Combating Counterfeit Medicines in GD, China

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Combating Counterfeit Medicines in GD

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Brief Introduction of Guangdong Province

Guangdong Profile

- Guangdong (hereafter GD) in the southern part of China
- 21 cities and 89 counties
- Populations: 86,420,000
- The first economic well developed province

- the province output value (GDP): 2,590 billion RMB in 2006
- 18 years occupying the head among the provinces continuously.
Manufacturers and Category

540 Pharmaceutical Manufacturers (plants)
Manufacturers and Category

most of manufactures (over 60%) producing chemical medicines and preparation of Traditional Chinese medicines
Guangdong is one of most flourished districts in exchange of medicines. GDFDA supervises more than 1,700 Wholesalers and over 43,000 Retailers.

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Wholesalers</strong></td>
<td>1720</td>
</tr>
<tr>
<td><strong>Retailers</strong></td>
<td>43745</td>
</tr>
</tbody>
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Medical Agencies

3 hospitals and 16 medical clinics per 100,000 people

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>hospitals</td>
<td>2391</td>
</tr>
<tr>
<td>hygiene agencies (infirmaries)</td>
<td>3310</td>
</tr>
<tr>
<td>community hygiene centers</td>
<td>734</td>
</tr>
<tr>
<td>medical clinics</td>
<td>7227</td>
</tr>
</tbody>
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The large hospitals and countryside hygiene agencies
GD government sets up ACF JOINT MEETING to implement “final responsibility policy”

Anti-counterfeit joint meeting system taking on great political commitments

Members of ACF joint meeting

- The deputy governor
- The provincial Public Security Department
- Administration For Industry and Commerce
- Quality Supervision and Inspection Institute
- prosecuting attorney
- People’s Court
- Food & Drug Administration
- other departments leadership
Main duties of Anti-counterfeit joint meeting

(1) summary on the work of the province to anti-counterfeit, effectiveness and problems,
(2) Enactment of this fiscal year Anti-counterfeit work program
(3) Approving the investment used for the sample taking/testing
Drug Administrative Authorities Play an Important Role on Anti-counterfeit
Effective surveillance /investigation and law enforcement is one of the most critical measures to ACF.

- Sampling and testing, releasing Quality Bulletin in GD.
- Organizing to investigate and punish illegal activities of counterfeiting.
- Monitoring the quality of medicines in markets, organizing market inspection.
- Dealing with complaints and reports of counterfeit.
“Vertical Management” is the drug administration system in GD.

The system covers not only drug administrative but also inside management affairs about personnel, finance and establishments.

FDAs at 3 levels can deal with the cases directly and all have the right of direct punishment. The higher level FDA owns the right of guiding, supervising to its lower level FDA.
Holding training programs (training courses, practices and seminars) for inspectors/surveillants

COUNTERFEIT DRUGS

Guidelines for the development of measures to combat counterfeit drugs

Department of Essential Drugs and Other Medicines
World Health Organization
Geneva, Switzerland
Anti-counterfeit needs technical support from the institutes for drug control

In order to combat counterfeit and evaluate the quality of medicines in market, targeted samples should be taken to those that enterprises and products that quality accident have been happened, and routine sampling from market. Institutes come out drug quality reports after Samples being tested in pharmacopoeia. Then FDAs take administrative processes and quality report of counterfeit to punish the illegal organizations or individuals while law enforce authorities take judicial / prosecuting processes in compliance with penal law and the forensic report to punish counterfeiters.

- **Sampling**
- **Testing**
- **Take administrative/judicial and prosecuting processing**

Pictures of legal judgment report
ACF needs technical support from the Drug Duality Control Institute

The institutes are fully well-equipped

Test equipments at all level basically cover all kinds of test requirement by "Chinese Pharmacopoeia"
The fast screening testing method to detect Viagra (Sildenafil citrate) appending in TCM

The method is a chemical detecting method which includes 3 reagents via 3 steps process to detect Sildenafil illegally appended in Traditional Chinese medicines.

*Easily handling/ Shortly processing, Low costs, Casual equipments,*

*Exclusive examination, highly sensitive,*

*On-the-spot testing, Accuracy of 100%*

*No false positive & No false negative*

The Fast screening kit is consisted of 3 reagents.

Diagram 2 the tube B reacted in a yellow turbidity by appending Viagra.

A—Negative
B—Positive (the yellow precipitate)
Cooperation to anti-counterfeit within 9 provinces in the Pan-PRD Region (Pear River Delta)

In order to increase efficiency of cooperative combating, “A pharmaceutical supervision and Inspections Cooperation agreement within Pan-PRD nine provinces “ was signed and cooperation committee set up in 2004. the first Cooperation Committee “ held in GuangZhou July 2005. Now the committee conference will be held annually.
Cooperation with police force is of the utmost importance for combating counterfeit

A startup ceremony of cooperation to anti-counterfeit with police force

Counterfeit is frequently encountered in many countries and areas, jeopardizing treatment outcomes and wasting resources. Counterfeiting is a crime which cannot be dealt with by FDA alone.
GDFDA and police force Cooperatively destroyed a beachhead for Counterfeiting

The counterfeit manufacturing are low profile and usually difficult to locate because of being in cottage industries – in homes, sheds.
GDFDA and police force Cooperatively destroyed a beachhead for Counterfeiting counterfeiting site in a small town.

Confiscating sets of equipment, compound, dexamethasone acetate cream copied a famous manufacture and 14 species of fake medicines and raw materials, publications and packaging materials, 7 suspicious individuals were arrested.
Exert a Co-function of Inspection and ADR Monitoring

ADR monitoring is also one key part of joint Anti-counterfeit, which is playing more and more important function.

If the serious ADR event is relevant to quality of medicine, GDFDA should follow up the case.

confirmed to be a counterfeit, substandard or inferior medicine, GDFDA should carry out actions to the product within GD.

In 2001 GD set up ADR Monitoring and report system. Guangzhou ADR Monitoring Centre officially founded after the incident of adverse reaction.
Boosting Role of cooperating ACF

Effective cooperation with different stakeholders

On April 11, 2006, GDFDA and the domestic and foreign pharmaceutical enterprises jointly held a meeting for the subject of "supporting reputed brand products, combating fakes, promoting development and building a harmonious GD". The meeting approved the "joint action for ACF", signed a joint proposal to ACF in this meeting.

a live TV program at GDTV "SHILONG Anti-Counterfeit Medicine TV Forum"
Joint Declaration on Combating Counterfeit

DECLARATION OF SHI LONG
Sharing practical knowledge to promote effectiveness of combating counterfeit
The second ACF forum for the subject of "exerting mobile technology to promoting ACF" in Shilong Town

Welcome you to take part in

The third SHILONG ACF FORUM for the subject “Combination of combating and vigilance to combat counterfeit” in 2008
A new ACF pattern of "Non-Counterfeit-Community" is initiated by GDFDA in 2006. The purpose is to improve collaboration among different stakeholders. In the pattern, the activities on ACF are uniformly led by the government. The government agencies and social forces will actively participate in the activities on ACF. Focuses on enhancing public awareness of protection and vigilance, responsibility of stakeholders and self-discipline of professionals. Aims at achieving non-counterfeit in the community, a complete counterfeit-free area -- no manufacturing, no sales and no usage of counterfeit medicines.

Establishing A Non-Counterfeit-Community

XiaoLan Town of ZhongShan City
ShiLong Town of DongGuan City
Strengthening Public education —— Promoting All Society awareness about Drug Safety

On preserving the Consumer Rights and Interests Day (March 15), Local FDA made a propaganda to masses for ACF and Educated masses how to distinguish genuine from fake medicine.

A local FDA made a propaganda to masses for promoting awareness of drug safety.
Guangdong ACF Report Platform

Cases of counterfeit medicine can be reported through the Internet system. Alternatively, reports can be submitted by other means of communication (email or fax or telephone or sending message SMS) to the secretariat which immediately will incorporate them into the system.
Rapid Alert System (RAS) for combating counterfeit and inferior medicines

- **Purpose and SCOPE**: Distributing alert notifications about specific counterfeiting incidents in a timely manner through the active communication system to government authorities and stakeholders.
- **CARRIER**: Mobile Phone or Internet Network
- **EFFECTIVENESS**: Stimulate rapid follow-up action on the reported cases, minimize adverse impacts of counterfeit medicine.
- **HEADWAY**: Successfully initiated in 3 cities.
**ACF ARMY carrying on War against Counterfeiter**

- The ACF ARMY consisted of departments of government and public conducted by a high power engine—the great political commitment of government. Taking advantage of mechanism—joint meeting system and vertical management mode.

A combat vehicle against counterfeiting being equipped with cannon and gun to ACF—drug administrative law and criminal law. And with Searchlight to search for Counterfeit—ADR monitoring. Landmine detector and Magnifier to detect counterfeit—the drug control testing.
Successful Elements of Anti-Counterfeit in GD

The ARMY against counterfeiting

Mechanism
(Great political commitment)

LAW
Drug & Penal

System
Vertical

Science
technology

Cooperation

Drug control institute

ADR monitoring Centre

A combat vehicle against counterfeiting with several wheels that is the critical elements to Anti-counterfeit.
Engine- Political commitment
Mechanism & System

Political commitment

- **Mechanism**
  1. Unified leadership
  2. Anti-counterfeit joint meeting
  3. Public Participation
  4. Combination of Combating & Vigilance

- **System**
  1. Vertical management mode Province, city and county levels joint-effort
  2. Nine provinces cooperation network
Law & Regulations

Cannon & Gun

(1) Linkage of drug law and penal law
(2) Linkage of administrative punishment and penal prosecution
(3) Balance of different goods laws, regulations and policies
(4) Share of information
(5) In compliance with GCP GSP GMP by compulsion
Science & Technology Administration assorts with technology

**Searchlight**- searching for faking

**Landmine detector**- for counterfeit

**Magnifier**-- screening counterfeit

**ADR monitoring pharmacovigilance**

1. Consultation from experts
2. Usage of high-tech
3. Promotion of Combating Technology
Cooperation

(1) Promoting the No counterfeit community

(2) Participation of public

(3) Involvement of professionals

(4) Cooperation between drug administrative authorities and stakeholders

(5) Cooperative combating within provinces
Reinforcing GREAT WALL for Anti-counterfeit

Social force are always an invincible army

(1) Strengthen the training of personnel

(2) Strengthen the assessment of work for anti-counterfeit

(3) Strengthen 86 million Citizen Awareness Campaign
Thank You!