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Administrative Measures for the Supervision of Distribution of Medical Devices

Chapter I General Principles

Article 1

The administrative rules are formulated in accordance with the Regulations on the Supervision and Administration of Medical Devices, with a view to strengthen the supervision and management of medical device distribution, standardize the distributing behaviors of medical devices, and guarantee the safety and validity of medical devices.

Article 2

All the medical device activities in the distribution, supervision and administration within the territory of the People's Republic of China shall comply with the administrative measures

Article 3

Food and drug administration department under the State Council is responsible for supervision and administration of medical devices distribution nationwide. Food and drug administration department of the local government at county level and above is responsible for supervision and administration of medical devices distribution in each administrative region.

Superior food and drug administration department shall be responsible for guiding and supervising the supervision and administration on medical device distribution conducted by subordinate food and drug administration department.

Article 4

Classified management shall be implemented for medical device distribution according to the risk level of medical device.

The distribution of Class I medical devices may be exempted from licensing and filing; filing management shall be implemented for the distribution of Class II medical devices; and licensing management shall be implemented for the distribution of Class III medical devices.

Article 5

The State Food and Drug administration shall formulate the administrative measures for the supervision of medical device distribution and supervise the implementation.

Article 6

The Food and Drug administration shall publish the information about the distribution certificate and record for medical device manufacture lawfully in time. The applicant can search the approval progress and results; and the public can look up about the approval results.

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Chapter II Distribution Licensing and Filing Management

Article 7

Enterprises engaged in medical device distribution shall meet the following conditions:

1. Possess the quality management institution or quality management personnel appropriate to the distributing scale and business scope; the quality management personnel should have the professional educational background or technical title in relevant disciplines recognized by the state;

2. Possess the distributing and storage site appropriate to the distributing scale and business scope;

3. Possess the storage conditions appropriate to the distributing scale and business scope. Storeroom may not be set up in case of the storage fully entrusted to other medical device distributing enterprise;

4. Possess the quality management system appropriate to the medical devices operated;

5. Possess the capability of professional guidance, technical training and after-sales service appropriate to the medical devices operated, or provide technical support by relevant institution as agreed.

The enterprises dealing with the distribution of Class III medical devices should also have the computer information management system complying with the requirements of the GSP for medical devices to ensure the traceability of the products operated. The enterprises dealing with the distribution of Class I and Class II medical devices are encouraged to establish the computer information management system complying with the requirements of the GSP for medical devices.

Article 8

The distributing enterprise dealing with the distribution of Class III medical devices should submit its application for the food and drug regulatory authority of the municipality with districts and submit the following materials:

1. Copies of business license and organization code certificate;

2. Copies of the ID cards, educational background or professional title certificates of legal representative, responsible person of enterprise, and quality director;

3. Explanation on the establishment of organizational structure and departments;

4. Explanation on business scope and business practice;

5. Copies of the geological location map, floor plan and house ownership certificate leasing agreement (attached with house ownership certificate);

6. List of distributing facilities and equipment;

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7. List of documents including distributing quality management system, working procedure, etc.;
8. Introduction of basic information of computer information management system and explanations on functions;
9. Authorization certificate of agent;
10. Other evidential materials.

Article 9

For the application for the licensing of the distribution of Class III medical devices submitted by applicant, the food and drug regulatory authority of the municipality with districts may deal with respectively according to the following situations:

1. If the item applied is within the term of reference of the department and the application materials are complete and consistent with the legal form, the department should accept the application;
2. If the application materials are incomplete or not inconsistent with the legal form, the applicant shall be informed of all contents to be added and/corrected in one time either on site or within five working days;
3. If the application materials have any error that can be corrected on the spot, the applicant should be allowed to make correction on the spot;
4. If the item applied is not falling into the term of reference of the department, the department should immediately make the decision on denial to accept the application and inform the applicant to submit application to relevant administrative department.

In case of acceptance or denial to accept the application for the licensing of medical device distribution, the food and drug regulatory authority of the municipality with districts should issue the Notice of Acceptance or Denial.

Article 10

The food and drug regulatory authority of the municipality with districts should examine and verify the application materials within thirty working days from the date of acceptance and carry out on-site verification according to the requirements of the Good Supply Practice for medical devices. In case of rectification required, the rectification time will not be included in the examination and verification time.

For those meeting specified conditions, the written decision on licensing shall be made according to laws and the License for Medical Device Distribution shall be issued within ten working days; for those not meeting specified conditions, if the written decision on denial is made, the reasons should be specified.

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Article 10

If the application for the licensing of medical device distribution directly relates to the major interest relationship between the applicant and others, the food and drug regulatory authority should inform the applicant and the interested party of the rights to apply for hearing enjoyable according to laws and regulations and the relevant provision of China Food and Drug Administration; while conducting examination of the licensing for medical device distribution, the food and drug regulatory authority, if deems the application as the major licensing item relating to public interest, should announce to the public and hold a hearing.

Article 12

In case of the distribution of Class II medical devices, distributing enterprise should file with the local the food and drug regulatory authority of municipality with districts, fill in the Class II Medical Device Distribution Filing Form, and submit the materials specified in Article 8 of these provisions (except for Item 8).

Article 13

The food and drug regulatory authority should verify the integrity of the materials submitted by enterprise on the spot; filing will be permitted for those complying with the provisions and issued with the certificate of filing for the distribution of Class II medical devices.

Article 14

The food and drug regulatory authority of the municipality with districts should carry out the on-the-spot verification on the distributing enterprise of Class II medical device according to the requirements of the Good Supply Practice for medical devices within 3 months from the filing date of the medical device distributing enterprise.

Article 15

The valid period of the License for Medical Device Distribution is five years, which shall indicate such items as license number, name of enterprise, legal representative, responsible person of enterprise, residence, site of business distribution, mode of distribution, business scope, address of warehouse, issuing body, issuing date, valid period, etc.

The certificate of filing for medical device distribution should indicate such items as the number, name of enterprise, legal representative, responsible person of enterprise, residence, site of business distribution, mode of distribution, business scope, address of warehouse, filing department, filing date, etc.

Article 16

The change of the items in the License for Medical Device Distribution may be classified into change of licensing item and change of registration item.

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Change of licensing items includes site of business distribution, mode of distribution, business scope, and address of warehouse.

Change of registration items includes other items beyond aforesaid items.

Article 17

In case of change of licensing items, the application for change of the License for Medical Device Distribution shall be submitted to the original issuing department. The materials relating to the change of contents as specified in the provisions of Article 8 of these provisions should be submitted.

If warehouse is arranged across administrative regions, applicant should handle the filing with the food and drug regulatory authority of the municipality with districts where the warehouse is located.

The original issuing department should verify within fifteen (15) working days after receiving the application for change and make decision on permission for change or denial for change; if on-the-spot verification should be conducted according to the requirements of the Good Supply Practice for medical devices, the decision on permission for change or denial for change shall be made within thirty (30) days after receiving the application for change. In case of denial for permission, the reasons should be specified in written and the applicant should be informed. The number and valid period of the changed *License for Medical Device Distribution* shall remain unchanged.

Article 18

For new independent site of business distribution, medical device distribution licensing or filing should be applied independently.

Article 19

In case of change of registration items, medical device distributing enterprise should timely handle the procedures for change with the food and drug regulatory authority of the municipality with districts.

Article 20

The medical device distributing enterprise existed due to splitting and merger should apply for change of licensing according to the provisions of these provisions; the medical device distributing enterprise dissolved due to splitting and merger should apply for cancellation of the License for Medical Device Distribution; and the medical device distributing enterprise newly established due to splitting and merger should apply for handling the License for Medical Device Distribution.

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Article 21

The registration applicant, filing applicant or manufacturing enterprise selling medical devices at their residences or manufacturing site may not handle distribution licensing or filing; in case of storing at other places and selling medical devices on the spot, they should handle the distribution licensing or filing according to provisions.

Article 22

If the valid period of the License for Medical Device Distribution is extended upon expiration, medical device distributing enterprise should submit the application for the extension of the License for Medical Device Distribution with the original issuing department six months before the expiration of the valid period.

Original issuing department should verify the application for extension according to the provisions in Article 10 of these provisions; if necessary, conduct on-the-spot verification, and make the decision on whether to approve the extension before the expiration of the valid period of the License for Medical Device Distribution. If the application for extension that meets the specified conditions is approved,the number of the extended License for Medical Device Distribution shall remain unchanged. Those not complying with the specified conditions should be instructed to make rectification within specified time; if the specified conditions still fail to meet the specified conditions after rectification. The application for extension shall not be approved and the reasons should be specified in written. If no decision is made overdue, it will be regarded as the extension is approved.

Article 23

In case of any change to the filing items such as the name of enterprise, legal representative, responsible person of enterprise, residence, site of business distribution, mode of distribution, business scope, address of warehouse, etc. in the filing certificate of medical device distribution, the filing should be changed in a timely manner.

Article 24

In case that the *License for Medical Device Distribution* is lost, medical device distributing enterprise should immediately publish lost declaration on the media designated by the original issuing department. After 1 month after the lost declaration is published, the application for re-issuance of the certificate shall be submitted to the original issuing department. The original issuing department should timely re-issue the *License for Medical Device Distribution*.

The number and valid period of the re-issued *License for Medical Device Distribution* shall be the same as the original certificate.

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Article 25

If the filing certificate for medical device distribution is lost, medical device distributing enterprise should immediately handle the procedures for re-issuance with the original filing department.

Article 26

If medical device distributing enterprise is investigated by the food and drug regulatory authority due to illegal business but the case has not been closed or receives the decision on administrative sanction, the food and drug regulatory authority of the municipality with districts should terminate the licensing until the case is completed.

Article 27

In case that the certificate of medical device distributing enterprise should be canceled according to the provisions of the laws and regulations or the valid period of the license has not expired but the enterprise proposes the cancellation with initiative, the food and drug regulatory authority of the municipality with districts should cancel the *License for Medical Device Distribution* according to laws and publish on website.

Article 28

The food and drug regulatory authority of the municipality with districts should establish the licensing filing such as the issuance, extension, change, re-issuance, revocation, cancellation, etc. of the License for Medical Device Distribution and filing information file of medical device distribution.

Article 29

Any unit and individual should not forge, alter, buy and sell, lease and lend the License for Medical Device Distribution and the filing certificate of medical device distribution.

Chapter III Distribution Quality Management

Article 30

Medical device distributing enterprise should establish the distribution management system covering the whole course of quality management according to the requirements of the Good Supply Practice for medical devices and properly keep the record, and ensure the distribution conditions and distribution behaviors to persistently comply with the requirements.

Article 31

Medical device distributing enterprise should bear the legal responsibility for the medical device buying and selling behavior committed by the administrative office or sales person in the name of

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the enterprise. The sales personnel of the medical device distributing enterprise selling medical device should have the letter of authorization affixed with the official seal of the enterprise. The letter of authorization should indicate the variety sold under authorization, region,and time limit and indicate the ID card number of the sales person.

Article 32

Medical device distributing enterprise should establish and execute the incoming inspection and recording system. The distributing enterprise dealing with the wholesale business of Class II and Class III medical devices and the retail business of Class III medical devices should establish sales record system. The information of incoming inspection record and sales record should be authentic, accurate, and complete.

For the enterprise dealing with the wholesale business of medical devices, the records of purchase, storage, and sales should meet the requirements on traceability.

Incoming inspection record and sales record should be kept for 2 years after the valid period of the medical device; if valid period is unavailable, the records shall be kept for no less than 5 years. The incoming inspection record and sales record of implantable medical devices should be kept permanently.

Other medical device distributing enterprises are encouraged to establish sales record system.

Article 33

Medical device distributing enterprise should purchase medical devices from the manufacturing enterprise or distributing enterprise with qualification.

Medical device distributing enterprise should agree on quality responsibility and after-sales service responsibility with supplier to ensure the safety use of medical devices after sales.

The medical device distributing enterprise agrees with supplier or appropriate institution that it will be responsible for the installation, maintenance, and technical training services of product may not establish the department dealing with technical training and after-sales service but should have appropriate management personnel.

Article 34

Medical device distributing enterprise should take effective provisions to ensure the transportation and storage process of medical devices to comply with the requirements of the instructions for medical devices or labels and marking, and keep proper record to ensure the safety of medical device quality.

If the instructions and label indicate that the medical devices should be stored at low temperature and in refrigeration, low-temperature, refrigeration facilities and equipment should be used for transportation and storage according to relevant provisions.

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Article 35

If medical device distributing enterprise entrusts other units to transport medical devices, the quality assurance capability of the medical devices transported by carrier should be assessed and evaluated, clearly defining the quality responsibility during the transportation to ensure the quality safety during transportation.

Article 36

Medical device distributing enterprise, if provides storage and delivery services to other manufacturing and distributing enterprises of medical devices, should sign written agreement with client, defining the rights and obligations of both parties, has the equipment and facilities appropriate to the conditions for product storage and delivery and scale, and the computer information management platform and technical means for conducting the real-time electronic data exchange and realizing the whole-course traceability of the product distribution with client.

Article 37

The distributing enterprise dealing with the wholesale business of medical devices should sell medical devices to the distributing enterprise or user unit with qualification.

Article 38

Medical device distributing enterprise should arrange full-time or part-time personnel in charge of after-sales management, find out the reasons for the quality problem complained by customer, take effective provisions for timely treatment and feedback, and properly keep the record; if necessary, inform the supplier and the medical device manufacturing enterprise.

Article 39

If medical device distributing enterprise has no the conditions for the original distribution licensing or does not comply with the filing information and cannot be contacted, after publication by the original issuing or filing department, the *License for Medical Device Distribution* should be canceled according to laws or indicated in the filing information of Class II medical device distribution, and announced to the public.

Article 40

The distributing enterprise of Class III medical device should establish quality management self-inspection system and conduct all-item self-inspection according to the requirements of the Good Supply Practice for medical devices, and submit annual self-inspection report to the local the food and drug regulatory authority of the municipality with districts at the end of each year.

Article 41

The distributing enterprise of Class III medical device resumes business after self-close-down for more than one year, it should report to the food and drug regulatory authority of the municipality

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with districts in written in advance; the business should not resumed until being inspected as complying with requirements.

Article 42

Medical device distributing enterprise should not operate the medical devices that are not registered or filed, without qualified certificate, and out-of-date, invalid, and washed out.

Article 43

In case of major quality accident occurred on the medical device operated by medical device distributing enterprise, it should report to the local the food and drug regulatory authority of the province, autonomous region or municipality directly under the central government within 24 hours, which will immediately report to China Food and Drug Administration.

Chapter IV Supervision and Management

Article 44

The food and drug regulatory authority should regularly or irregularly conduct supervision and inspection on the compliance of medical device distributing enterprise with the requirements of the Good Supply Practice and supervise and urge enterprises to standardize distributing activities. The annual self-inspection report on the all-item self-inspection conducted by the distributing enterprise of Class III medical devices according to the requirements of the Good Supply Practice for medical devices should be examined; if necessary, field inspection should be conducted.

Article 45

The food and drug regulatory authority of province, autonomous region or municipality directly under the central government should compile the supervision and inspection plan for the medical device distributing enterprises within respective administrative region and supervise the implementation. The food and drug regulatory authority of municipality with districts should formulate the supervision focus, inspection frequency and coverage of the medical device manufacturing enterprise within respective administration region and organize the implementation.

Article 46

The food and drug regulatory authority organizing supervision and inspection should formulate inspection scheme,clearly defining the inspection criteria, record the inspection conditions on the spot according to facts, and inform the inspected enterprise of the inspection results in written. If rectification is required, the rectification contents and rectification time limit should be defined and follow-up inspection should be implemented.

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Article 47

The food and drug regulatory authority should strengthen the random inspection on medical devices.

The food and drug regulatory authority above the level of province should timely publish medical device quality announcement according to the conclusions of the random inspection.

Article 48

In any of the following circumstances, the food and drug regulatory authority should strengthen field inspection:

1. Severe problems existed in the supervision and inspection in last year;
2. Subject to administrative penalty due to violation of relevant laws and regulations;
3. Class III medical device distributing enterprise newly established;
4. Other circumstances deemed by the food and drug regulatory authority as necessary to conduct field inspection.

Article 49

The food and drug regulatory authority should establish the routine supervision and management system for medical device distribution and strengthen the routine supervision and inspection on medical device distributing enterprises.

Article 50

Unannounced inspection may be implemented by the food and drug regulatory authority on the medical device distributing enterprise existed with potential safety hazard of product complained and reported or indicated by other information and found out in routine supervision and inspection or the medical device distributing enterprise with bad behavior record.

Article 51

In any of the following circumstances, the food and drug regulatory authority may question the responsibility of the legal representative or responsible person of medical device distributing enterprise.

1. Severe potential safety hazard existed in distribution;
2. The product operated has been reported or complained or exposed by media for several times due to quality problem;
3. The credit rating is evaluated as the enterprise with bad credit;

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4. Other circumstances deemed by the food and drug regulatory authority as necessary to question the responsibility.

Article 52

The food and drug regulatory authority should establish the archives for the supervision and management on medical device distributing enterprise, record licensing and filing information, results of routine supervision and inspection, investigation and treatment of illegal act, etc., and implement focused supervision and management on the medical device distributing enterprise with bad credit record.

Chapter V Legal Responsibility

Article 53

In any of the following circumstance, the food and drug regulatory authority above the level of county shall be instructed to make correction within time limit and warned; if the medical device distributing enterprise refuses to make correction, a fine above RMB 5,000 but below RMB 20,000 shall be imposed;

1. Medical device distributing enterprise fails to handle the change of registration items according to the provisions of these provisions;
2. Medical device distributing enterprise dispatching sales personnel to sell medical devices fails to provide the letter of authorization according to the requirements of these provisions;
3. The distributing enterprise of Class III medical devices fails to submit annual self-inspection report to the food and drug regulatory authority before the end of each year.

Article 54

In any of the following circumstances, the enterprise shall be instructed to make correction by the food and drug regulatory authority above the level of county and a fine above RMB 10,000 but below RMB 30,000 shall be imposed:

1. The business conditions of medical device distributing enterprise have changed and no longer complied with the requirements of the Good Supply Practice for medical device but the enterprise has not make rectification according to provisions;
2. Medical device distributing enterprise changed site of business distribution or address of warehouse and expanded business scope without authorization or set up warehouses arbitrarily;
3. The distributing enterprise dealing with the wholesale business of medical devices sells medical devices to the distributing enterprise or user unit without qualification;
4. Medical device distributing enterprise purchases medical devices from the manufacturing and distributing enterprise without qualification.

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Article 55

The enterprise deals with medical device distributing activities without permission or fails to handle the procedures for extension according to laws but still deals with medical device distribution after the valid period of the License for Medical Device Distribution expires shall be punished according to the provisions in Article 63 of the Regulations on the Supervision and Management of Medical Devices.

Article 56

The enterprise providing false information or obtaining the License for Medical Device Distribution with other deception means shall be punished according to the provisions in Article 64 of the Regulations on the Supervision and Management of Medical Devices.

Article 57

The enterprise forging, altering, buying and selling, leasing or lending the License for Medical Device Distribution shall be punished according to the provisions in Article 64 of the Regulations on the Supervision and Management of Medical Devices.

If any enterprise forges, alters, buys and sells, leases or lends the filing certificate for medical device distribution, it shall be instructed to make correction by the food and drug regulatory authority above the level of county and a fine below RMB 10,000 shall be imposed.

Article 58

The enterprise failing to file according to the provisions of these provisions or providing false information during filing shall be punished according to the provisions in Article 65 of the Regulations on the Supervision and Management of Medical Devices.

Article 59

In any of the following circumstances, the enterprise shall be instructed to make correction by the food and drug regulatory authority above the level of county and be punished according to the provisions in Article 66 of the Regulations on the Supervision and Management of Medical Devices:

1. Operate the medical devices not complying with the compulsory standard or not complying with the technical requirements of the products registered or filed;
2. Operate the medical devices without qualified certificate, out of date, invalid and washed out;
3. Still refused to stop the distribution of medical devices after being instructed to stop the business by the food and drug regulatory authority.

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Article 60

In any of the following circumstances, the enterprise shall be instructed to make correction by the food and drug regulatory authority above the level of county and be punished according to the provisions in Article 67 of the Regulations on the Supervision and Management of Medical Devices:

1. The instructions and labels for the medical devices operated do not comply with relevant provisions;
2. Failure to transport and store medical devices according the instructions and labels and marking of medical devices.

Article 61

In any of the following circumstances, the enterprise shall be instructed to make correction by the food and drug regulatory authority above the level of county and be punished according to the provisions in Article 68 of the Regulations on the Supervision and Management of Medical Devices:

1. Distributing enterprise fails to establish and execute the incoming inspection and recording system for medical device according to the provisions of these provisions;
2. The distributing enterprise dealing with the wholesale business of Class II and Class III medical devices and the retail business of Class III medical devices fails to establish and execute sales record system according to the provisions of these provisions.

Chapter VI Supplementary Provisions

Article 62

The following terms referred in these provisions shall have the following meanings:

Medical device distribution refers to the behavior of providing medical device products by the way of buying and selling, including procurement, acceptance, storage, sales, transportation, after-sales service, etc.

Medical device wholesale refers to the medical device distribution behavior of selling medical devices to the distributing enterprise or user unit with qualification.

Medical device retail refers to the medical device distribution behavior of directly selling medical devices to consumers.

Article 63

The management provisions on Internet-based medical device distribution shall be formulated by China Food and Drug Administration separately.

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Article 64

The formats of the License for Medical Device Distribution and the filing certificate for medical device distribution shall be uniformly formulated by China Food and Drug Administration.

The License for Medical Device Distribution and the filing certificate of medical device distribution shall be printed and produced by the food and drug regulatory authority of the municipality with districts.

The arrangement mode of the number of the License for Medical Device Distribution is: XX Food and Drug Distribution License No.XXXXXXXX. In which,

The first X indicates the abbreviation of the province, autonomous region or municipality directly under the central government where the licensed department is located;

The second X indicates the abbreviation of the municipal administrative region with districts;

The third X to the sixth X represent the four-digit licensing year;

The seventh X to the tenth X represent the four-digit licensing serial number.

The arrangement mode of the filing number of the filing certificate of Class II medical device distribution shall be: XX Food and Drug Distribution Filing No. XXXXXXXX.

In which,

The first X indicates the abbreviation of the province, autonomous region or municipality directly under the central government where the filing department is located;

The second X indicates the abbreviation of the municipal administrative region with districts;

The third X to the sixth X represent the four-digit filing year;

The seventh X to the tenth X represent the four-digit filing serial number.

Article 65

The business scope specified in the License for Medical Device Distribution and the medical device distribution filing certificate shall be determined according to the management category, classification and coding, and name of medical device. The management category, classification and coding, and name of medical device shall be verified according to the classified catalog of medical devices promulgated by China Food and Drug Administration.

Article 66

These provisions shall put in force from October 1, 2014, also abolish the Provisions for the Management of the License for Medical Device Distributing Enterprises promulgated on August 9, 2004 (the former State Food and Drug Administration decree No.15) shall be repealed simultaneously.

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