Going mainstream
Promoting the use of quality-assured generic medicines

This webinar will start shortly

Use Q&A window to post questions (not “Chat”)
- “Q&A” to send your questions to the panellists
- “Chat” ONLY when sharing comments or documents with all participants

Please keep all comments respectful and constructive

The session is recorded for viewing on demand
- Slides and recording will be shared after the session
WHO Guideline provides strong recommendation for one pricing policy

1. External reference pricing
2. Internal reference pricing
3. Value-based pricing
4. Mark-up regulation across the pharmaceutical supply and distribution chain
5. Promoting price transparency
6. Tendering and negotiation

7. Promoting the use of quality-assured generic and biosimilar medicines
8. Pooled procurement
9. Cost-plus pricing for setting the price of pharmaceutical products
10. Tax exemptions or tax reductions for pharmaceutical products

https://www.who.int/publications/i/item/9789240011878
Today’s Panellists

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Generic Medicines in France
Principles and Challenges

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WHO Webinar 18 - 23/02/2023
A growing but still lagging market

Growth in generic market share (in volume and value)

Source: ANSM / CEPS

Market share (volume) vs. Market share (value) from 1999 to 2021.
A growing but still lagging market
Compensating the growing prices of innovative medicines

• Until the 1990s, a market characterized by low prices and high volumes of medicines
• From the mid-1990s onwards, prices of medicines with a strong added therapeutic value were enhanced in exchange for the development of generics and price reductions on older medicines

Making health professionals and patients accountable for medicines prices

• Until the 1990s, health professionals and patients were relatively insensitive to the price of reimbursed medicines
• From the end of the 1990s onwards, a policy aimed at guiding the choices of these actors in favor of the least expensive drugs, with equivalent efficacy.
The 3 pillars of the French generics policy

The legal definition of generic medicines (1996)

- Same essence: same active ingredient (in quality and quantity), same galenic form, same bioavailability
- Different apparences allowed
- Quality check by the French Medicines Agency (ANSM)
The 3 pillars of the French generics policy

Administrative pricing of reimbursed generics (from 1996 onwards)

A price competition administered by the public authorities
The 3 pillars of the French generics policy

Mobilisation of pharmacists, physicians and patients (from 1999 onwards)

- Substitution right and mobilization of pharmacists (1999)
- Generic commitment contract and premiums with physicians and pharmacists (from 2006 onwards)
- Non-reimbursement of the price difference between generics and originator drugs (TFR) (from 2003 onwards) or conditioning of third-party payment (by the pharmacist) to the acceptance of generics by patients (from 2006 onwards)
Obstacles to the development of generics in France

Anti-generic strategies from originator companies
- Marginally improving and patenting old medicines to escape generics competition
- Promoting new medicines and denigrating generics to physicians

Physician (and patient) preferences for new & brandname medicines

Low prices, nonprofitable markets and supply disruptions
Patients' and physicians' relationships with generics

A matter of quality

- A cheap look and an unobservable essence
- Less practical generics (to be identified, to be swallowed, to be cut...)
- A price differential that could be explained by savings on quality?
- Less efficiency or less placebo effect? Greater side effects or greater nocebo effects?

⇒ Poor medicines for low-status physicians and poor people?

A matter of attachment

- A practical and symbolic attachment of the patient to his medication
- An attachment between the doctor and his patient via the medication
- An attachment that varies according to the characteristics of the drugs, diseases and patients, and according to the duration and effectiveness of the treatment.

⇒ An issue with substitution rather than with generics
Taux de substitution des antiépileptiques

Carbamazépine / Tegretol 200 mg Crp
Carbamazépine LP / Tegretol LP (moyenne des groupes 200 et 400 mg)
Gabapentine / Neurontin (moyenne des groupes 100 mg, 300 mg, 400 mg, 600 mg et 800 mg)
Lamotrigine / Lamictal (moyenne des groupes 25 mg, 50 mg, 100 mg et 200 mg)
Valproate de sodium / Depakine (moyenne des groupes 200 mg, 200 mg/ml et 500 mg)
Valproate de sodium LP / Depakine Chrono 500 mg
Ensemble des groupes génériques
Patients' and physicians' relationships with generics

A matter of price

- The impact of TFR (non-reimbursement of price differential) on the choice of generics

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**Graph:**
- **Groupes Génériques sans alignement du prix du princeps sur le TFR (22 groupes, 8 molécules)**
- **Groupes Génériques avec alignement du prix du princeps sur le TFR au 5/01/2004 (2 groupes, 1 molécule)**
- **Groupes Génériques avec alignement immédiat du prix du princeps sur le TFR (39 groupes, 20 molécules)**
- **Ensemble du Répertoire**
Unequal distribution of generics and two-tier healthcare

Before

Carte de la substitution en 2005

After

Carte de la substitution en 2011

Unequal distribution of generics and two-tier healthcare
Conclusion

A multi-instrumental policy
- Playing on the qualities, prices and reimbursement of medicines
- Playing on the interests and strategies of the various market players (pharmaceutical companies, pharmacists, physicians, patients)

A market competition rather than a price competition
- An alliance between generic companies and pharmacists vs. an alliance between originator companies and physicians (with public authorities and patients as arbitrators)
- A spread of generics in the opposite direction to new medicines

Can we talk about French generics?
- Some issues raised by generics are common to all countries (quality, price…)
- … but many are specific to the organization of the French healthcare system (administrative price setting, reimbursement policy, physicians’ and pharmacists’ organization…)
Thank you for your attention!

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AGENDA

• South Africa Today
• FIP Position on generic medicines
• Generic medicine policy in South Africa
• Impact of policy
• Views by HCP/Patients
• Conclusion
Promoting the use of quality-assured generic medicines

SOUTH AFRICAN DEMOGRAPHICS

59,39 million - 2021
Middle Income
R462 billion healthcare spend
Gov Health-R259b -$16.4B
48.7% on public health and
52.3% in private

Life expectancy: F 65 / M 59 years
Infant mortality rate:
24/1,000 live births

South Africa Top 10 Causes of Death
1. HIV/AIDS
2. Ischemic heart disease
3. Stroke
4. Lower respiratory infections
5. Diabetes
6. Tuberculosis
7. Road injuries
8. Interpersonal violence
9. Neonatal disorders
10. Diarrheal diseases

GBD Compare 2019, South Africa
Where substitution is allowed by legislation and regulation—the responsibility for selection of the generic or biosimilar pharmaceutical product—unless specified otherwise—will be that of the pharmacist.

Therapeutic interchange is a collaborative action between the prescriber and the pharmacist designed to achieve maximum therapeutic benefit for the patient.

For non-biological medicines, it is recommended that prescribers use the international non-proprietary name (INN) to reduce errors.
Promoting the use of quality-assured generic medicines

Medicine regulations in SA governed by the *Medicines and Related Substances Control Act (101 of 1965)*, which came into effect in 1967

PRE-1994 - commissions of inquiry to investigate various aspects of medicines policy:

- **Snyman Commission 1962**
- **Steenkamp Report 1978**
- **Commission of Inquiries 1986**

Each identified problems with medicines supply related to overuse of branded medicines and poor uptake generic equivalents

“to promote the availability of safe and effective drugs at the lowest possible cost”

Achieved by monitoring and negotiating drug prices and by rationalising the drug pricing system in the public and private sectors, and by promoting the use of generic drugs”.

**Mandatory offer of generic substitution by all dispensers**

Enabled by Act 90 of 1997- subject of the PMA court challenge- brought into effect in 2003
MECHANISM

✓ Create a transparent pricing system (Single Exit Price SEP)
✓ Promote use of generics via compulsory generic substitution
✓ Regulate reimbursement of dispensers
✓ Control wholesale and intermediary margins (NOT ACHIEVED)
✓ Fix and publish the manufacturers price
✓ Prevented the offering discounts/rebates from manufacture to patients inc healthcare providers

Mandatory substitution law is only aimed at the private sector in South Africa
Public sector-standard treatment guidelines by using a national medicines list-tender-generics
(Gray et al., 2016).
The study on both the originator and generic molecules indicated that the introduction of the SEP regulations had a major impact on medicine pricing in South Africa both immediately and over the ten-year study period.

<table>
<thead>
<tr>
<th></th>
<th>Originator (%)</th>
<th>Generic (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Core</td>
<td>2.45-39.12 (mean=19.78)</td>
<td>18.50-91.50 (mean=62.45)</td>
</tr>
<tr>
<td>Regional Core</td>
<td>-1.77-42.17 (mean=23.38)</td>
<td>0.70-78.03 (mean=44.62)</td>
</tr>
<tr>
<td>Supplementary</td>
<td>-11.68-55.86 (mean=22.87)</td>
<td>9.78-78.49 9 (mean=48.37)</td>
</tr>
</tbody>
</table>

Systematic assessments and monitoring based on standard indicators recommended by WHO/HAI


SEP REGULATION-IMPACT ON MEDICINE PRICES

Generic Glibenclamide

Originator Salbutamol Syrup

Prais-Winsten and Cochrane-Orcutt regression - lag(1)
Affordability concerns are particularly prevalent for products targeting non-communicable diseases (NCDs).

In India and South Africa, an essential treatment for breast cancer can cost around 10 years of average annual wages.
38.3% in 2004
56.2% in 2015
81.3% in 2021

Generic uptake:
1. HIV/AIDS benefits (94.2%),
2. Non-PMB chronic benefits (90.9%)
3. Oncology (86.7%)
4. OTC benefits at 75.7%

## GENERIC UTILIZATION RATES

### Table 4 Generic utilisation rate and generic uptake by benefit category

<table>
<thead>
<tr>
<th>Benefit category</th>
<th>2021</th>
<th></th>
<th></th>
<th>2020a</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Generic utilisation rate (%)</td>
<td>Genericised (%)</td>
<td>Generic uptake (%)</td>
<td>Generic utilisation rate (%)</td>
<td>Genericised (%)</td>
<td>Generic uptake (%)</td>
</tr>
<tr>
<td>Acute</td>
<td>66.4</td>
<td>78.6</td>
<td>84.5</td>
<td>64.4</td>
<td>76.9</td>
<td>83.8</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>68.1</td>
<td>72.4</td>
<td>94.2</td>
<td>75.8</td>
<td>80.9</td>
<td>93.8</td>
</tr>
<tr>
<td>Non-PMB chronic</td>
<td>84.3</td>
<td>92.7</td>
<td>90.9</td>
<td>77.0</td>
<td>92.4</td>
<td>83.4</td>
</tr>
<tr>
<td>Oncology</td>
<td>65.1</td>
<td>75.1</td>
<td>86.7</td>
<td>59.9</td>
<td>72.6</td>
<td>82.5</td>
</tr>
<tr>
<td>OTC</td>
<td>47.2</td>
<td>62.4</td>
<td>75.7</td>
<td>47.7</td>
<td>62.8</td>
<td>75.9</td>
</tr>
<tr>
<td>Other</td>
<td>10.3</td>
<td>14.5</td>
<td>71.5</td>
<td>23.2</td>
<td>29.4</td>
<td>78.9</td>
</tr>
<tr>
<td>PMB</td>
<td>72.6</td>
<td>91.7</td>
<td>79.2</td>
<td>71.9</td>
<td>90.2</td>
<td>79.8</td>
</tr>
</tbody>
</table>

§ MMR 2020

Promoting the use of quality-assured generic medicines
Promoting the use of quality-assured generic medicines

SOUTH AFRICA - DRUG SALES FORECAST - ZAR BN

Source: National Statistics, Fitch Solutions
Funders (medical schemes) – used a co-payment system to promote generic substitution

Policy change is complex- Impacts economic growth, job creation, and a threat to business viability

Court Challenge,
Requires regular monitoring. (16% of originator molecules were withdrawn (8 of 50))

Pricing Transparency to a certain point- gap in logistic fee
No international benchmark-still 25% more than the international costs

The supply chain can also be severely impacted when there is an over-reliance on only a few manufacturers of finished products or raw materials, such as APIs.

In 2020, stock-outs (limited suppliers), exacerbated by the COVID-19 pandemic, made it virtually impossible to fill prescriptions for psychiatric drugs and oral contraceptives in South Africa.
It was hypothesised that increased generic entry would result in price competition and a reduction in drug prices suggesting that the calculated price differential would be larger as the number of generic drugs on the market increased (Bangalee, Varsha, & Suleman, Fatima. (2016))

Appendix A – 19: Metformin 500mg brands in 2014
Cost saving from the use of generic medicines for the treatment of the most common non-communicable diseases in adults in South Africa-Redhi DG (2015)
Majority of the population rely on public sector and are more exposed to free generics.

Quality of these generic medicines is still doubted (Gray, Suleman, Patel, & Bannenberg, 2015).

Generics being often confused with counterfeits medicines (Bangalee & Suleman, 2016a; Patel, Gauld, Norris, & Rades, 2012).
• Pharmacists-82% of pharmacists stated there is no difference in safety between original brand and generic

• Majority of respondents (74%) believed that generic medicines are therapeutically equivalent to the original medicines

• 39% of pharmacists stated that original medicines are of a better quality than their generic counterparts

Source: Exploring pharmacists' views, knowledge and perceptions regarding generic medicines in the Western Cape - Naseema Shaikh
CONSUMER KNOWLEDGE AND PERCEPTION

There was no statistically significant association between consumer knowledge and gender (98.6% M vs 94.4% F)

Decision for their choice of medicine (generic or branded) is contingent on quality (98.8%), efficacy (73.2%), safety (71.8%), and MCC approval (46.6%)

Knowledge concerning generic and brand medicines was the nurse (majority of 23.6% followed by the doctor (majority of 16.1%), and a pharmacist (majority of 4.2%,)

There was no association (p = 0.745, Cramer’s V = 0.076) observed between knowledge of generics and age groups.

There was no association between knowledge of generic medicines and race

Consumer knowledge and perceptions on medicines in terms of generics Ntombiyoxolo Vanessa Mchunu
Prof. Fatima Suleman, Dr. Velisha Perumal-Pillay
Regulatory change is a process
Requires transparency by all players
Needs constant M&E – unavoidable consequences
Must go to full plan to achieve desired outcomes
Policies on promoting the use of generic medicines in China

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Dr. Yangmu Huang, deputy dean, researcher and doctoral supervisor in the Department of Global Health, School of Public Health, Peking University.

Research Background: After earning her MD and Ph.D. from the School of Public Health, Peking University, she did two years’ post-doctoral work in the School of Pharmaceutical Science, Peking University, and then worked as visiting scholar in Department of global health, University of Washington.

Research Area: R&D and global health, global health governance, infectious disease, nutrition and food safety, and health emergency, from a health equity perspective.

Recent research topics:
- R&D and access to medical products for vulnerable population globally, especially those for emerging infectious diseases (EID), neglected tropical diseases (NTD), VPD, AMR, etc.
- Research on the Chinese nutrition package (YYB) and its future global development.
- Evaluation of emergency operations centre (EOC) in African countries.
- Time trends in Infectious diseases mortality/incidence across the BRICS/ASEAN.
01
Country profile

02
Relevant policies on generic medicines

03
Achievements

04
Next steps
PART 01 ▶ Country Profile
Country Profile

Population structure

Fig. 1a Proportion of China’s population

18% (2nd)

Fig. 1b Population age structure of China

Fig. 1c Child mortality in China, 1990–2019

Health status

Health Expenditure

Fig. 1d Life expectancy at birth in China, 1990–2019

Fig. 1e Health Spending in China

Fig. 1f UHC effective coverage index in China

Source: China National Bureau of Statistics (NBS); www.healthdata.org
The Current Status of Generic Medicines

**Market occupancy**
Second-largest pharma market, USD 141.112 billion in 2021
Generic medicines accounted for 63% of the Chinese market

**Market price**
20–90% lower than the price of corresponding original medicines

**Market size**
Market reached CNY 808.7 billion in 2020, and is expected to continue to grow at an annual market growth rate of 4.2%

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2. Data source: Frost & Sullivan’s analysis
4. ispe.org: China: Pursuing Quality for Generics & Biosimilars
PART 02

Relevant policies on generic medicines in China
Relevant policies on generic medicines in China

- Improve research and development (R&D)
- Improve quality
- Improve access
Improve R&D: Release of generic medicine catalogue

In order to guide the R&D direction of pharmaceutical enterprises, the National Health Commission of China has successively released two batches of generic medicine catalogs.

Date of released:
• October 10, 2019 (1st)
• February 20, 2021 (2nd)

Selection criteria:
• The patent expires or is about to expire
• No application from pharmaceutical enterprises
• Clinical shortage

Content:
• 49 medicines
• 56 dosage forms

Fig. 2a Treatment field distribution of the generic medicine catalogue

- Rare disease
- Cancer
- Psychoneurosis
- Respiratory system disease
- Antibiotic
- Endocrine system disease
- Cardiovascular diseases
- Urological diseases
- Antivirus
- Others
Improve R&D: Establish Pharmaceutical Patent Linkage System

On July 4, 2021, the Measures for the Implementation of the Mechanism for Early Settlement of Drug Patent Disputes (interim) began to be implemented. China's pharmaceutical patent linkage system was initially established, providing legal support and guarantee for both original and generic pharmaceutical enterprises.

Fig.2b China’s Drug Patent Linkage System Procedures

MAH: Marketing Authorization Holder
ANDA: Abbreviated new drug application
CDE: Center For Drug Evaluation
NMPA: National Medical Products Administration
CNIPA: China National Intellectual Property Administration

Improve R&D: Establish Pharmaceutical Patent Linkage System

China’s drug patent linkage system is basically modeled on the United States system, including *patent information registration system, patent declaration system, patent challenge procedure* and *market exclusivity policy*, but it has also adjusted according to China’s actual situation.

China

- Patent Information Platform: zldj.cde.org.cn
- Arbitration institution: Beijing Intellectual Property Court and SIPO
- Litigation time: 45 days
- Stay of generic approval: 9 months
- Market Exclusivity: 12 months

America

- Patent Information Platform: Orange Book
- Arbitration institution: Federal Court and USPTO
- Litigation time: 45 days
- Stay of generic approval: 30 months
- Market Exclusivity: 180 days
Improve quality: *Consistency Evaluation of Drugs (GQEC)*

China has made continuous efforts to effectively avoid market disruption caused by inferior generic drugs.

**Start-up phase**

2012 - 2014

- Propose to carry out Consistency Evaluation of Drugs
- Define the evaluation object, time limit and reference reagent

**Preparation phase**

2015 - 2016

- Clarify reagent selection, approval process, management and policy
- Propose to strive to basically complete the project in about 5~10 years

**Implementation phase**

2017 -

- Announce the first batch of drugs that passed the consistency evaluation
- Add chemical injection

Improve quality: Reform the review and approval system

In order to optimize the process, reduce the backlog of applications and strengthen supervision, since August 2015, China has issued several documents to reform the review and approval system, including increasing the registration fee, adjusting the registration classification, and requiring drug companies to conduct self-inspection of clinical trial data, etc.

Table.2a Series of documents on the review and approval system reform

<table>
<thead>
<tr>
<th>Data</th>
<th>Publisher</th>
<th>Policies and regulations</th>
<th>Key points and objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 Aug 18</td>
<td>The State Council</td>
<td>Opinions on the reform of drug and medical device review and approval system*</td>
<td>Starting point of reform</td>
</tr>
<tr>
<td>2015 Dec 1</td>
<td>NMPA</td>
<td>Announcement on the implementation of record-filing management for the Bioequivalence Trials of Chemical Drugs</td>
<td>Bioequivalence Trials of Chemical Drugs Changed from approval to record-filing management</td>
</tr>
<tr>
<td>2016 Mar 4</td>
<td>NMPA</td>
<td>Announcement on the release of work plan for the reform of chemical drug registration classification</td>
<td>Adjust the chemical drug registration classification</td>
</tr>
<tr>
<td>2017 Oct 8</td>
<td>The State Council</td>
<td>Opinion on deepening the reform of the review and approval system and encouraging the innovation of drugs and medical devices*</td>
<td>Guide the research and development and production of generic drugs and provide the public with greater access to the drugs. A linked review and approval regime shall be implemented under which the drugs are reviewed and approved along with their excipients and packaging materials</td>
</tr>
<tr>
<td>2018 Mar 21</td>
<td>The State Council</td>
<td>Opinions on reform to improve adequate supply of generic drugs and usage*</td>
<td>Promote the research and development of generic drugs, enhance the quality and efficacy of generic drugs, increase the capability of guaranteeing the supply of medicines</td>
</tr>
<tr>
<td>2019 Mar 25</td>
<td>NMPA</td>
<td>Selection and determination procedures for reference listed drug of chemical generic drugs</td>
<td>Standardize the review and consistency evaluation of generic drugs, optimize work procedures</td>
</tr>
<tr>
<td>2020 Jun 29</td>
<td>NMPA</td>
<td>Registration classification and requirements for application dossiers of chemical drugs</td>
<td>Renew the registration classification and requirements</td>
</tr>
</tbody>
</table>

*Milestones and programmatic documents for the reform of drug review and approval system

Improve access: the National Centralized Drug Procurement pilot (‘4+7’ policy)

In January 2019, 11 cities were selected to carry out ‘4+7’ city drug volume-based purchasing pilot. The significance is to determine the contractual relationship between price and volume. The larger the volume, the lower the price.

Fig. 2c Logical framework of the ‘4+7’ policy
**Improve access:** the National Centralized Drug Procurement pilot (‘4+7’ policy)

The multi-sectoral collaborations among different departments from top to bottom have promoted the implementation of the pilot and provided evidences for future expansion.

![Organizational framework of "4+7" city drug volume-based purchasing and using pilot program](image)

*Fig.2d Organizational framework of "4+7" city drug volume-based purchasing and using pilot program*

For the drugs that meet the standards, the negotiation process shall be adjusted according to the number of the applicant enterprises to minimize the unit price of drugs.

**Fig.2e Selection flow chart of "4+7" city drug volume-based purchasing**

Improve access: *Unified medical insurance payment standard*

With the '4+7' policy, NHSA also put forward requirements for the price of drugs that were not selected, and started the pilot work of medical insurance payment standards. Through the double oppression of policy and market, the unselected generic pharmaceutical enterprises were forced to adjust their product structure, reduce the unit price of drugs, and actively develop and innovate.

- If the price of non selected drugs is more than twice the price of selected drugs at the end of 2018, the payment standard will be no less than 30% of the original price in the next year, and will be adjusted to the price of selected drugs before 2021;
- Encourage the initiative to reduce the price and converge to the winning standard;
- If the price is within 2 times (including 2 times) of the winning price and the winning price, the winning price shall be the payment standard in principle.

China continued to strengthen the crackdown on monopolistic acts in the field of APIs to guarantee the supply of generic pharmaceutical raw materials and market stability. From 2015 to 2020, five typical cases were reported, with fines exceeding CNY 350 million.

Table 2b: Representative cases of anti-monopoly law enforcement in API field in China in recent years

<table>
<thead>
<tr>
<th>Aberrant activities</th>
<th>Penalty amount (CNY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abuse of market ascendancy</td>
<td></td>
</tr>
<tr>
<td>Refuse to trade without justified reasons</td>
<td>500,000.00</td>
</tr>
<tr>
<td>Attach unreasonable trading conditions</td>
<td>2,474,000.00</td>
</tr>
<tr>
<td>Refuse to trade without justified reasons</td>
<td>330,000,000.00</td>
</tr>
<tr>
<td>Horizontal monopoly agreement</td>
<td></td>
</tr>
<tr>
<td>Conclude and implement the monopoly agreement of boycott trade</td>
<td>2,604,000.00</td>
</tr>
<tr>
<td>Conclude and implement monopoly agreements with fixed commodity prices</td>
<td>12,834,000.00</td>
</tr>
</tbody>
</table>

Source: Jing Chen, Pingan Fan, Sheng Han, etc. Analysis of generic drug policy in China. World Clinical Drugses. 42(1). 16-20.
PART 03  >  Achievements
Increase number of Companies passing GQEC

Since the release of the first batch of Qualified generic drugs in 2017, the number of companies that pass the consistency evaluation increased year by year. By the first quarter of 2021, 2178 drugs in China had passed the consistency evaluation.

Increase R&D investment intensity

An empirical study shows that GQEC of generic drugs has a significant positive impact on the R&D investment intensity of chemical generic drug companies.

Increase enthusiasm for first generic drug research

From 2016 to 2020, the application and approval of ANDA have increased significantly, and the willingness of pharmaceutical enterprises to innovate and develop has increased significantly.

Under the influence of the National-level Drug Pricing Negotiations (NRLD), the average price decrease of the first-negotiated and re-negotiated medicines are 60.7% and 26.4%.

Under the influence of the ‘4+7’ policy, the defined daily drug cost (DDDc) of bid-winning original and generic drugs, as well as non-winning original drugs, decreased by 44.44%, 79.00% and 15.10%.

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**Fig.3d Status of medicines negotiated in China NRDL from 2016 to 2019.**

• Among the ‘4+7’ List drugs, the volume proportion of generic drugs increased from 60.73% to 77.80%

• After the ‘4+7’ policy intervention, 17.08% of the original medicines in DDDs (defined daily doses) were substituted by generic medicines

• The use proportion of higher-quality medicine raised prominently from 39.66% to 91.93%

Next Steps

The office of GQEC evaluation: An expert committee of more than 70 renowned experts

- Develop the consistency evaluation system
- Provide guidance for industries
- Continuous dialogs between regulators and pharmaceutical industries
  Companies can seek help from medicine review agencies
- Adhere to consistency evaluation in the review of medicines
- Ensuring generic medicines work the same as brand-name medicines
- Strengthen supporting policy
- Policies to reinforce the entrepreneurs' enthusiasm for passing GQEC evaluation
- Implement education programs
- Enhancing public awareness of the safety and efficacy of generic medicines

Source: Press conference of the Chinese National Health Commission on July 22, 2022
THANKS
谢谢
Panel discussion
Press Information Bureau
Government of India
Ministry of Health and Family Welfare

Promoting use of Generic Medicines in the Country

Government of India is aware that despite the orders of the Courts and the relevant regulations of the Medical Council of India, generic medicines are not being prescribed by most medical practitioners. In this regard, clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drug. Further, the erstwhile Medical Council of India (MCI) had issued circulars where all the Registered Medical Practitioners have been directed to comply with the aforesaid provisions.

The National Medical Commission Act, 2019 empowers the appropriate State Medical Councils or Ethics and Medical Registration Board (EMRB) of the Commission, to take disciplinary action against a doctor for violation of the provision of the aforesaid Regulations. When complaints are received against the violation of code of ethics for doctors, such complaints are referred by EMRB (previously by erstwhile MCI) to the concerned State Medical Councils where the doctors/medical practitioners are registered. States have been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities.
Despite the long history and the established role of generic medicines, why do some stakeholders continue to show reluctance in using generic medicines?

› For example, a 2022 Press Release from the Government of India noted that “Generic medicines are not being prescribed by most medical practitioners” (see previous page)

› In your view, what are some of the contextual factors for consideration?
Systematic reviews* have shown clinical equivalence between generic and their originator alternatives. All medicines are susceptible of being substandard and falsified, and paying higher price does not guarantee quality.

In your view, what could be done to build trust in the medicines and the institution in protecting consumer welfare?

› Communication about regulatory process of approving generic medicines and monitoring of safety signal
› Communication about research showing equivalence in clinical outcomes
› Media reporting and better communication of science to the general public

*Examples for illustration only
Could policies or market competition push the price of generic medicines too low, potentially putting reliable supply at risk especially at times of global inflation?

› How could policies be ‘agile’ to maintain a good balance between financially responsible while maintaining access?
› Is paying more for generic medicines a solution to promote greater use? And how much more?

See examples of debate here:
Many countries have a suite of supply and demand side policies to promote the use of generic medicines, in line with WHO Guideline.

For countries authorities looking to build a stronger system to improve the use of generic medicines, what would be your top 3 suggestions?
Q&A with the audience
Upcoming webinars

- TBC: Value assessment through HTA to inform medicine pricing

WHO Technical Advisory Group on Pricing Policies for Medicines

- **Call for Experts reissued** to take account of the need for diverse perspectives from different regions, especially from low and middle-income countries, and for gender balance.

[https://www.who.int/news-room/articles-detail/call-for-experts--who-technical-advisory-group-on-pricing-policies-for-medicines](https://www.who.int/news-room/articles-detail/call-for-experts--who-technical-advisory-group-on-pricing-policies-for-medicines)