the Pharmaceuticals and Medical Devices Agency (PMDA) to ensure efficient product development and rapid registration. For clinical trials, sponsors are normally required to submit Clinical Trial Notification (CTN) to PMDA 30 days prior to the scheduled start date of clinical trials, now it allows that after completing the necessary PMDA review, sponsors can initiate clinical trials of COVID-19 products without waiting 30 days;When an immediate Institutional Review Board (IRB) meeting is needed to initiate the clinical trial quickly, IRB meeting can be conducted online, such as via email, without having to be on site. This delay is to respond to the urgent need for medical devices in EU member states and to avoid the risk of shortage of necessities due to the insufficient number of notified body.

Table 1. Emergency medical device registration and review procedure comparison among China, US and Canada

Country Item	China	US	Canada
Organization	NMPA, provincial and municipal administration bureau review and approve respectively.	FDA manages centralizedly, solely responsible for review and approval.	Health Canada manages centralizedly, solely responsible for review and approval.
Legal system	Specialized *Emergency Medical Device Approval Procedure*, which is valid within the legal validity period.	*1) FD&C Act* stipulates the launch of EUA in case of emergency, and *EUA of Medical Products and Related Authorities* covers drugs, medical devices and vaccines, which are valid within the legal validity period; 2) There is no regulation enforceable at law specifically for medical devices.	*1) Food and Drugs Act* stipulates the launch of IO in case of emergency, and *Medical Devices Regulations* stipulates the SAP, which are valid within the legal validity period; 2) If several IOs made for specific situations expire, they become invalid; 3) There is no regulation enforceable at law specifically for medical devices.
Registration procedure	Time limit is shortened, but the standard isn't lowered.	FDA appropriately relaxes the review requirements, and time limit is shortened.	Time limit is shortened.
Registration document	Be consistent with routine.	Formulate EUA registration document templates for various emergency medical devices.	Issue the guidance of application document requirements of IO authorization.
Review procedure	1) Emergency approval 2) Conditional approval 3) Priority approval	EUA	1) Three pathways of IO authorization 2) SAP
Review characteristic	1) Early intervention 2) On the premise of emergency confirmation 3) Continuable registration	1) Pre-EUA 2) Sort EUA applications by priority 3) EUA is invalid upon ending and registration can't be continued	1) Three expedited authorization pathways 2) SAP for special patients

5.2 EU

5.2.1 Legal system

On May 5, 2017, the EU issued the new *Medical Devices Regulation (MDR)*, with a transitional period of three years from the old *Medical Devices Directive (MDD)*. However, the implementation of MDR has been delayed for a year due to COVID-19 and other factors. This delay is to respond to the urgent need for medical devices in EU member states and to avoid the risk of shortage of necessities due to the insufficient number of notified body.

As the general leading regulation of medical devices, MDR makes comprehensive and detailed provisions on all aspects of medical devices from definition to CE certification. *Commission Recommendation (EU) on conformity assessment and market surveillance procedures within the context of the COVID-19 threat* makes special provisions on the conformity assessment procedures for personal protective equipment and medical devices in the context of COVID-19. (29) In addition, the EU issued *Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context*, which lists technical guidance requirements for various medical devices. (30)

5.2.2 Emergency registration review measures

The registration review procedure for emergency medical devices in EU is generally consistent with the routine situation. Firstly, the manufacturer prepares and submits technical documents, then the notified body carries out conformity assessment procedures and issues certificates, and finally the manufacturer draws up a declaration of conformity and puts a CE mark on the product, which allows the product to circulate freely on the EU market.

In order to better respond to COVID-19, the European Commission issued *Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context*, question 5 points out that: To protect health, upon appropriate and reasonable request, member states can approve the sale of certain devices that have not yet implemented conformity assessment procedures on the domestic markets of the member states concerned. (30) Since the EU has many member states, it is impossible to make unified specific provisions on the registration procedures of each member state. Therefore, each member state will formulate its own registration and review system for emergency medical devices according to the regulations issued by the EU. For example, Germany established the special approval system for emergency medical devices based on article 59 of MDR. (31)

6. Reflections and enlightenment

When a public health emergency happens, the overall response policy made by the country plays a decisive role in the solution effect and actual impact. It is neither scientific nor objective to simply judge that a policy has significant advantages or is effective. Due to the differences of organizations and legal systems in different countries, their registration review systems are different. Based on the previous discussion, the following will analyse comparatively based on the emergency registration and review system of these five countries, in order to summarize experience and enlightenment.

6.1 Efficient and complete legal system

Compared with USA, Canada and other countries, China has more perfect legal system in the registration and review of emergency medical devices. China issued a special law, namely *Emergency Medical Device Approval Procedure*, which stipulates the registration and review system of emergency medical devices comprehensively and systematically. Compared with other countries, USA, Canada and Japan all refer to emergency response system at the legal level. For example, USA promulgated the *Emergency Use Authorization of Medical Products and Related Authorities*, which stipulates the authorization for the use of medical products in emergency situations. However, this law covered drugs, medical devices and vaccines, which lacked pertinence. In Canada, in some provisions of *Food and Drugs Act* and *Medical Devices Regulations*, the import, sale and use authorization of medical devices in the case of significant health risks are only briefly explained, without detailed regulations. In Japan, only in the *Pharmaceuticals and Medical Devices Act*, the application situation of special approval is explained, but there is no corresponding lower-level law. The EU does not elaborate on the registration and review of emergency medical devices either at the legal level or regulatory level, but only issued some relevant notification documents and guidelines. In addition, both national and provincial medical products administration in China can formulate regulations, but states of USA have no corresponding legislative authority. Proper streamlining government and delegating authority and efficient and complete legal system can ensure the smooth development of emergency review when public health emergencies occur and that enterprises and other stakeholders can have the evidence to follow.

6.2 Perfect emergency registration review mechanism

China, USA and Canada all have special registration review mechanisms for emergency medical devices. For example, China mainly uses emergency approval procedures, supplemented by conditional approval and priority review and approval. USA implements the emergency use authorization system; Canada adopts IO authorization system and SAP. Japan and the EU only take some detailed measures to speed up the review on the basis of regular registration review mechanism. The establishment of emergency approval procedure is an important part of China's medical device review approval system under public health emergencies, which plays an important role in speeding up the review and approval of medical devices needed in the state of emergency. With the continuous deepening of China's medical device system reform and the accumulation of experience in dealing with the COVID-19 epidemic, the mechanism of emergency medical device registration and review is gradually improving. Establishing and

optimizing the review approval mechanism of medical devices in emergency situations is conducive to rapid response when public health emergencies occur again, promoting the optimization of the workflow of the whole system of medical device review and approval, and promoting the improvement of the overall level of medical device review and approval in China.

6.3 Scientific security and risk balancing mechanism

From the perspective of the review process, China carries out the registration review of emergency medical devices in accordance with the principle of "no reduction in procedures, no reduction in standards", and the inspection of the quality management system is carried out in parallel with the technical review; However, FDA requires that on the basis of the benefit outweighs the risk, the performance of the product is "possibly effective", the level of evidence can be lower than the effectiveness standard of FDA's conventional listing approval, and limits or exempts part of the quality management system inspection; (32) The EU stipulates that under reasonable circumstances, some products can be exempted from conformity assessment procedures and CE mark; In Japan, clinical trial applicants are allowed to initiate clinical trials without waiting 30 days after completing the necessary PMDA review. In addition, the registration validity period of China's emergency medical devices is usually six months to one year, and the registration can be extended by submitting the post-marketing research data regularly. FDA requires the approved medical devices to be invalid since the date HHS announced the termination of EUA, and within the validity period FDA will carry out irregular flight inspection of the listed emergency products, if the product quality does not meet the standard, the EUA will be withdrawn; if applicant wants to continue to be on the market after the expiration date, he needs to go through the normal registration procedures. Therefore, China should establish scientific safety and risk balance mechanism of medical devices, in combination of China's national conditions and the specific situation of the public health event, we shouldn't be blind and impulse to lower the standard of review, and shouldn't stick to normal thinking either, but keep a balance between safety and risk, make effective control measures to take the necessary risks.

6.4 Comprehensive emergency management measures

In order to timely meet the surging demand for medical devices under public health emergencies, it is necessary not only to ensure the rapid listing of emergency medical devices under the perfect registration review mechanism, but also to consider the necessity of pre-review and the accessibility of medical devices. At present, China only takes the measures of assigning special personnel to guide the registration work and reviewing the application materials at any time, which has indeed shortened the time limit in the review and approval process, but the chain is slightly shorter in terms of the whole process of responding to public health emergencies. FDA proposed the pre-EUA mechanism in the emergency use authorization system, allowing enterprises to pre-declare before the issuance of EUA orders by the minister of HHS. However, according to China's regulations, registration and review can be carried out only after the NMPA decides to start the emergency procedures, which has a certain lag. In terms of improving accessibility of medical devices, Health Canada carries out the SAP that allows healthcare professionals to apply for acquiring and using customized and unlicensed medical devices for patients and issued relevant documents to guide them. Although China has added the emergency use system of medical devices in the new version of *Regulations for the Supervision and Administration of Medical Devices*, (33) it is only a brief overview and there is no relevant supporting documents. In conclusion, in order to minimize the impact of public health emergencies on the public and society, China should consider emergency management measures to deal with potential major threats that have not yet occurred, and prioritize emergency response under certain conditions. And regulatory incentive policies can be formulated to encourage relevant enterprises to innovate actively, ensure that governments can intervene in areas that may be threatened in advance, form a safer and more effective production and management system, and enhance technology and emergency reserve. At the same time, from the perspective of patients, on the basis of ensuring the safety and effectiveness of medical devices, appropriate measures should be taken to ensure the supply of medical devices to meet the emergency needs of patients.

7. Conclusion

On the basis of maintaining its own institutional advantages, China should learn from foreign experience to further optimize the registration and review system of emergency medical devices, so as to improve the ability of response and implementation of China in public health emergencies.

Author Contribution

Yiming Xu and Mingyang Wu have made substantial contributions to the conception and design of this work. Wei Chen and Siyi Ge have taken part in revising work critically for important intellectual content. Yi Liang has revised work and approved the final version to be published.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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