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**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

WS/T 598.8-2018

**Indicators of health statistics - Part 8: Drugs and medical
material supply
(English Translation)**

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Foreword

The WS/T 598 Health Statistics Indicators are divided into the following nine sections.

- Part 1. General;
- Part 2. Health status of residents;
- Part 3. Health impact factors;
- Part 4. Disease Control;
- Part 5. Maternal and Child Health Care;
- Part 6. Health supervision;
- Part 7. Medical services;
- Part 8. Supply of medicines and sanitary materials;
- Part 9. Health resources.

This part is the eighth part of WS/T 598.

This part is drafted in accordance with the rules given in GB/T 1.1-2009.

This part is proposed by the National Health Standards Committee Information Standards Committee.

This section is mainly drafted by. General Hospital of the People's Liberation Army, National Health and Family Planning Commission Statistical Information Center, National Health and Family Planning Commission Department of Materials Policy and Essential Medicines, Information Center of the State Food and Drug Administration, and State Food and Drug Administration Product Registration Management Division, Consumer Products Division of

the Ministry of Industry and Information Technology, Department of Market Order of the Ministry of Commerce, School of Medicine, Shanghai Jiaotong University.

1 Scope

This section specifies the statistical indicators and indicators related to the supply of medicines and sanitary materials in the health statistics indicators.

This section applies to the use, distribution and sharing of statistical data of health administrative departments and medical and health institutions at all levels.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document.

For undated references, the latest edition (including all amendments) applies to this document.

WS/T 598.1 Health statistics indicators Part 1. General

3 Terms and definitions

The following terms and abbreviations, as defined by WS/T 598.1, apply to this document.

Indicators of drugs and medical material supply it reflects statistical indicators such as the production, circulation, procurement, distribution, use, quality and safety of pharmaceuticals and sanitary materials in a certain period of time.

4.1 Drug and Sanitation Materials Supply Support Indicators Public Attributes

The public attributes of the supply and safety indicators for pharmaceuticals and sanitary materials are shown in Table 1.

Table 1 Public Attributes of Statistical Indicators for Supply of Medicines and Sanitary Materials

Attribute type	attribute name	attribute value	Identification class	Version	V1.0	Registration Authority	National Health Standards Committee	Information Standards Committee	Relational classification	Management class	National Health and Family Planning Commission	Statistical Information Center	Registration status	standard status	Submitted to the General Hospital of the Chinese People's Liberation Army
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4.2.1.1 Pharmaceutical production and circulation

IHS04.01.001 identifier Chinese name drug registration number English name Number of registered drugs Unit of measurement Define the total number of drugs that have been

reviewed and approved by the national food and drug regulatory authorities at the end of the year.

Calculation method

The indicator shows the number of approved drug registrations at the end of the year. Drugs are diseases that are used to prevent, treat, and diagnose people, and purposefully regulate human physiology.

And specify substances with indications or functional indications, usage and dosage, including Chinese herbal medicines, Chinese patent medicines, chemical raw materials and their preparations.

Agents, antibiotics, biochemicals, radiopharmaceuticals, serum, vaccines, blood products and diagnostics. Drug registration refers to national food and drug the supervisory and administrative department shall, according to the application of the drug registration applicant, follow the legal procedures, the safety, validity and quality of the drug to be marketed for sale.

Control, etc., to review and decide whether to agree with the approval process of their application.

Survey method comprehensive investigation Data source drug registration database Release frequency year IHS04.01.002 identifier Chinese name Chinese medicine protection varieties English Name Number of protected Traditional Chinese Medicine Unit of measurement Define the total number of Chinese medicine protection varieties approved by the State Food and Drug Administration at the end of the year.

Calculation method

The indicator indicates the total number of traditional Chinese medicine protection varieties during the protection period, including the number of first-time protected varieties, the number of extended protected varieties and the number of protections of the same variety.

investigation method Data source Chinese medicine variety protection database Release frequency year IHS04.01.003 Chinese name "Pharmaceutical Production License" Number of enterprises with drug production licences Unit of measure Define the number of companies approved by the provincial food and drug regulatory authorities and issued to the Pharmaceutical Production License at the end of the year.

Calculation method

The indicator description includes the number of certified enterprises that were issued to the Pharmaceutical Production License issued during the reporting period and issued within the validity period.

Survey method comprehensive investigation Data source food and drug regulatory statistics annual report Release frequency year IHS04.01.004 Chinese name

"Pharmaceutical Business License" Number of enterprises with drug business licences Unit of measure Define the number of enterprises approved by the prefecture-level food and drug supervision department and issued to the Pharmaceutical Business License at the end of the year.

Calculation method

The indicator description includes the provincial food and drug supervision department issued to the pharmaceutical wholesale enterprise and the county-level food and drug supervision and administration department to the pharmaceutical retail enterprise.

The sum of the number of Pharmaceutical Business Licenses. According to the certificate issued in the report period, issued before the year and within the validity period.

Survey method comprehensive investigation Data source food and drug regulatory statistics annual report Release frequency IHS04.01.005 Number of pharmaceutical manufacturers with Chinese name certified by GMP Number of drug manufacturing enterprises with GMP certifications Unit of measure According to the provisions of the "Administrative Measures for the Certification of Pharmaceutical Production Quality Management Regulations" at the end of the year, the on-site inspection and audit are in compliance with the "Quality Management Regulations for Pharmaceutical Production".

Fan requires the number of pharmaceutical production enterprises issued by the State Food and Drug Administration to the Drug GMP Certificate.

Calculation method

The indicator shows the cumulative number as of the end of the year.

Survey method comprehensive investigation Data source GMP certified enterprise database Release frequency year IHS04.01.006 Chinese name pharmaceutical production enterprise main business income Main business income of drug manufacturing enterprises Unit of measurement Define the income from the main business such as sales of goods and provision of labor services by pharmaceutical production enterprises in a certain region during the reporting period.

Calculation method

Indicators indicate that medicines include chemical raw materials, chemical preparations, Chinese medicine decoction pieces, proprietary Chinese medicines, and biological preparations.

Survey method comprehensive investigation Data source medical statistics annual report Release frequency year IHS04.01.007 Chinese name, total profit of pharmaceutical production enterprises Total profits of drug manufacturing enterprises Unit of measurement Defining the income of various pharmaceutical production enterprises in a certain area during the production and operation process after deducting various expenses.