The Global Language of Business

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The Global Language of Business

Improving patient safety with an efficient and effective drug tracing and tracking system.

Traceability from global manufacturer's perspective

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October 25th, 2016

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RDPAC Introduction

Regulatory Policy on Drug Tracing and Tracking

Advocacy and Collaboration

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Advocacy and Collaboration

National Health and Wellness Conference 19th August 2016

President Xi stressed at National Health & Wellness Conference **'Public Health'** should be given priority in China's development strategy

Xi said health is a prerequisite for people's all-round development and a precondition for economic and social development

Central Government Key Points

- Promote *healthy lifestyles*
- Strengthen *healthcare services*
- Improve *health protection*
- *Build healthy environment*
- Develop *health-related industries*

What we do is important

We can make a difference

RDPAC - Introduction

Healthier China Through Innovation

RDPAC - Introduction

38 Member Companies. RDPAC represents the leading multinational companies with pharmaceutical R&D capabilities here in China.

Innovation. For many years they have brought Innovation to China in the form of advanced medications to meet Chinese patients' needs, and in the standards to improve the quality of care

Today, RDPAC members launch about 80 percent of innovative medicines in China.

Investment. Investment across the provinces, where RDPAC members are growing local capabilities.

49 *Manufacturing plants.*

31 *Centers for Research & Development.*

RDPAC - Introduction

Remarkable Progress

- The science of medicine has never been harder, but also never been more promising.
- Medicines are helping to bring down cancer death rates and increase survival rates.
- We're making enormous progress against heart attack, stroke and related vascular diseases.
- There's also good news on new treatments for diabetes.
- What makes this possible is our industry's investment in research and development.

RDPAC - Introduction

Key Facts

- There are more than 7,000 potential new medicines in development around the world.
- Today, a full 42% of those 7,000 are personalized medicines.
- And 72% of oncology medicines in development are potential personalized medicines, illustrating our industry's commitment to furthering advances in targeted therapy.

RDPAC - Introduction

Key Facts

- Today, RDPAC members launch about 80 percent of innovative medicines in China. That takes investment across the provinces, where RDPAC members are growing local capabilities.

- Overall, 9 billion RMB is being plowed into research and development in China every year.

- That translates into the potential for good jobs, growing technology excellence, and the potential for cures for China's patients.

RDPAC - Introduction

Challenges & Opportunities

- There is a big opportunity for China to grow as a hub for global research and development.
- This will only be possible with continued, sustained investment.
- China will need to have the policies that attract that kind of investment – policies that signal certainty and clarity to innovative companies considering investment.

Global standards including drug tracing and tracking could benefit a range of patient safety and supply chain efficiencies.

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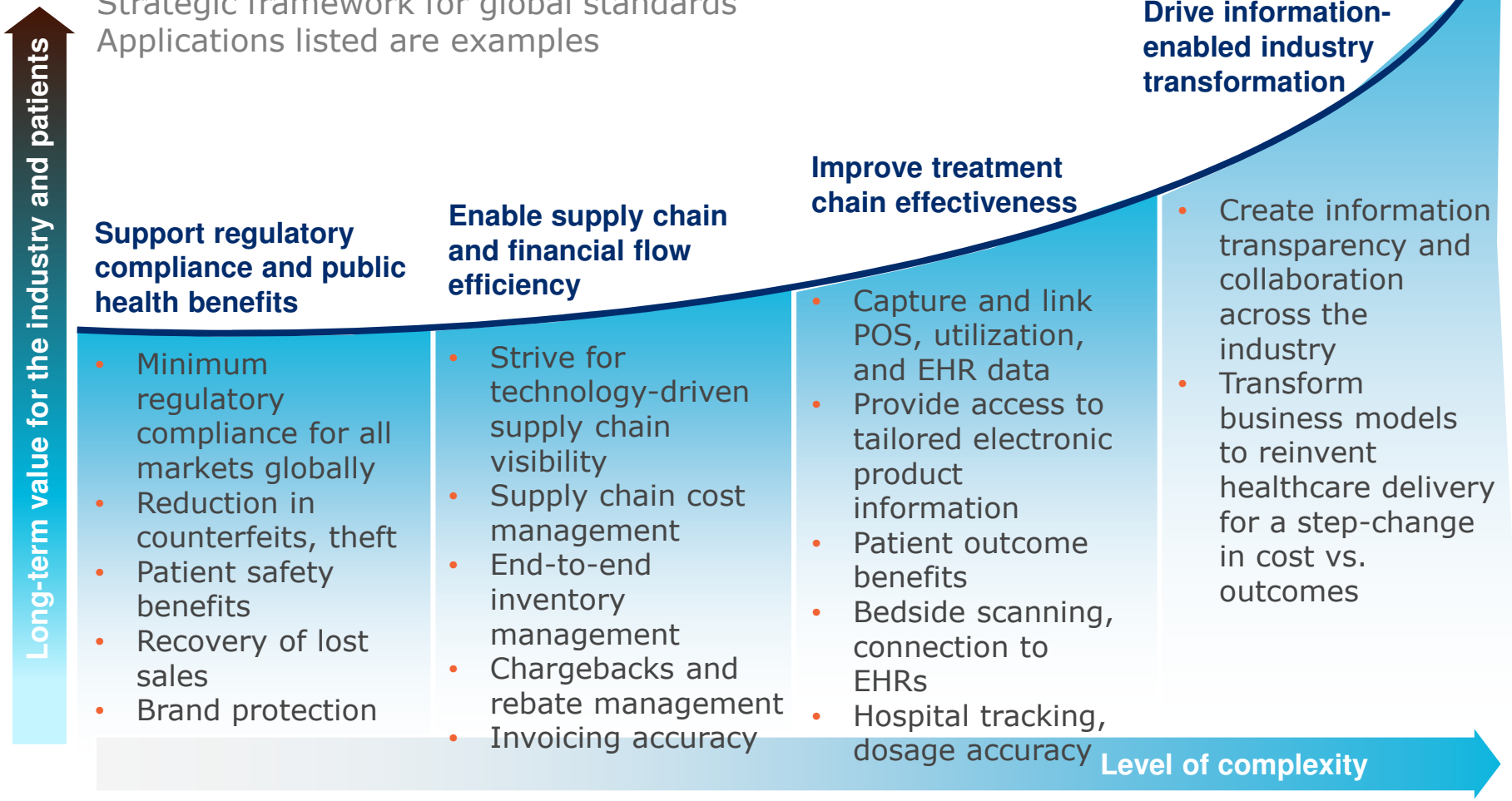
Global standards including drug tracing and tracking could benefit a range of patient safety and supply chain efficiencies

Strategic framework for global standards
Applications listed are examples



NOTE: Long-term value and complexity are indicative; steps are not necessarily sequential

Source: McKinsey report, "Strength in Unity: The promise of global standards in healthcare"

For hospitals, global standards in drug tracing and tracking can help ensure the "Five Rights"

1 Right Patient

The patient's identity must be verified against the prescription to ensure the **right patient** is receiving treatment;

2 Right Medication

The provider must verify that **the right medication** is used;

3 Right dose

The **right dose** should be confirmed against the prescription

4 Right time

Medications should be given at the **right time**; and

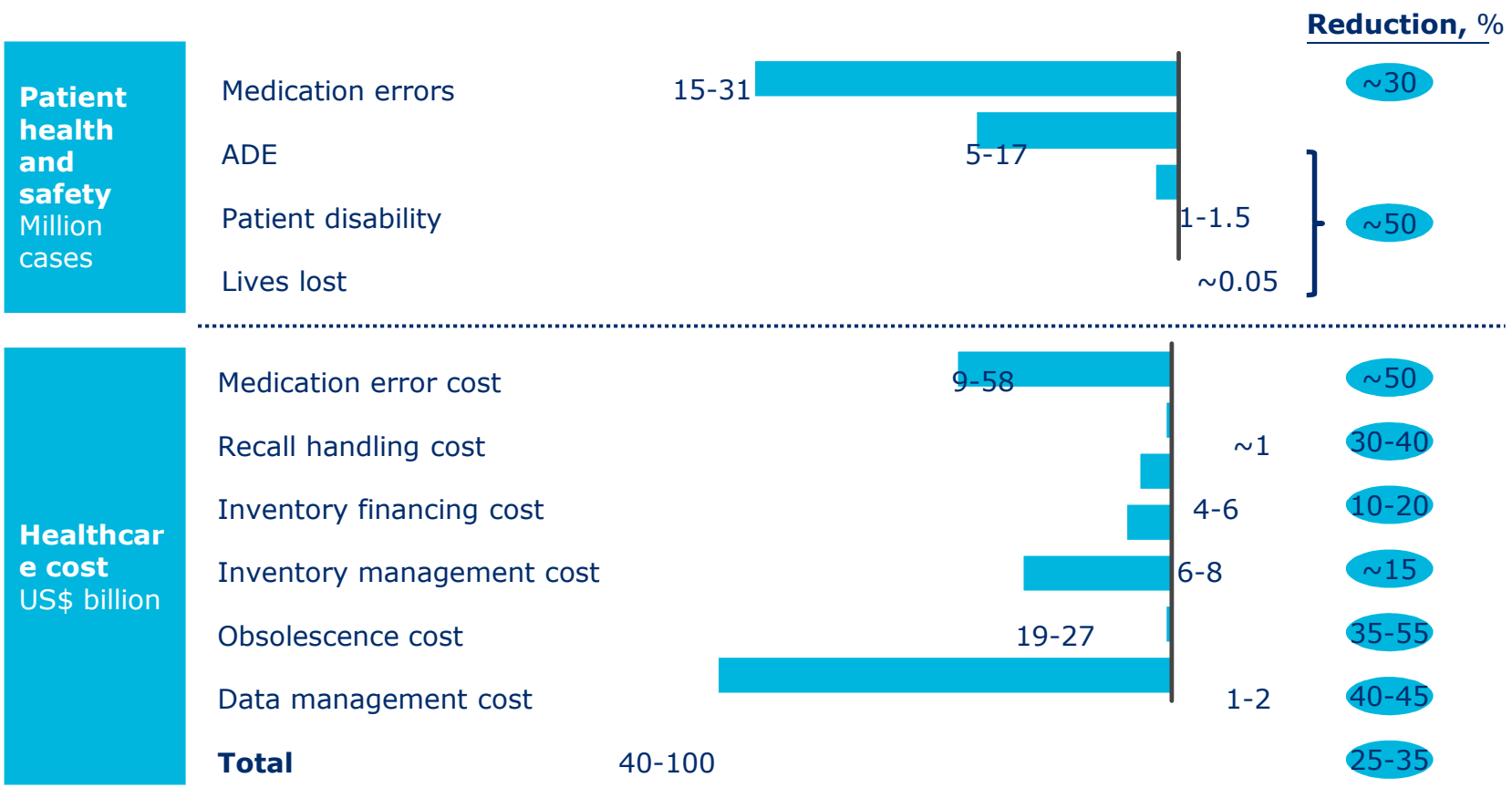
5 Right route

Medications that can be given in different ways, such as intra-muscularly or intravenously, must be given via the **right route**;

Source: McKinsey report, "Strength in Unity: The promise of global standards in healthcare"

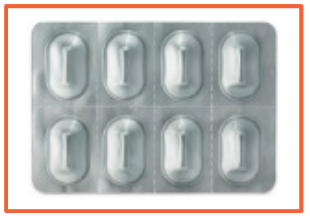
Global standards in drug tracing and tracking could enable substantial patient safety benefits and healthcare cost reduction

Impact of global standard



Source: McKinsey report, "Strength in Unity: The promise of global standards in healthcare"

Proper barcoding enables these benefits by capturing product and location information

	Product identification on secondary packaging		Product identification on primary packaging
	Without serialization	***With serialization***	
Information on barcode	• Product identification • Lot number • Expiry	• Product identification • Lot number • Expiry • Serial number	• Product identification
Selected benefits	• Inventory management • Recall effectiveness for pharmaceuticals	• Medication authentication • Recall effectiveness for implanted devices	• Prevention of medication errors
Examples	• Identifies product	• Identifies one pack of a product	• Identifies single unit packaging of product
			

Source: McKinsey report, "Strength in Unity: The promise of global standards in healthcare"

In China, regulatory policy on drug tracing and tracking is being developed

Jan. 2016	Opinions for Accelerating Establishment of Important Product Trace and track system issued by the State Council
Feb. 2016	Notice on Suspending the Implementation of National Drug Electronic Supervision Code – CFDA
Feb. 2016	Notice for Soliciting Public Opinions on Revision of Good Supply Practice for Pharmaceutical Products – CFDA
Apr. 2016	Notice on implementing the newly revised Regulations on the Administration of Circulation of Vaccines and Vaccination – CFDA and MHFP
May. 2016	Opinions on Further Improving Food and Drug Traceability System (draft for soliciting public opinions) – CFDA
Jul. 2016	Decision of the CFDA on the Revision of Good Supply Practice for Pharmaceutical Products (CFDA Decree No.28) - CFDA

Source: CFDA

Opportunities and challenges of regulatory policy on drug tracing & tracking

Opportunity

- Manufacturer's responsibility
- Appropriate IT technology and commonly used product identification
- Voluntary use of 3rd party service provider
- Role of industry associations
- Information sharing and exchange

Challenge

- Lack of tangible implementing and systematical coordination
- Need CFDA clarity on key uncertain areas

RDPAC Activities

- Establishment of Manufacturing & Supply Chain Working Group and Drug Trace and Track sub-working Group – 2015
- The development of RDPAC White Paper on China electronic bar code –Feb 2016
- RDPAC comment letter to CFDA on revised GSP and Opinion on Further Improving Food and Drug Traceability System in Mar and May, 2016
- Communication and collaboration with RxGSP – since May 16
- Industry seminar on Drug Trace and Track – July 2016
- International Symposium on Supply Chain Security and combating Counterfeit Dugs – Oct 28, 2016

Establish Efficient and Effective Drug Trace and Track System for the Patient Safety

RDPAC Objectives on China's Drug Electronic Supervision Barcode System

- Key Objectives:
  - Provide history and background of China drug electronic barcode system;
  - Identify existing problems of China's drug supervision electronic barcode system;
  - Provide preliminary recommendations for future policy on drug trace and track system.

Existing Problems on China's Drug Electronic Supervision Barcode System

I. Reduced management efficiency of the supply chain
   - Application of bar code prior manufacture of each batch;
   - Not compatible with logistics code;

II. China's drug electronic barcode system is not aligned with domestic and international practices (such as GS1 standards)

III. Regulatory objective of ensuring safe access to medicines for the public failed to be achieved
   - Low scan rate (<5%) of China electronic bar code at dispenser (pharmacy and hospital);
   - Lose of traceability during the supply chain;

IV. Security issues of database
   - Ownership of the data;
   - Security of the database.

GS1 Barcode		China Drug Electronic Supervision Barcode
For global use	1	For use in China only
Coverage of all industries (pharmaceuticals, medical devices, others)	2	Drug products only
Barcodes are assigned to enterprises through GS1 globally. Enterprises then take the charge of coding and allocation in respect of their products. Barcodes are managed by independent third-party standardization organizations	3	The CFDA/China Drug Electronic Supervision Network create and assign barcodes to each manufacturer under the administration of government departments
- Adoption of unified international coding standard and structure - Possession of more than 40 national and international standards of bar-coding, carrier and information transmission	4	No corresponding international standards and industry standards
Support one-dimensional codes, two-dimensional codes and RFID labels	5	One-dimensional code
One identification number for one item (drug) may also be achieved through the utilization of application identifiers of serial numbers	6	One code for one item
Open system. Anyone may scan barcode to read relevant information from the database	7	Closed data management system. Information must be provided based on back-office database
Low management cost	8	High management cost
Powerful identifiers	9	- Information cannot be acquired from the barcode without the internal database - Access to logistics platforms must rely on the central database - Is not compatible with public logistics platforms
Visually clear	0	Not visually clear. Information must be accessed through internal data link

RDPAC Preliminary Recommendations

Preliminary recommendations

- Enhancing the responsibilities of drug manufacturers and mobilizing social resources for the supervision of drug safety
- Accept and adopt electronic supervision barcoding in line with international practices
  - Encourage of use of international standards;
  - Allow manufacturer choose international standards or China electronic barcode;
- Importance of database management
  - Database owned by manufacturer or the volunteering third party selected by manufacturer;
  - Compatible of China electronic barcode with international standards.

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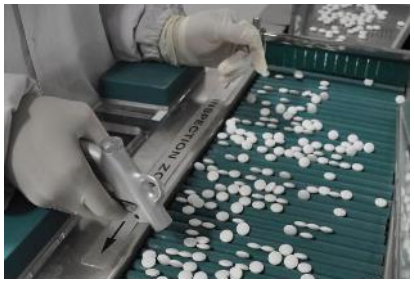
All stakeholders in the value chain can play a role in developing global standards for drug tracing & tracking

Manufacturers



- Largest and most global players
- Create visibility to true demand patterns
- Improve control over product shipment and usage conditions

Distributors and wholesalers

- Develop products and services for total supply chain connectivity
- Act as 'connectors' to improve materials handling, booking, planning, resource allocation and balancing
- New business models, e.g. customer order management, invoicing, etc.

Hospitals and pharmacies

- Develop supplier requirements and drive adoption up the supply chain
- Integrate pharma and medical products segments
- Understand how suppliers use of global standards improves total cost of ownership and safety metrics

Regulators

- Consider how to begin working together with the private sector to develop a clear vision for global standards
- Strive for minimal fragmentation of regulations globally

Source: McKinsey report, "Strength in Unity: The promise of global standards in healthcare"

Industry Seminar on Drug Trace & Track System

- The Associations: PSM, CPIA, SH-MITA, RDPAC
- The third parties: Alibaba Health, GS1, Acctrue, 301 Hospital

40~ experts attended the seminar on July 26th 2016

Next Step

International symposium to share international best practices

PSM CHINA
药品安全合作联盟
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS.

International Symposium on Drug Supply Chain Security & Combating Counterfeit Drugs
October 28, 2016; Beijing, China

Next Step- PSM Project

Collaborate with PSM on in-depth research on drug trace and track system

- Provide recommendations on the next phase policy development
- Find out feasible solutions on trace and track system

2016 年 8 月 31 日

关于深入开展中国药品安全追溯系统研究的提案

药品安全合作联盟/北京药盾公益基金会

2016-08-31

自去年下半年以来，国家发布了一系列关于药品安全追溯体系的文件，包括去年年底国务院的《关于加快推进重要产品追溯体系

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