CFDA Reform and ICH Membership

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Disclaimer

- This presentation reflects the views of the speaker and does not reflect official CFDA, or other government opinion or policy.

- I have nothing to disclose.

CFDA

New Drug Availability in China

291 NMEs in the US (2004–2014)

79 (27%) of the 291 NMEs in China

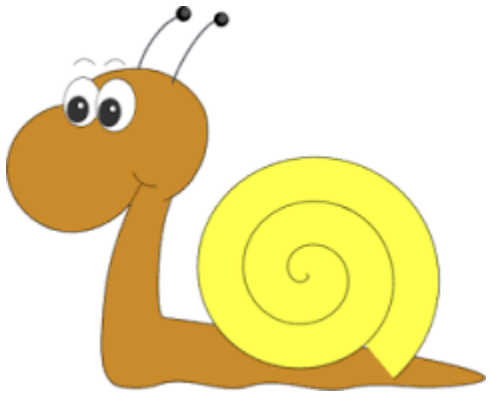
Nature Reviews Drug Discovery

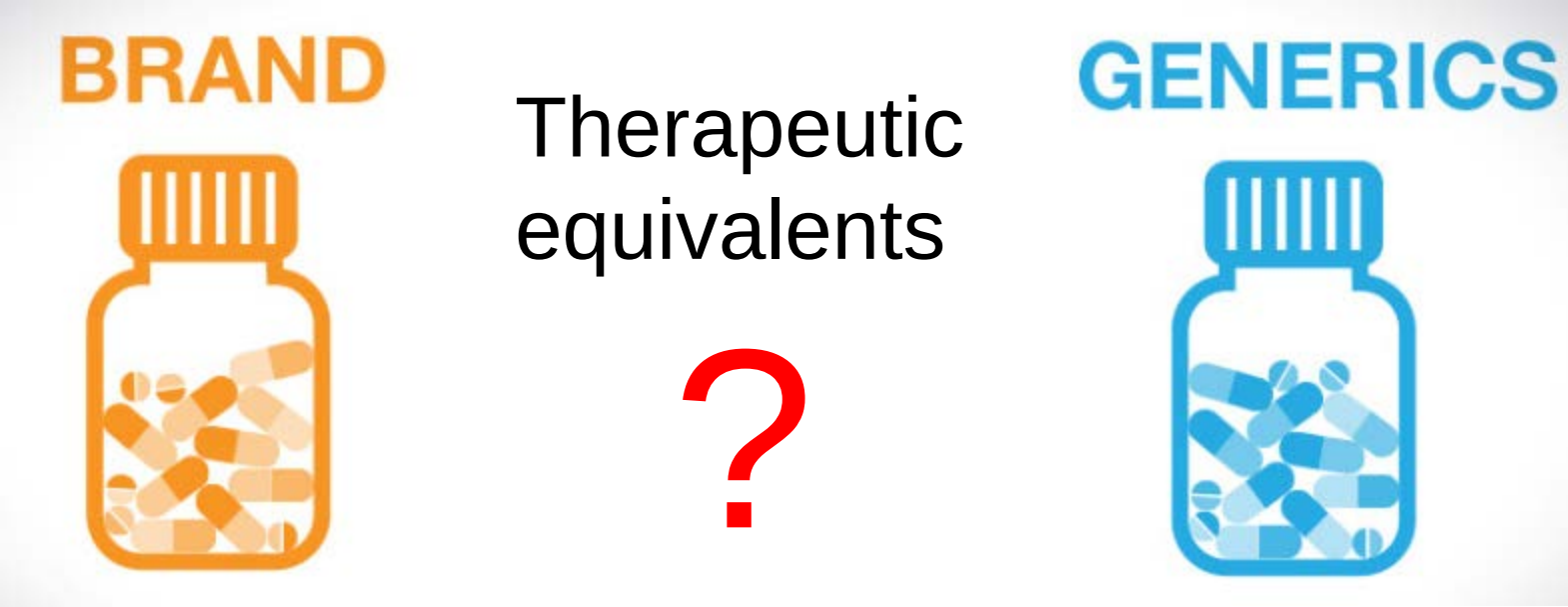
Regulatory watch: Innovative drug availability in China (21 October 2016)

New drugs are available 3-5 years behind developed countries.

CDE had 120 reviewers in 2015

Serious backlog of applications





Therapeutic equivalents

?

No official identified RLD (reference listed drugs)

No Orange Book

Commitments from the State Council

国家食品药品监督管理总局
China Food and Drug Administration

国务院关于改革药品医疗器械审评审批制度的意见

国发〔2015〕44号

2015年08月18日

各省、自治区、直辖市人民政府，国务院各部委、各直属机构：

近年来，我国医药产业快速发展，药品医疗器械质量和标准不断提高，较好地满足了公众用药需要。与此同时，药品医疗器械审评审批中存在的问题也日益突出，注册申请资料质量不高，审评过程中需要多次补充完善，严重影响审评审批效率；仿制药重复建设、重复申请，市场恶性竞争，部分仿制药质量与国际先进水平存在较大差距；临床急需新药

Reform policies in CFDA

- 1. Priority review procedure
- 2. Stricter GLP/GCP requirements
- 3. HR reforms
- 4. Generic drug reforms

1. Priority review procedure

This procedure was created to cut the time it takes for some significant drugs to reach market in Feb. 2016.

Priority review procedure

- Drugs for seven groups of patients may benefit from this procedure:
  - cancer
  - rare diseases
  - AIDS
  - tuberculosis
  - viral hepatitis
  - pediatric patients
  - elderly patients

2. Stricter GLP/GCP requirements

Fabricating GLP/GCP data in China could lead to criminal charges (New judicial interpretation by China's Supreme Court on Sept. 1, 2017)

最高人民法院最高人民检察院关于办理药品、医疗器械注册申请材料造假刑事案件适用法律若干问题的解释

来源：最高人民法院　发布时间：2017-08-14 17:00:32　字号：+ −　打印本页

《最高人民法院、最高人民检察院关于办理药品、医疗器械注册申请材料造假刑事案件适用法律若干问题的解释》已于2017年4月10日由最高人民法院审判委员会第1714次会议、2017年6月8日由最高人民检察院第十二届检察委员会第65次会议通过，现予公布，自2017年9月1日起施行。

最高人民法院　　最高人民检察院

2017年8月14日

Stricter GLP/GCP requirements

This not only applies to manufacturers, but also to GLP/GCP institutes and CROs.

3. HR reforms

- ✓ Reviewers from 120 in 2015 to 600 in 2017
- ✓ Competitive payment system
- ✓ Recruitment of international talents

4. Generic drug reforms

For already marketed generic drugs:

Generic quality consistency program was created in 2016 to ensure therapeutic equivalence.

Generic drug reforms

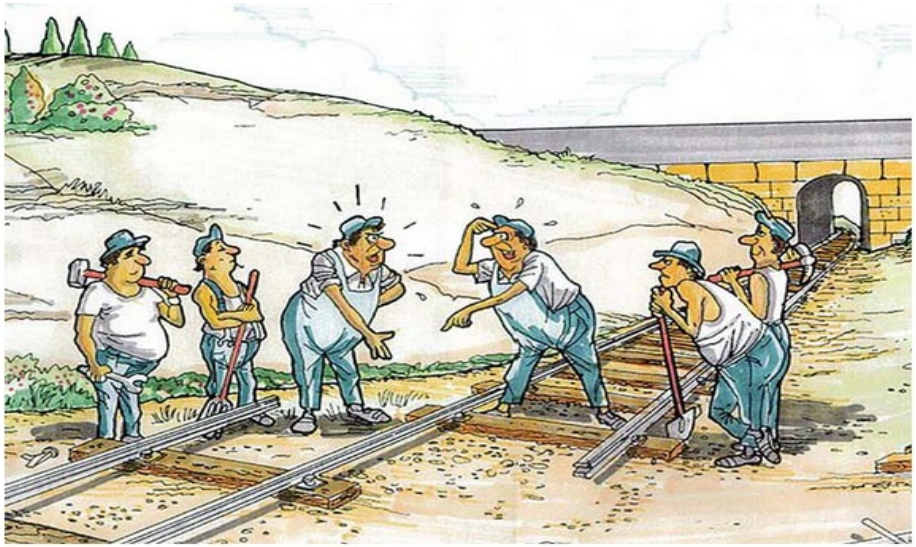
For new generic drugs:

Stricter pharmaceutical equivalence and bioequivalence requirements;

Orange Book (draft) in Sept. 2017

Objective

Aligning CFDA’s regulations with global standards



ICH membership

The ICH Assembly approved the CFDA as a new Regulatory Member in June 2017.

A milestone for CFDA modernization.

ICH membership

For domestic Chinese companies:

Survival of the fittest

ICH membership

For multinational pharmaceutical companies:

Timely and efficient introduction of new drugs to China

Thanks!

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