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# State Drug Administration
# Action plan to accelerate the promotion of smart drug supervision

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By the China National Drug Administration Comprehensive and Planning Finance Department

Since the 19th National Congress of the Communist Party of China, according to the decision-making arrangements of the Party Central Committee and the State Council on cybersecurity and informationization, drug supervision and management departments at all levels have actively explored the use of information technology to enhance drug regulatory capabilities and promote the realization of drug, medical device and cosmetics regulatory business networks. To establish a daily regulatory data to facilitate access to information, strengthen network infrastructure and security protection, and make important progress. However, there are also problems such as insufficient top-level design, decentralized system construction, lack of innovative applications, and insufficient data support. To speed up the drug wisdom supervision, building supervision "large-scale systems, a large platform, big data" to achieve supervision and cloud computing, big data, integration and development "Internet +" such as information technology, creating new regulatory approach, service reform and development, the development of The plan below.

## First, the overall requirements

### (1) Guiding ideology

Carry out the spirit of the 19th National Congress of the Communist Party of China, adhere to the people-centered, deepen the reform of "distribution management" , follow the "four most stringent" requirements of General Secretary Xi Jinping , implement the national drug supervision and management work deployment, and strengthen the layout of wisdom supervision and planning, fully Give full play to the leading role of overall planning, adhere to a blueprint in the end, coordinate management, collaborative construction, and achieve the integration of supervision and information technology; give full play to the advantages of cloud computing, accelerate the integration of regulatory business systems, and realize the overall deployment and upgrade of business systems. Support; give full play

to the advantages of big data, strengthen the construction of data centers, implement precise supervision and scientific supervision, improve the efficiency of supervision; give full play to the advantages of "Internet+" , enhance the convenience of supervision, promote social co-governance, promote sunshine supervision, and let the problem products Those who are hiding in the body and illegally making sellers cannot escape the law network and constantly improve the people's sense of gaining access to drugs.

### (2) Basic principles

**Adhere to people-oriented.** Establish a people-centered development concept, practice the service tenet of governing for the people, take the drug intelligence supervision information construction as the entry point, comprehensively improve the supervision ability and service level, and not only serve the supervisors, improve work efficiency and supervision effectiveness. It is also necessary to serve the public and enhance the sense of security and happiness of the people.

**Insist on innovation and development.** Follow the informatization construction and the "Internet+" development law, create an open and inclusive innovation environment, encourage diversified technology, mechanism and construction model innovation, strengthen the development of regulatory data and the application of new technologies, and promote the drug safety governance system and governance Modernization.

**Adhere to the demand orientation.** Starting from the actual needs of supervision work, combined with the characteristics of supervision business and the new system of supervision, focusing on resource integration, data sharing and business collaboration, further clarify the ideas and framework of information development, and gradually build a practical and easy-to-use information support system.

**Adhere to overall integration.** Further strengthen the construction of information system and standard system, strengthen the top-level design, break the old model of decentralized construction, build a deep integrated information system platform according to the regulatory categories, realize cross-system collaborative work, and ensure regulatory information of national bureaus and local regulatory authorities. The construction plan is consistent, standardized and unified, with different emphasis and synergy.

**Adhere to shared openness.** National, provincial levels regulatory data center backbone to "a product" during "an Enterprise" as the focus, aggregation, management, sharing, regulation and opening large data resources, services, supervision, industry and the public. Innovate the "Internet+" government service, accelerate the promotion and application of mobile internet technology, and realize the transformation and upgrading of regulatory services.

**Adhere to safety and control.** Firmly establish "bottom line thinking" and strictly abide by network information security. Adhere to the simultaneous advancement of safety and development, establish a network information security protection system with reliable technology and fine management, implement a normalized security inspection system, improve the network security emergency management system, and improve the network security emergency response capability.

### (3) Development goals

2020, established in line with the development trend of information technology drug regulatory information construction technology and application framework. On this basis, then after 3-5 years, information technology to promote the depth of integration and supervision, supervision of the formation of a new situation "strict control" plus "smart pipe".

**The infrastructure is further consolidated.** Building a drug regulatory cloud, breaking the physical barriers between systems and realizing resource sharing. Comprehensive use of Internet, national e-government network and other network resources build a national drug supervision network, to achieve high-speed, smooth network.

**The data foundation is further consolidated.** Formulate standards for drug regulatory informationization standards, speed up the integration of regulatory data such as policies and regulations, administrative licensing, batch issuance, inspection, and adverse reaction monitoring; collect and aggregate industry-related data according to regulatory requirements. By the end of 2019 to rationalize resource pooling data channels, open up *"islands of information"* State Bureau data centers and units directly under, the achievement of national, provincial levels of data centers and data exchange; by 2020, the basic realization of the data resource efficient acquisition and effective integration, big data fusion applications and achieved initial results.

**The level of business application has further improved.** Establish synergistic and efficient three business application platforms for pharmaceuticals, medical devices and cosmetics, realize online management of important regulatory services, timely uploading of information, timely disposition of problems, record traces of the whole process, explore drug safety risk management based on big data, and gradually improve supervision. Predictability, targeting, timeliness.

**The capacity of government service has been further improved.** Establish an "Internet+Government Services" platform, continue to deepen the "distribution service" reform, and optimize access services. Make full use of the "Internet+" information technology, build a network government service hall, realize online processing of drug regulatory government affairs, and effectively improve the service capacity and level of drug regulatory government affairs.

**Network information security has been further strengthened.** Improve the network security management system, establish a security operation and maintenance integration platform, strengthen security protection technology, realize unified network security protection based on big data and cloud computing technologies, and timely discover and effectively dispose of various network attack threats and security incidents.

## Second, the key tasks

### (1) Integrating the basic platform

**Building a drug regulatory cloud.** The construction of the Drug Administration Cloud of the National Bureau will provide necessary support for the completion of regulatory data and application integration for the national bureaus and relevant units. Build infrastructure cloud platforms and integrate existing infrastructure to enable on-demand deployment of

infrastructure resources. After the technical review of the existing government information system of the national bureaus and subordinate units, the government has gradually moved to the drug supervision cloud to realize the overall deployment upgrade and cloud transformation. Provincial drug regulatory authorities can rationally plan and layout according to business needs, and flexibly adopt self-construction, renting local government affairs cloud or third-party cloud to build a provincial drug supervision cloud. Through the construction of national and provincial drug regulatory clouds, the two levels of regulatory services will be interconnected, the information support environment will be optimized, and the cloud service capability of the drug regulatory system will be enhanced.

| Task column 1 Drug supervision cloud construction |
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| Accelerate the upgrading of the infrastructure of the National Office computer room and form a self-built cloud platform. On this basis, expand the cloud resources by purchasing third-party cloud services to form a drug monitoring cloud of the National Bureau of the hybrid cloud model. The drug supervision cloud is used as a hardware infrastructure platform for the supervision of data and application integration by the national bureau and related departments, opening up barriers to hardware resources of various business systems, realizing resource sharing, improving resource efficiency, and avoiding redundant construction and waste of resources. Which has been gradually build business applications migrate to the cloud and drug supervision, upgrade network infrastructure, disaster recovery and integration of business systems infrastructure and business data.<br>According to local conditions, provincial bureaus can build cloud platforms by renting government cloud, self-built cloud and leasing third-party cloud to realize hardware resource integration and optimize information support environment. |

## (2) Smooth network interconnection

**Strengthen the construction of internal and external networks of e-government.** The National Bureau further improved the access to the e-government external network, and fully relied on the national e-government external network to realize the interconnection and interoperability of the national bureau, the subordinate units, and the provincial drug regulatory department business network, forming a “one national network” for drug supervision , mainly carrying The drug regulatory department performs functions and provides business services systems for the public, and provides necessary support for network interconnection for information resources sharing , and at the same time realizes interconnection with various national departments. Build a national government e-government intranet, mainly carrying internal office and other business information systems, achieving secure interconnection with the national e-government intranet, and exchanging data below confidential level to improve the security protection of national bureaus' confidential information and sensitive information processing. Level.

| Task column 2 National Bureau e-government internal and external network construction |
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| Promote the access work of the e-government extranet, realize the connection between the national extranet and the national e-government external network, and rely on the national e-government extranet to gradually realize the network interconnection with the national departments and local regulatory departments according to the work requirements. .<br>Construction of the National Bureau e-government intranet. Relying on the national e-government network, the construction of the National Bureau of secret-level network, and security within the country-wide e-government network docking, and to e-government network |

as the basis for exchange of confidential data below the rank. According to the actual work needs, the national government e-government intranet will be gradually extended to relevant units.

### (3) Improve standard specifications

**1. Improve the standard system for drug regulatory information.** According to the drug regulatory business needs and the actual application system construction, in line with the principle of urgency and use first, enrich and improve the drug regulatory information standard system, and accelerate the revision and revision of information technology standards. The National Bureau strengthens the overall coordination of the revision and revision of key informationization standards in the field of drug regulation, absorbs provincial drug regulatory authorities to participate in standard revision and revision, and encourages third-party scientific research and technical units to participate and provide technical support. Strengthen drug regulatory information standards related work of international exchanges and cooperation, speed up international standards conversion landing, focusing on medicines regulatory information standards with international standards benchmarking work.

**2. Promote the implementation of standards.** Through the way of national government leading co-ordination and provincial bureaus to coordinate participation, strengthen the publicity and application of various informationization standards, explore standard conformity testing, and promote drug regulatory information sharing, business collaboration and big data applications. Set up a column on the website of the National Bureau to publicize the drug regulatory information standard system and promote the consistency between regulatory data standards and industry data standards.

| Task column 3 Construction of drug regulatory information standard system |
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| According to the state to promote e-government requirements, aggregate, sort, develop suitable information technology standards and drug regulatory needs, focus on electronic certificates, pharmaceuticals traceability, drugs are archives, medical coding database and cosmetics regulation five aspects of 20 information Their preparation work. Strengthen international exchanges and cooperation in drug regulatory information standards, actively carry out research and coordination of electronic transmission standards for regulatory information related to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, and participate in international standards revision and revision, focusing on drug regulation Benchmarking of informatization standards and international standards.<br>Promote the publicity of information technology standards. In accordance with the principle of "newly adopted standards, established benchmarking, and gradual transition", standard publicity work will be carried out in multiple channels, at multiple levels and in multiple forms. Strengthen the promotion and interpretation of standard application subjects and promote the implementation of standard applications. We will carry out the compliance testing of drug regulatory information standards, focus on the effective implementation of standards compliance testing, and promote the implementation of drug regulatory information standards. Establish and improve the standard management system and provide convenient standard inquiry and download services for the society on the website of the National Bureau. |

### (4) Strengthening data management

**1. Clarify the responsibility of data management.** Formulate rules and regulations such as drug regulatory data resource sharing management methods, and further clarify the rights and responsibilities of the production, preservation, update, use, sharing, opening and maintenance of drug regulatory data. The confidentiality must be kept

confidential, the disclosure must be disclosed, and the sharing must be Sharing, from the source to break the situation of their own battle, to avoid the formation of "data islands."

**2. Promote data sharing and sharing.** In accordance with the "*Guidelines for the Compilation of the Catalogue of Government Information Resources (Trial)"* (Development and Reform High Technology [ 2017 ] No. 1272 ), the National Bureau, the directly affiliated units, and the provincial bureaus separately compile and compile the government information resources catalogues of the department and the level, and follow the information. The resource catalogue carries out data exchange and supports the mutual recognition and sharing of government information resources across regions, levels, and departments. Establish and improve the operational mechanism of national drug regulatory data exchange and sharing, rely on the national e-government external network, and use the national and provincial data center as the main channel and core node to realize the interconnection and co-construction and sharing of the two-level data center, and then realize Collection and sharing of national drug regulatory data .

| Task column 4 Construction and management of drug regulatory data sharing platform |
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| Establish a data management system mechanism. To formulate supporting systems for drug regulatory data resource sharing management methods, the national bureaus and provincial bureaus separately compile and compile the government information resource catalogues at the same level, and carry out the exchange and sharing of data resources of national and provincial data centers in accordance with the information resource catalogue. Develop unified technical specifications and standards to form a unified mechanism for data collection, analysis and processing, and data access.<br>In-depth data management and strengthen the standardization and standardization of data management. Carry out the main data management work, use administrative management and information technology to carry out the governance and optimization of drug regulatory data, online dynamic monitoring data exchange and sharing, implement data quality assessment and evaluation, and improve data quality and data management. |

**3. Promote the construction of the “drug regulatory data sharing platform”.** Relying on the data sharing platform to expand the data resources of the National Bureau data center, collect and collect various types of drug regulatory data, relevant market subject data, and third-party institutional data, and create a unified and authoritative national drug regulatory big data center to achieve unified management of data. To drugs, medical devices, cosmetics regulatory main line of business planning and comprehensive development and utilization of data resources, establish regulatory systems and data resources of the whole process subject database contains all varieties. Establish a variety of files covering the whole life cycle of medicines, medical devices and cosmetics, and gradually realize “one product, one file” and “one enterprise and one file”. In accordance with relevant regulations, data openness and sharing services are provided externally through the drug regulatory data sharing platform. Strengthen the security management of data centers, do a good job of data security, improve data encryption and desensitization, and improve data privacy protection mechanisms.

| Task Box 5 Establish a portfolio of pharmaceutical, medical device and cosmetic products |
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| Establish a variety file information management system for pharmaceuticals, medical devices and cosmetics, collect, correlate and display the product variety information scattered in different units and departments, realize the management of the product category “one product |

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| and one file", and realize the whole life week of the product. Management, facilitating business collaboration and data sharing, providing data support for regulatory decision-making and providing data resources for social co-governance.<br>Based pharmaceutical data lifecycle management needs to build a nationwide, "take effective" one of the trusted security and reliable drug information collection platform, and ensure that the platform, data and user security protection to meet the requirements to ensure collection of drug information Compliance use. |

**4. Strengthen data analysis, application and cooperation.** The use of big data technology means to achieve unified management, analysis and utilization of data resources, and explore a new type of regulatory data application model based on information collection and sharing, information disclosure as a means, and credit management as the core. Encourage drug supervision departments at all levels in cooperation with relevant market players, third-party organization that brings together businesses, products, and other large data resources, a wider range of information-sharing mechanism. Using Internet information as an important source, strengthen Internet information collection and analysis, study Internet information characteristics, and provide daily supervision. Establish a long-term working mechanism, improve data quality, promote regulatory digitalization, and improve the accuracy, targeting and scientific of supervision.

| Task Box 6 Data Application and Cooperation |
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| Enrich the data resources of the China Food and Drug Administration Data Center. Combine existing resources in the data center, introduce relevant data such as market and industry in various forms, and expand data center resources. Explore the establishment of a big data research work mechanism, multi-participation, and expand the breadth and depth of data research.<br>Guided by business needs, the company continuously strengthens the analysis and mining of drug regulatory data and collaborative applications and builds a series of analysis reports and products for drug regulatory big data.<br>Establish a data cooperation mechanism, explore innovative cooperation models, and carry out multi-field cooperation with government departments, universities, scientific research institutions, etc., revitalize data center data resources, serve regulatory services, and serve the industry. |

### (5) Enhance application services

**1. Promote the "Drug Regulatory Application Platform".** To further optimize the drug regulatory application structure, in accordance with the principle of division of powers, the national bureaus and provincial bureaus have different emphasis on jointly promoting the construction of drug regulatory application systems. The National Bureau establishes a regulatory system for pharmaceuticals, medical devices, and cosmetics, and establishes application systems covering key business areas such as administrative approval, supervision and inspection, inspection and monitoring, and risk analysis according to the type of business in each sector. Each section unified access to the national bureau "drug regulatory application platform" to achieve unified portal login and a unified user management and data sharing between applications and business systems together.

The provincial bureaus may, according to the division of powers, follow unified standards, build and improve business systems covering administrative examination and approval, supervision and inspection, inspection and monitoring, and risk analysis within their respective administrative regions, and make full use of the sharing mechanism of the

two-level data center to strengthen the business with the national bureau. Collaboration and system linkage. Will encourage the provincial bureau and the National Bureau of provincial government information systems into a close business relationship with the National Bureau of "drug regulatory application platform", flexible access platform or by way of the overall business data exchange and sharing of common build drug regulatory "big system" .

| Task column 7 Construction of national drug regulatory application platform |
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| The construction of the national drug regulatory application platform, relying on the application platform to integrate the national drug regulatory government information system, to solve the problem of difficult interconnection, difficult information sharing and difficult business coordination of drug regulatory government information systems, and gradually form department linkage and business synergy. All types of established systems should be standardized and upgraded before being incorporated into the "drug regulatory application platform" of the national bureau; all new systems should be constructed in accordance with the access specifications of the "drug regulatory application platform".<br>The National Drug Regulatory Application Platform implements five basic functions: unified portal management, single sign-on, integrated to-do list, progress query, statistical analysis, online supervision and message push, etc.; unified user management, support for user hierarchical management and master-slave accounts association management; unified authentication management, support for password authentication, dynamic password and CA certification; unified audit management, standardize government information systems audit behavior by analyzing logs, supports early warning, decision-making and visual display; unified prepare case management, drug regulatory government The information system is filed and managed, and the record number is issued to the government information system that meets the requirements. |

**2. Improve the level of "Internet+Government Services".** Adapt to the development needs of "Internet+government services", build an integrated online public service system for the public, and explore a new model of "Internet+government services" for public participation. Platform to accelerate the construction of "Internet+government services" to promote the integration of online service platform and service hall entity, provide one-stop services to achieve the whole process of dynamic supervision of all matters, providing online and offline functionality complementary and mutually reinforcing government services, "Let More information runs, people run less errands." Through the Internet, the online inquiry and customized push of information for the public is realized, the information disclosure is strengthened, the information disclosure service level is improved , the transparent open government is created, the public drug safety awareness is raised, and the quality and safety mechanism of the public participation is formed. Promote the integration of websites and mobile applications of the units directly under the National Bureau, develop a website group management platform, build a platform structure for interconnection, open up information barriers, avoid redundant construction, promote intensive sharing, and improve the management and service level of the website of the National Bureau. Smart government website.

| Task column 8 National Bureau "Internet + Government Services" platform construction |
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| In accordance with the "*Notice of the General Office of the State Council on Printing and Distributing the Guidelines for the Construction of the "Internet+Government Services*" Technical System" (State Council Letter [2016 ] No. 108 ), the construction of the government service platform of the State Drug |

Administration, including the government service management platform and government services Data sharing platform and government service portal.

Construction of government service management platform and government service data sharing platform, integration of government service information system resources, promotion of government service process optimization, strengthening of mutual recognition and sharing of government service information resources, multi-party utilization. The government service management platform is the platform for the administration of government affairs service management, operation management, etc., the source of government service portal information, the channel for business access system access, and the government service data sharing platform to achieve government service. Aggregation and sharing of information data.

Establish a government service portal to achieve unified entry, unified application, unified acceptance, centralized processing, unified feedback and full process supervision of government service matters to meet the needs of convenience. The government service portal unifies and publishes the government service information, accepts the application information, and feedbacks the relevant acceptance, handling and results information to the applicant, enhances the transparency and convenience of the government service, enhances the level of intelligence of the government service, and makes the business and the masses more convenient. Faster and more satisfying.

Promote the integration of websites and mobile applications of the units directly under the National Bureau, explore the platform structure for building interconnections, and provide multi-channel government services through websites, mobile terminals, and self-service terminals.

**3. Carry out pilot demonstration of smart supervision.** According to the division of powers, local regulatory authorities with authority are encouraged to carry out pilot demonstrations in the fields of drug traceability supervision, application of unique identification of medical devices, electronic licenses, production process supervision, and risk analysis, and promote the intelligent upgrading of regulatory measures. Encourage enterprises to develop digital upgrading, production and business activities electronic traces of the whole process, improve production and business activities associated data authenticity and reliability, strengthen cooperation with the regulatory authorities, the formation of positive interaction with the wisdom of regulators, to promote enterprise restructuring and upgrading. The regulatory authorities use intelligent monitoring equipment and mobile Internet to improve the drug intelligence supervision system and form a multi-level intelligent supervision and awareness system.

| Task column 9 Drug traceability collaborative service and supervision system construction |
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| The National Bureau establishes a drug traceability collaborative service and supervision system: First, build a drug traceability collaborative service platform, provide public services for enterprises, the public, and regulatory departments, and play a role of "bridge" and "hub" in the traceability system to provide pharmaceutical companies. And the basic information of the product, the filing and management services of the drug traceability code coding rules, and the address service of different drug traceability systems, to assist in the interconnection and interoperability of different drug traceability systems. The regulatory requirements of data acquisition, the drug to achieve traceability data cleaning, association, complete traceability data standardization. The second is to build a national drug traceability supervision system to achieve the source of drugs, traceable, emergency recall and emergency deployment. Through the application and summary analysis of drug traceability data, monitor the flow of drugs, and play the role of retrospective information in the work of problem product recall and emergency response mechanism, and further explore the application value of drug traceability information in supervision and inspection, product sampling and daily supervision. Early warning, analysis, and judgment of circulation anomalies. |

| Task column 10 National drug regulatory electronic license database construction |
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| The construction content of the national drug regulatory electronic license database mainly includes: on the basis of the national standards of electronic licenses, improve the relevant specifications and management methods for electronic licenses for drug supervision. Establish a national drug regulatory electronic license management and service platform, realize the issuance, unified management and unified verification of electronic licenses; establish a national drug regulatory electronic license database, and collect national electronic license data to meet the requirements of national collaborative sharing. In the end, it will realize the convenience of e-license-based services, enhance the ability of smart supervision, and make information disclosure more transparent, accurate and timely. |

### (6) Strengthening information security

**1. Improve the drug safety and security system.** Establish and improve the information security management system, strengthen the construction of the network security emergency response center, strengthen the information network infrastructure security protection and user personal information protection, carry out level protection and grading filing, level evaluation, etc., and establish information security for all parties to cooperate with each other. Prevention, monitoring, reporting, response and response mechanisms, put up "Internet+" security core technology. Establish and improve the confidentiality review system, increase the protection of important data involving state secrets, trade secrets, personal privacy, etc., and improve the level of information security support and risk prevention. Pay attention to the security risks brought by technology integration, improve the security management of data sharing and open up, and explore the establishment of a data security certification evaluation system to ensure data security.

**2. Build a "safe operation and maintenance integration" network security model.** Increase network security investment, use the drug supervision cloud as the basis of operation and maintenance platform, establish a "safe operation and maintenance integration" mode, and achieve unified monitoring, unified management and unified security protection of cloud resources and Shangyun's government information system. Concentrate on operation and maintenance, comprehensively use a variety of operation and maintenance methods, improve the scientific, standardized and professional level of operation and maintenance, implement the information security level protection requirements stipulated by the Network Security Law from technical support, and achieve network security and refined management. Regularly carry out assessment and rectification work for network and information system security, timely find and find security vulnerabilities and hidden dangers, and timely rectify and ensure long-term security of network security.

| Task column 11 National Bureau Security Operation and Maintenance Platform Construction |
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| Gradually integrate operation and maintenance resources, and finally realize the large operation and maintenance model that combines network hardware infrastructure and network security. Construction of a security management and operation and maintenance monitoring platform, with services and important data assets as protected objects, monitoring and operation and maintenance of front-end sensing devices, infrastructure, and cloud platforms. Extensions on safety management and operation and maintenance monitoring platform situational awareness system, using big data analysis techniques, layers of monitoring data aggregation, processing, analysis, and business operation situation, unified display safe operational state, and operating systems, From the three dimensions of business security, data security, and IT critical infrastructure security, security management is visible, measurable, manageable, and controllable. |

**3. Establish a sound trust system.** In combination with business systems and network security, a variety of authentication methods are used to build a trust system for national offices, enabling electronic identification, intelligent identity authentication, business authorization, and user auditing. Strengthen the security monitoring of important systems and key links such as electronic licenses, variety files, and unified identity authentication, improve access control of business application systems, and ensure the security of business systems and data resources.

| Task column 12 National Bureau trust system construction |
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| In conjunction with the National Bureau information system application status and the National Bureau of trust body system planning objectives, the National Bureau of building trust system to ensure communication of confidentiality, integrity and non-repudiation, and compatibility considerations from the system, certificate-related platform provides docking interface. The implementation platform supports multi-certificate mutual recognition. First, according to the relevant national policy requirements, the implementation of domestic password algorithm protection. After the completion of the national bureau trust system to support the relevant cryptographic algorithms specified by the state, based on the national e-government external network construction of the national bureau trust system to achieve the interface with the national e-government trust system, to meet the country's network and information security, electronic certification system construction, etc. Relevant policies. Second, the national trust system of the National Bureau was initially established. After the completion of the National Bureau of trust system, through the effective integration of internal systems and third-party CA certificate trust, to achieve internal office security and safety for the public service of effective integration. It conforms to the national overall construction idea of information system integration and sharing and solves the historical problems of multi-service systems and multiple sets of CAs that are not recognized by each other in the drug supervision system. |

### (7) Promoting the application of new technologies

**Promote regulatory transformation and upgrading with technology.** Accelerate the application of new technologies such as mobile Internet, Internet of Things, big data, artificial intelligence, blockchain, etc. in drug smart supervision, strengthen supervision of new formats such as drug network sales, and strengthen upstream and downstream regulatory data collection and information sharing. Integrate product life cycle data to form a comprehensive range of decision support information for product production, operation, and supervision. Strengthen the technical cooperation between the regulatory authorities and enterprises and third-party organizations, and jointly build a regulatory data analysis laboratory; vigorously promote mobile application development in the regulatory business field and public service , provide diverse and convenient channels for enterprises and the public, and strengthen the supervision department and Public communication.

| Task column 13 Mobile application management platform construction |
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| Developed research and construction of the National Office's mobile application management platform, including mobile device management, mobile application management, mobile content management, mobile user management and mobile application security management, enabling mobile access, application development testing, application release, and security. Stable operation and unified operation management, fully consider the security of the mobile terminal, and ensure the security of users, business applications, business data and other aspects. |

## Third, strengthen organizational implementation

### (1) Strengthen organizational leadership

Drug supervision departments at all levels should attach great importance to fully understand the importance of the Internet, big data, etc. to enhance regulatory capacity, improve governance, and tangible strengthen organization and leadership. The main responsible comrades should personally deploy and pay close attention to implementation. It is necessary to clarify the work organization, personnel and responsibilities, and promote the comprehensive coordination department of informatization, the support department of information technology and the business department to actively cooperate and participate in the construction of drug wisdom supervision.

### (2) Accelerating system construction

Establishing and improving relevant rules and regulations for informatization construction is the basis for promoting the supervision of drug wisdom and is the prerequisite for carrying out work in various related fields. It is necessary to speed up the construction of supporting systems, put the system construction in the same important position as the project construction, and establish an institutional system such as unified management of basic platforms, unified management of data resources, unified management of construction funds, unified management of security protection, and project life cycle management.

### (3) Improve the working mechanism

Give full play to the demand of the national bureau's regulatory business departments, and the regulatory business departments should propose system construction needs and form a demand guidance mechanism; give full play to the overall coordination role of the national bureau's informatization authorities, and form an overall coordination mechanism; give full play to the national bureau information center The top-level planning and technical guidance role, the establishment of information-based project management system, improve the project record, review and evaluation, implementation process supervision, comprehensive review after acceptance, and other work links to form a life-cycle management mechanism for information projects. The State Bureau shall approve the project or file for the informatization project constructed by the bureau and each directly affiliated unit.

### (4) Implementing supervision and assessment

The National Bureau establishes an information project management system and implements one-on-one registration and full-time supervision of the informationization projects of the bureaus and subordinate units. The wisdom of local regulatory supervision into the performance appraisal system, the local drug regulatory authorities to push forward the wisdom of the regulatory effectiveness of scientific evaluation. Strengthen positive incentives and prior trials and encourage local governments to carry out pilot projects in building data centers, integrating systems, sharing data, and exploring key areas of application, and promoting and implementing them after summing up and improving.

| Task column 14 Information project management system construction |
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| Strengthen the overall management of drug regulatory information construction, improve the information management project management system, establish an information project management system with information project management as the core function, and gradually incorporate all informatization projects of the national bureaus and subordinate units into the system for management. Through the information project management system to achieve full life cycle management of the key stages of the information project, strengthen supervision and assessment, and improve the comprehensive effectiveness of information projects. |

## (5) Paying attention to personnel training

Internally, we must give full play to the role of the existing talent team, and adopt cutting-edge technical training, smart supervision special training, seminar exchanges, field research and other forms to carry out study and training. Externally, relying on the intellectual resources and research platform of universities and scientific research institutions, we can establish a joint training base and improve the technical level of supervisors. Support the full use of various professional talent resources through entrustment, strategic cooperation, and academic exchanges. Pay attention to the cultivation of the political quality of the information team, ensure the integrity of the government, and encourage the role.

ANNEX (omitted)

National Drug Administration Comprehensive and Planning Finance Department Issued May 23, 2019