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China issues the National Essential Medicines List (2018 edition): Background, differences from previous editions, and potential issues

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Summary **On October 25, 2018, the National Health Commission of China issued the National Essential Medicines List (2018 edition) [NEML (2018)]. The NEML (2018) contains 685 drugs, which consist of 417 chemicals and biological products and 268 Chinese patent medicines. Compared to the 2012 version of the NEML, a total number of 165 drugs were added, representing an increase of 31.7%. The biggest increase (90.9%) is in Chinese patent medicines for surgical use. The NEML (2018) set up the category of pediatric medications for the first time, and 11 cancer drugs were added. The NEML (2018) is characterized by: "basic" to "comprehensive" coverage, it includes both Chinese and Western medicines, it now includes pediatric drugs, and more cancer drugs have been added. There are several issues with the new NEML such as the link between the essential medicines system and the medical insurance system and establishment of firm support for implementation.**

Keywords: National Essential Medicines List, essential medicines system, comparative analysis

1. Introduction

On October 25, 2018, the National Health Commission of the People's Republic of China issued the National Essential Medicines List (2018 edition) [NEML (2018)] (*1*). On May 1, 2013, China issued the 2012 edition of the National Essential Medicines List [NEML (2012)]. With further development of the national economy and continued healthcare reform, the NEML (2012) could not be fully adapted to meet the clinical need for essential drugs. On September 19, 2018, the General Office of the State Council issued its *Opinions on Improving the National Essential Medicines System* (*2*). In this context, the National Health Commission issued the NEML (2018).

Essential medicines are drugs that meet basic medical and health needs, that come in suitable dosage forms, that are reasonably priced, that are in sure supply, and that are available to the public. Modifying the list of essential medicines will definitely play an important role in improving the drug supply system and ensuring the use of drugs by individuals. Moreover, the NEML (2018) is sure to have a positive impact on medical reform, to lower drug prices, and to reduce the medical economic burden on individuals.

The aim of this article was to describe four aspects of the NEML (2018): underlying policies, differences between the NEML (2018) and the NEML (2012), the characteristics of the NEML (2018), and potential issues.

2. Underlying policies

Creating a "Healthy China" has become a national strategy since the *Outline for the "Healthy China 2030"* Plan was issued and implemented on October 25, 2016 (*3*). In order to promote a "healthy China," the State Council promulgated and implemented the *13th Five-Year Plan for Hygiene and Health* on December 27, 2016

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(*4*). The *Outline for the "Healthy China 2030" Plan* and the *13th Five-Year Plan for Hygiene and Health* clearly seek to consolidate and improve the essential medicines system. Improvement of the national essential medicines system was listed as a key task for healthcare reform in 2018. On September 19, 2018, the General Office of the China State Council issued its *Opinions on Improving the National Essential Medicines System*.

China launched the National Essential Medicines Action Plan in 1979. The first edition of the National Essential Medicines List that included only Western drugs was completed in August 1981. A National Essential Medicines List that included both Chinese and Western drugs was issued in 1996, and the list was revised four times: in 1998, 2000, 2002, and 2004 (*5*). Amidst a new round of comprehensive healthcare reforms, China issued its *Opinions on Implementing the National Essential Medicines System* with a list of 307 essential medicines on August 18, 2009 (*6*), and the list was updated in 2012. On May 1, 2013, China officially implemented the NEML (2012) (*7*).

The establishment of an essential medicines system is a key component of the reform of China's healthcare system. Its implementation is first mainly placed on primary care facilities. The essential medicines system seeks to encourage patients to receive treatment from primary care facilities, to provide for basic coverage of drugs, and to reduce the burden of medication expenses, which will hopefully reduce the total cost for patients (*8*). However, the NEML (2012) could not be fully adapted to the meet the clinical need for essential medicines. Moreover, there is a gap between the quality of generics and brand name drugs. Furthermore, the drug supply mechanism is still with some flaws which need additional adjustment (*9,10*). A new edition of the National Essential Medicines List, which is the most important part of the essential medicines system, was recently issued.

3. The difference between the NEML (2018) and NEML (2012)

3.1. *Changes in the total number of drugs*

The NEML (2018) is divided into three parts: chemicals and biological products, Chinese patent medicines, and Chinese herbal medicines. The list includes 417 chemicals and biological products and 268 Chinese patent medicines, for a total of 685 drugs. The NEML (2012) included 317 chemicals and biological products and 203 Chinese patent medicines, for a total of 520 drugs. As shown in Figure 1, a total number of 165 drugs were added, reflecting an increase of 31.7%. The added drugs include 100 chemicals (an increase of 31.5%) and 65 Chinese patent medicines (an increase of 32.0%). Section III of the NEML (2018) states that Chinese herbal medicines meet all standards for essential medicines, but no detailed drugs' name is listed.

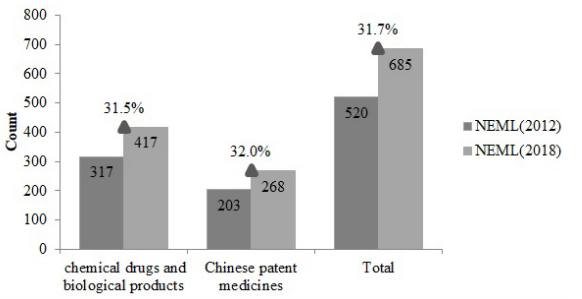

Figure 1. Changes in the total number of drugs on the NEML (2018) and NEML (2012). NEML, National Essential Medicines List.

3.2. *Change in the types of drugs*

One hundred and ninety-six new drugs were added and 31 drugs were removed from the NEML (2012). Nine of those drugs are listed under another classification in the NEML (2012), and indications for these drugs have been changed in the NEML (2018). In actuality, a total of 187 new drugs were added and 22 drugs were removed from the drugs listed in the NEML (2012).

Changes in chemicals and biological products are shown in Table 1. As is apparent from Table 1, the number change of types of most drugs have increased except for anti-allergic drugs, drugs to regulate water, electrolytes, and the acid-base balance, diagnostic agents, otolaryngologic drugs, and birth control. The biggest numerical increase was in cardiovascular drugs, hormones and endocrine drugs and antimicrobials. The biggest proportional increase was in vitamins and minerals, respiratory drugs, and hormones and endocrine drugs. A point particularly worth mentioning is that there are 3 new pediatric drugs and biological products and 11 new anti-tumor medications.

The number change of types of Chinese patent medicines is shown in Table 2. As is apparent from Table 2, types of Chinese patent medicines have increased to varying degrees. The biggest numerical increase was in internal medications, since 29 drugs were added to the list. The biggest proportional increase (90.9%) was in surgical medications. Pediatric Chinese patent medicines were not listed on the NEML (2012), but 13 pediatric Chinese patent medicines were added to the 2018 edition.

4. Characteristics of the NEML (2018)

4.1. *From "basic" to "comprehensive" coverage*

When establishing its essential medicines system, China referenced the World Health Organization's Model List of Essential Medicines (denoted here simply as "the WHO List"). The WHO List is designed to help Member States select and purchase essential medicines and to meet national basic health needs with reasonable

Table1. Changes in chemicals and biological products on the NEML (2018) and NEML (2012)

Primary drug category	NEML (2018)	NEML (2012)	Number of new drugs added	Number of drugs removed	Net increase	Net increase as a percentage	Percent increase
Antimicrobial	54	43	13	2	11	11.0%	25.6%
Antiparasitic	8	7	1	0	1	1.0%	14.3%
Anesthetic	10	8	4	2	2	2.0%	25.0%
Analgesic, antipyretic, anti-inflammatory, anti-rheumatic, anti-gout medication	15	11	5	1	4	4.0%	36.4%
Nervous system medication	21	18	4	1	3	3.0%	16.7%
Psychiatric medication	32	22	10	0	10	10.0%	45.5%
Cardiovascular medication	48	34	17	3	14	14.0%	41.2%
Respiratory medication	16	10	7	1	6	6.0%	60.0%
Digestive system medication	29	24	8	3	4	5.0%	20.8%
Urinary system medication	9	7	2	0	3	2.0%	28.6%
Blood medication	26	21	7	2	5	5.0%	23.8%
Hormone and endocrine medication	36	24	14	2	12	12.0%	50.0%
Antiallergic medication	5	5	0	0	0	0.0%	0.0%
Immune system medication	4	3	1	0	1	1.0%	33.3%
Antineoplastic agent	35	26	11	2	9	9.0%	34.6%
Vitamins, minerals	11	6	5	0	5	5.0%	83.3%
Water, electrolyte, and acid-base balance regulator	8	8	0	0	0	0.0%	0.0%
Antidote	8	7	1	0	1	1.0%	14.3%
Biological products	5	4	1	0	1	1.0%	25.0%
Diagnostic agent	5	5	0	0	0	0.0%	0.0%
Skin medication	10	8	3	1	2	2.0%	25.0%
Ophthalmic medication	7	5	2	0	2	2.0%	40.0%
Otolaryngologic medication	4	4	1	1	0	0.0%	0.0%
Obstetric and gynecological agent	7	6	1	0	1	1.0%	16.7%
Birth control	1	1	0	0	0	0.0%	0.0%
Pediatric medication	3	0	3	0	3	3.0%	—
Total	417	317	121	21	100	100.0%	31.5%

NEML, National Essential medicines List.

Table 2. Changes in the Chinese patent medicines on the NEML (2018) and NEML (2012)

Primary drug category	NEML (2018)	NEML (2012)	Number of new drugs added	Number of drugs removed	Net increase	Net increase as a percentage	Percent increase
Internal medication	166	137	38	9	29	44.6%	21.2%
Surgical medication	21	11	10	0	10	15.4%	90.9%
Gynecological medication	24	20	4	0	4	6.2%	20.0%
Ophthalmic medication	8	7	2	1	1	1.5%	14.3%
Otolaryngologic medication	18	13	5	0	5	7.7%	38.5%
Orthopedic medication	18	15	3	0	3	4.6%	20.0%
Pediatric medication	13	0	13	0	13	20.0%	—
Total	268	203	75	10	65	100.0%	32.0%

NEML, National Essential medicines List.

pricing and reliable quality (*11*). China implemented its national essential medicines system in 2009. The first objective was to ensure that most people do not spend exorbitantly on basic medical care. Second, primary care facilities should play a fundamental role in providing basic medical care. Therefore, the 2009 edition and the 2012 edition of the NEML mainly list inexpensive drugs. However, a total number of 165 drugs were added to the NEML (2018), further expanding the diseases it covers. Different types of drugs to treat the same disease are included on the list. This indicates that the standard for including drugs in the list is no longer based solely on price but on including as many drugs that treat common diseases as possible.

4.2. *Both Chinese and Western medicines are equally important*

The NEML (2018) added a total number of 65 Chinese patent medicines, thus expanding indications and for Chinese medicines. The *Opinions on Improving the National Essential Medicines System* states that "Chinese and Western medicines are equally important and the appropriate number of essential medicines should be selected." Thus, one goal of the NEML (2018)

is to support the development of Chinese medicine industry and to spur the pharmaceutical industry to produce Chinese medicines (including ethnic medicines) and innovative domestic medicines.

4.3. *Addition of pediatric medications and expansion of cancer medications*

For a long time, the demand for basic medical and health services for children in China far exceeded what was on offer, indicating that the pediatric drug market needed to be enhanced. Irrational drug use on children is still common (*12*). There are few medications specifically for children. Even worse, pediatric medications are seriously inadequate, their ingredients are unclear, their indications are vague, their dosage forms are limited and they are difficult to administer, and relevant guidelines and catalogues of pediatric medications are lacking (*13*). The NEML (2018) now includes 22 pediatric medication in different types or dosage forms, which will hopefully promote the accessibility and safety of pediatric medications (*14*). A point worth mentioning with regard to the revised list is the increase in the number of anti-tumor medications. The Chinese Government has made every effort to lower taxes on and prices of anti-tumor drugs in 2018. There were no anti-tumor drugs in the NEML (2009) but 26 in the NEML (2012). Eleven new anti-tumor drugs have now been added to the list.

5. Potential issues

The NEML (2018) covers a wider range of drugs than previous versions. It lists different types of drugs that can meet the multiple treatment needs of patients with different diseases. Moreover, further regulation of dosage forms and indications will greatly help to increase the production and distribution of essential medicines, it will facilitate their procurement and rational use, it will help determine how to reimburse their costs, and it will help to fully monitor those drugs. However, there are several issues with implementation of the NEML (2018).

5.1. *The link between the National Essential Medicines System and the Medical Insurance System*

The *Opinions on Implementing National Essential Medicines System* stipulates that all essential medicines should be included in the list of drugs to be reimbursed under medical insurance and that more of the cost of essential medicines should be reimbursed in comparison to non-essential medicines. The addition of 165 new drugs to the NEML (2018) will apply further financial pressure to the medical insurance system. The medical insurance system is not designed to address problems posed by pharmaceuticals. Therefore, the impact that the new drug list and related policies will have on the medical insurance system is still unclear. The National Essential medicines system and the medical insurance system are complementary (*15*). Expansion of the essential medicines list will ensure that everyone benefits from basic medical and health services. However, the financial impact on the medical insurance system needs to be determined from the perspective of medical economics. The level of coordination between the two systems will have a huge impact on the implementation of National Essential Medicines List.

5.2. *Provision and improvement of support*

According to a document on interpretation of the NEML (2018), revision of the essential drug list is based on the clear and relatively perfect standard of inclusion and exclusion. This lays a solid foundation for future revision of the list. However, revision depends specifically on support from corresponding policies.

China's regulation of essential medicines can be divided into direct regulation and indirect regulation. Direct regulation includes control of the highest retail price and "zero markup" by chain stores, while indirect regulation includes a bidding system for procurement of essential drugs (*16*). The "zero markup" policy dictates that "the sales price will not differ from the purchase price" (*17*), so public medical and health care facilities will have no interest in the volume of drugs they sell. This will help to eliminate "prescriptions in volume" and other problems associated with superfluous treatment. However, effective support policies and system guarantees must be provided in order to smoothly transition to the "zero markup" policy. Important aspects include modification of medical prices and financial support for public health care providers.

Any reform of the healthcare system is a one-size-fits-all move, and reforms must be coordinated. This is especially true for the essential medicines system, which involves links such as production, distribution, use, and reimbursement of costs (*18*). Reforming each link will have an impact on existing interests. These interests must be properly handled, policies must be coordinated, and comprehensive support must be provided to effectively promote implementation of the NEML (2018).

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