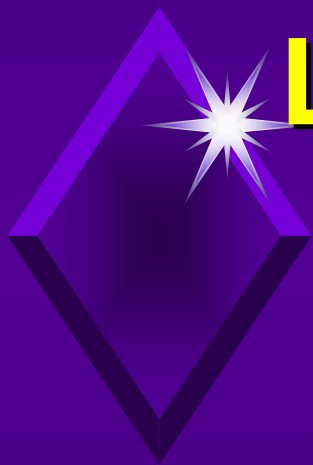


Safety Supervision after the Launch of Drugs in China



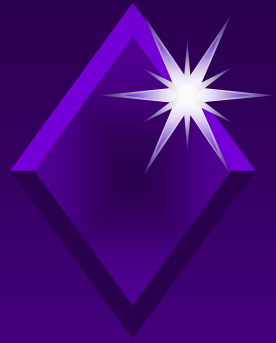
**Li Jinju, Department of Drug
Safety & Inspection, State Food
and Drug Administration**

April 2008



Safety Supervision after the Launch of Drugs

- I. Reevaluation after the Launch of Drugs
- II. Monitoring of Adverse Reactions to Drugs
- III. Follow-up Random Quality Inspection after the Launch of Drugs
- IV. Follow-up Inspection of Drug GMP
- V. Recall of Drugs



I. Reevaluation after the Launch of Drugs

Scope:

Drug safety

Drug efficacy

Controllability of drug quality

Basis of re-registration 5 years after the launch of drugs



Article 121 of Procedures for the Administration of Drug Registration

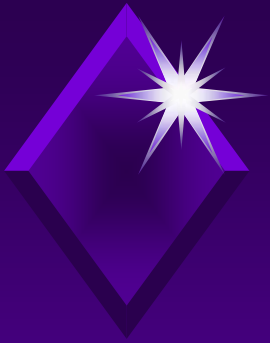
Within the valid period of the drug approval document, *Certificate of Registration of Imported Drug* or *Certificate of Registration of Medical Product*,

The applicant shall conduct a systematic evaluation of the drug's safety, efficacy and quality control.



II. Monitoring of Adverse Reactions to Drugs

1. The system of laws and regulations is in place and improving.
2. The supervisory system is in place and improving.
3. Above 4,000 enterprises have passed the GMP certification.
4. Adverse reaction monitoring bodies of three levels are:
 - ◆ improving and optimizing the national reporting and monitoring system of adverse reactions to drugs
 - ◆ drafting the Procedures for the Monitoring and Administration of Adverse Reactions to Drugs



Specific Actions

- Nationwide action of bringing “local standards” up to “national standards”
(Standard)
- Organizing nationwide drug quality random inspection and notification
(Quality)
- Monitoring of adverse reactions: taking control measures where seriously adverse reactions are discovered
(Safety)



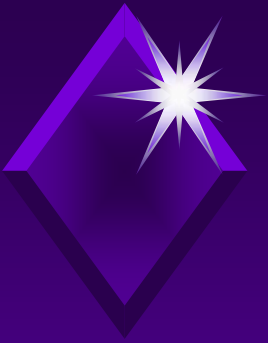
Measures against drugs with seriously adverse reactions

- Suspension of production (houuttuynia)
- Instructions for amendment (concurrent use of ceftriaxone sodium and calciferous solution)
- Focus monitoring (adverse events)



III. Follow-up Random Quality Inspection after the Launch of Drugs

- Improving and optimizing the national random drug quality inspection system
- Establishing and optimizing the random drug inspection system suited to China's national conditions
- Formulating random drug inspection plans and schedules annually
- Quick means of market testing: quick test vehicle



IV. Drug Recall System of China



Establishing and optimizing a drug recall system suited to China's national conditions

The SFDA enacted *the Procedures on the Administration of Drug Recall* on December 12, 2007, introducing international practices such as recall classification.



V. Follow-up Inspection of Drug GMP

- Process verification of launched variety
Flight inspection, regular inspection and follow-up inspection of GMP
- Stationed inspector: external monitoring
- Quality authorizer: internal monitoring
- Establishment of non-spot monitoring system: improved degree of informatization



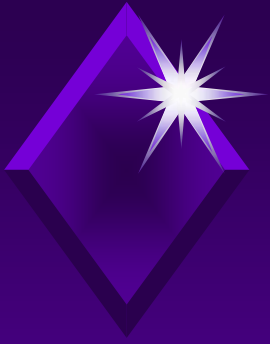
Conclusion

Safety supervision after the launch of drugs in China:
The position of the safety supervisory body in the whole supervisory system should be improved, and financial transfer and payment strengthened.

More attention is paid; the performance is improving.

However, we are still growing in this field.

There is much foreign experience that we can draw on.



Thank you!

