

Appendix 2 List of policy documents, issuing agencies and key contents (ranked by year of issuance)

Year	Title of reform documents	Issuing agencies	Key contents
2009	Implementation Opinions on Establishing the National Essential Medicine Policy	Ministry of Health, National Development and Reform Commission, Ministry of Industry and Information, Ministry of Supervision, Ministry of Finance, Ministry of Human Resources and Social Securities, Ministry of Commerce, National Food and Drug Administration, National Administration of Traditional Chinese Medicine	Establishment of NEMP and its matching policies
2009	Regulation on the National Essential Medicine List (Temporary)	Ministry of Health, National Development and Reform Commission, Ministry of Industry and Information, Ministry of Supervision, Ministry of Human Resources and Social Securities, Ministry of Commerce, National Food and Drug Administration, National Administration of Traditional Chinese Medicine	Regulation on the National Essential Medicine List including selection criteria and process.
2009	Implementation of Performance-based Payment at Public Health and Primary Healthcare Institutions	Ministry of Human Resources and Social Securities, Ministry of Finance, Ministry of Health	Reform of the compensation system of PHCs, including performance-based salary plan to sustain the financial development after the implementation of Zero Mark-up Policy
2009	Notice on Strengthening Quality Supervision and Assurance for Essential Medicine	National Food and Drug Administration	Quality of essential medicines, monitor the adverse reactions from essential medicines
2010	Guiding Opinions on Establishing and Regulating the Procurement Mechanism for Essential Medicines in	Office of the State Council of China	Implementation of of provincial procurement for NEMPs

	Government-owned Primary Healthcare Institutions		
2010	Notice on Issuing the Working Standard for the Bulk Procurement of Medicines for Hospitals	Ministry of Health, National Development and Reform Commission, Ministry of Supervision, Ministry of Financing, China Food and Drug Administration, et al.	Implementation plan for the procurement of NEMP
2010	Opinions on Establishing Comprehensive Compensation Mechanism at Primary Healthcare Institutions	Office of the State Council of China	Establishment of comprehensive compensation mechanism at PHCs to sustain the financial development after the implementation of Zero Mark-Up policy
2011	Opinions on Ensuring the Supply of Essential Medicines for Infectious Diseases and Emergency Medicines	Office of Ministry of Health, Office of Ministry of Industry and Information	Shortage management for essential drugs
2011	Regulation on the clinical management of drugs	Ministry of Health, National Administration of Traditional Chinese Medicine , State Commission of Supply and Security	Special managements for glucocorticoid drugs, narcotic drugs, psychotropic drugs, antibacterial drugs and Chinese herbal medicines and other drugs
2012	Notice on the Designated Manufacture for Essential Medicines with High Risk of Shortage	Ministry of Industry and Information, Ministry of Health, National Development and Reform Commission, National Food and Drug Administration	Designation of manufacturers for essential medicines with high risk of shortage
2012	Regulation on the clinical application of antibacterial drugs	Ministry of Health	Administration of antibacterial drugs
2013	Opinions on Enhancing and Improving the National Essential Medicine and Establishing the New Operation	Office of the State Council of China	Scale up of NEMP to non-government owned PHCs

	Mechanism at Primary Healthcare Institutions		
2013	Opinions on deepening the reform of drug review and approval to further encourage drug innovation	The State Food and Drug Administration of China	Accelerated market authorization for innovative patent drugs or drugs addressing current gaps in clinical need
2014	Opinions on Ensuring the Supply of Commonly Used Medicine with Low Prices	National Health and Family Planning Commission, National Development and Reform Commission, Ministry of Industry and Information, Ministry of Finance, Ministry of Human Resources and Social Securities, Ministry of Commerce, National Food and Drug Administration, National Administration of Traditional Chinese Medicine	surveillance and storage of the drugs included on the shortage list
2014	Notice on Ensuring the Procurement of Commonly Used Medicines with Low Price	Office of National Health and Family Planning Commissions	Bulked bidding and procurement policy to all medicines
2014	Opinions on Further Strengthening the Provision, Use and Management of Medicines at Primary Healthcare Institutions	National Health and Family Planning Commission	Scale up of NEMP to public township hospitals in rural areas and public hospitals in urban areas
2015	Guiding Opinions on improving the bulked procurement for public hospitals	Office of the State Council of China	Bulked procurement with the guaranteed procurement volume of medicines
2015	Charging standards and Implementation Rules for drug and medical device registration	The State Food and Drug Administration of China	Waiver of the registration fee for innovative patent drugs

2015	Issuance of the Summary from 2014 and Work Plan for the Healthcare System Reform 2015	Office of the State Council of China	Scale up of Zero Mark-up Policy to all county public hospitals and city public hospitals in pilot sites
2015	Guiding Opinions on Improving the Bulked Procurement of Medicines in Public Hospitals	Office of the State Council of China	Classified pricing strategies
2015	Notice on Implementing and Improving the Bulked Procurement of Medicine in Public Hospitals	National Health and Family Planning Commission	Classified pricing strategies
2015	Notice on the Issuance of Clinical Guideline of Antibiotics (2015)	Office of National Health Commission, Office of National Administration of Traditional Chinese Medicine	Regulation on the retail of antibiotics
2016	Notice on the Issuance of National Action Plan for Stopping Antibiotics Resistance (2016-2020)	National Health and Family Planning Commission, National Development and Reform Commission, Ministry of Education, Ministry of Science and Technology, Ministry of Industry and Information, Ministry of Finance	Supervision on the R&D, manufacturing, distribution and use of antimicrobial drugs
2016	Opinions on Further Improving and Reforming the Manufacturing, Supplying and Using of Medicine	Office of the State Council of China	Implementation plans for the accelerated market authorization
2016	Opinions on Establishing the Quality and Bioequivalence Assessment on Generic Medicines	Office of the State Council of China	Establish Bioequivalence Assessment on Generic Medicines
2016	Notice on Establishing Designated Manufacturer for Clinical Necessary and Shortage in Supply Medicines	National Health and Family Planning Commission, Ministry of Industry and Information, National Development and Reform	Storage of shortage drugs by all government owned PHCs and public hospitals from the designated manufacturer

		Commission, National Food and Drug Administration	
2016	Notice on the Sound Implementing of National Negotiation and Bulk Procurement of Medicine	National Health and Family Planning Commission, National Development and Reform Commission, Ministry of Human Resources and Social Securities, Ministry of Commerce, National Food and Drug Administration	Classified pricing strategies
2016	Opinions on the Implementing the Dual Invoice for the Bulk Procurement of medicine in Public Hospitals	Healthcare Reform Office of the State Council, National Health and Family Planning Commission, National Food and Drug Administration, National Development and Reform Commission, Ministry of Industry and Information, Ministry of Commerce, State Taxation Administration and National Administration of Traditional Chinese Medicine	Dual invoice
2017	Notice on Promoting the Supply of Shortage Medicine	National Health and Family Planning Commission, National Development and Reform Commission, Ministry of Industry and Information, Ministry of Finance, Ministry of Human Resources and Social Securities, Ministry of Commerce, National Food and Drug Administration, et al	Accelerated market authorization for drugs with limited supply and addressing urgent clinical needs
2017	Opinions on the Fully Implementation of Price Reform	National Development and Reform Commission	Zero mark-up for medical disposable products
2017	Opinions on deepening the reform on the review and approve to encourage the innovation of drugs and medical devices	National Medical Products Administration	Patent policy for first domestic generic drug

2017	Opinions on encouraging the prioritized review and approve on innovative drugs	The State Food and Drug Administration of China	Implementation plans for the accelerated market authorization
2017	Opinions on Further Improving and Reforming the Manufacturing, Supplying and Using of Medicine	Office of the State Council of China	Implementation plans for the accelerated market authorization
2017	Issuance of the Work Plan for the Healthcare System Reform 2017	Office of the State Council of China	Scale up of Zero mark-up policy to all public hospitals national wide
2018	Issuance of the National Essential Medicine List (2018)	National Health Commission and National Administration of Traditional Chinese Medicine	Issuance of the third edition of NEML
2018	Opinions on Enhancing the Supply and Use of Generic Medicine	Office of the State Council of China	Enforced patent policy
2018	The list of rare diseases (first edition)	National Health Commission, Ministry of Science and Technology, Ministry of Industry and Information, National Medical Products Administration, National Administration of Traditional Chinese Medicine	The first edition of Rare Disease List to encourage the R&D of orphan drugs
2018	Opinions on Improving the National Essential Medicine Policy	Office of the State Council of China	Inclusion of equipment and use of essential medicines as an evaluation criterion for each province
2018	Document on 4+7 bulked procurement for drugs	United procurement office	Bulked Procurement and Reference Price policy
2018	2019 Work Plan for the Adjustment of National Insurance Reimbursable List (Exposure Draft)	National Health Insurance Administration	Accelerated market authorization for drugs with limited supply and addressing urgent clinical needs

2018	Notice on the Issuance of Prescription Audit Guideline for Hospitals	Office of National Health Commission, Office of National Administration of Traditional Chinese Medicine	Pharmacists and prescription audits
2019	Opinions on enhancing the performance assessment for public tertiary hospitals	Office of the State Council of China	Assessment of rational use of medicines for all hospitals including private sectors hospitals
2019	Notice of the performance assessment on the rational use of drugs for hospitals.	Office of National Health Commission.	Assessment of rational use of medicines for all hospitals including private sectors hospitals
2019	Notice on the continuously improving the clinical management on the antibiotics	Office of National Health Commission	Classified management on antibacterial drugs
2019	National monitoring drug list for the rational use (Chemicals and biological products) (first cohort)	Office of National Health Commission and Office of National Administration of Traditional Chinese Medicine	Issuance of National key monitoring and rational drug catalogue to regulate medicines of high price, high volume or non-therapeutic auxiliary medicines
2019	Opinions on ensuring the supply and stabilizing the price of shortage medicines	Office of the State Council of China	Integration of the shortage medicine monitoring platform with multiple sources from hospitals, NMPA, NHSA, etc.
2019	Notice on Organizing and Using the Medicines from National Bulk Procurement	Office of the State Council of China	Bulk Procurement and Reference Price policy
2019	Opinions on the Matching Strategies of Insurance for the National Bulk Procurement for Medicine	National Healthcare Security Administration	Bulk Procurement and Reference Price policy
2019	The National Law of Pharmaceutical Products Management (amendment)	The State Council	Accelerated approval for medicines and the MMAS

2019	Law of Essential Health Services and Health Promotion	The State Council	Promote the NEMP and R&D of drugs; establishment of tracking mechanism for the whole life span of drugs
2020	Notice in the issuance of the national shortage drug list management	Office of National Health Commission, Office of National Development and Reform Commission, Office of Ministry of Industry and Information, Office of Ministry of Financing, Office of Ministry of Biological Environment, Office of Ministry of Commerce, Office of National Property Commission of State Council, Office of State Administration for Market Regulation, Office of National Health Security Administration, Office of National Chinese Medicines Administration, General Office of National Medical Products Administration, Office of State Army Commission of Supply and Security	Management plan on the list of shortage medicines
2020	Regulation on the Drug Manufacture and Management Plan for Drug Registration	State Administration for Market Regulation	Qualifications, management and supervision for drug manufacture, and registration of drugs, including the accelerated registration for breakthrough new drugs.
2020	The Interim Management Plan of the Insurance Reimbursable Drugs	National Healthcare Security Administration	Selection of NIDRL and the reimbursement for drugs on NIDRL