Discussion paper on global harmonization of the traceability system for drugs with globally harmonised barcodes

Purpose

The purpose of this paper is to facilitate the discussions for a transition toward a globally harmonised barcoding system for pharmaceuticals in China, using GS1 global standards and building on the success of the existing national traceability system. GS1 Healthcare recommends:

- *To transition from the national numbering scheme to the global GS1 numbering scheme (GS1 Global Trade Item Number with the relevant Application Identifiers)*
- *To transition from linear barcodes to two-dimensional barcodes (GS1 DataMatrix) due to the increase of information in the code*

This move to global standards will enhance the competitiveness of Chinese producers by reducing the complexity of production and cost of traceability. It will reinforce China's commitment to patient safety based on globally traceable medicines.

On GS1 Healthcare[1]

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. GS1 Healthcare members include over 70 leading Healthcare organisations worldwide *(listed in the table below)*.

1WorldSync	DHL Exel Supply Chain	Movilitas Consulting
3M	Dirk Rodgers Consulting	Norfolk and Norwich NHS Trust
Abbott Laboratories	Edwards Lifesciences	Novartis
AbbVie	Eli Lilly and Company	OCS Checkweighers
Ace Ventures GmbH	Erasmus MC Hospital Rotterdam	Oracle
Actavis	Excellis Health Solutions	Pall Medical
Actelion Pharmaceuticals	F. Hoffmann-La Roche	Pfizer
Advanco	Filip Vtori	Premier
AMAG Pharmaceuticals	Frequentz	Purdue Pharma
AmerisourceBergen	Fresenius	Ramsay Health Care
Amgen	GE Healthcare	rfXcel
Astra Zeneca	Geneva University Hospital	SecTrace
Axway	GHX	Septodont
Baxalta	Gilead Sciences	Smiths Medical
Baxter	GlaxoSmithKline	St James's Hospital
Bayer	H.D. Smith	Systech International
B. Braun	Hong Kong Hospital Authority	Takeda Pharmaceuticals
Be4ward	Iberia Rehabilitation Hospital	Teleflex

1 www.gs1.org/healthcare

Becton, Dickinson & Co	Innovit Inc	Teva Pharmaceuticals
Bernhoven Hospital	International Hospital Federation	TraceLink
Blue Sphere Health	Johnson & Johnson	Universitair Medisch Centrum
Bristol-Myers Squibb	King Faisal Specialist Hospital & Research Centre	USDM Life Sciences
Cardinal Health	Marsh Consulting	UPS
CHI Robert Ballanger	McKesson	Vesdo
Cook Medical	Mettler Toledo PCE	Videojet Technologies Suisse GmbH
Covectra	Medtronic	Wiener Krankenanstaltenverbund (Vienna Hospital Association)
CSL Behring GmbH	Merck	

China existing legal framework on pharmaceutical identification

In 2006, the China State Food and Drug Administration (CFDA) launched the Chinese Electronic Drug Monitoring Network with the objective to better supervise the entire supply chain of pharmaceutical products. By rolling out electronic monitoring, the CFDA expects to effectively prevent counterfeit drugs from entering into the legitimate supply chain as well as to enable efficient recalls of pharmaceutical products with quality defects. It was initially applied to domestically produced narcotics and psychotropic drugs and subsequently to some domestically produced high-risk pharmaceutical products, including blood products, vaccines, injectables and compound preparations containing ephedrine, codeine and diphenoxylate. All essential drugs have been subject to inclusion in the Electronic Drug Monitoring Network as of February 2012. The CFDA extended the system to all pharmaceutical formulations marketed in China in 2015[2].

Manufacturers must record product-specific serial numbers on the national monitoring website[3], apply the barcodes to the products and activate the Government issued Electronic Drug Monitoring Code (EDMC) serialisation codes in the monitoring website.
Distributors of said products must scan the barcodes upon receiving and reselling the products to ensure consistency between transactional and transportation records. Consumers can verify product authenticity by entering the serial numbers in the national monitoring website or through the national service hotline.
Manufacturers of imported drugs must appoint a pharmaceutical manufacturer, a pharmaceutical distributor or its affiliates in China to act as a local agent and coordinate with the regulatory authorities. To avoid having the local trading companies apply

2 http://www.sfda.gov.cn/WS01/CL0460/69368_1.html
3 http://www.drugadmin.com/

barcodes on the external packages of imported drugs, the CFDA made it clear that the application of barcodes is part of the pharmaceutical manufacturing process and can only be carried out by foreign manufacturers or by the approved domestic repackaging manufacturers.

These requirements increase the complexity of supply chain management by foreign pharmaceutical manufacturers as they have to establish a communication protocol with their local coordinating agents for timely exchange of product-specific information and inventory data to ensure correct application of barcodes and oversight of in-market circulation. They also have to put in place proper control over their local coordinating agents to ensure accurate data entry and retrieval in and out of the CFDA's monitoring database.

GS1 traceability standards in Healthcare

GS1 Traceability Standards provide a complete set of standards for implementing traceability to enable full actionable visibility of pharmaceuticals and medical devices from point-of-production to point-of-sale, point of dispense or point-of-care and to ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.
GS1 standards are ISO-compliant[4] and likewise, ISO standards are a mainstay of the references within GS1 documents.

As background, the GS1 Global Trade Item Number (GTIN) is the foundation of the GS1 System (formerly EAN/UCC System). In the GS1 System, GTINs uniquely identify items that are traded in the supply chain, such as pharmaceuticals. GS1 Application Identifiers (AIs) are used to communicate item-specific/production information in a barcode (e.g., batch/lot number, serial number, expiration date).
The DataMatrix is a 2-dimensional (2D) bar code that efficiently allows the encoding and marking of a greater amount of data within a smaller space and that provides error detection and correction capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label.
The GTIN and AIs encoded in a GS1 data carrier, usually a GS1 DataMatrix barcode, provide the basis for unambiguous identification of pharmaceutical products globally and enables traceability across all packaging levels.

4 . http://www.gs1.org/docs/gs1_iso_brochure.pdf
. see further CEN ISO TS 16791, which addresses Requirements for international machine-readable coding of medicinal product package identifiers

In addition, the GS1 standards enable manufacturers, distributors and providers to share accurate, standardised and synchronised traceability data electronically.
Thus, the GS1 System of standards builds a global and secure framework for end-to-end traceability systems.

In most countries today, the regulatory requirements for drug traceability are implemented using GS1 standards. In practice, the GS1 GTIN is encoded in a GS1 DataMatrix with an expiration date, a batch/lot number and a serial number.

In China in particular, more than 40 standards based on the GS1 system and compatible with global standards have been developed and widely adopted throughout China over the past 20 years in various industry sectors, including retail, logistics, healthcare, as well as in many government departments.
In the Healthcare sector, over 7000 global pharmaceutical manufacturers are using GS1 standards, and more than 160 hospitals have successfully implemented traceability systems by adopting GS1 standards since 2006[5].

Implementation cost of the China system of drug traceability

External serial numbers for China must be uploaded and downloaded from the national monitoring website. This implies uploading or downloading a specific program for serial numbers as well as adaptations with mapping tables for data structure as the Chinese product code does not fit into the usual data structure.
The effort to develop and test the relevant upload/download program took approximately six months and the average cost was US$250'000 for a global manufacturer[6]. In parallel, the process to upload and download numbers is, and will be continuously required, and the stock level of serial numbers must be monitored.
In addition, adding capability to store the EDMC serialisation codes as an externally provided number in the standardised serial number management system, adding additional checks and balances to make sure EDMC serialisation codes printed on the cartons are valid, has a total cost of US$3 million for a global manufacturer[7].

Linear barcodes as mandated by the CFDA cannot be printed online in the required quality, size and speed on packaging lines. As a result, manufacturers are using preprinted serialized packaging material to overcome this restraint.

5 Based on data provided by the CFDA
6 Figures reflecting an average of the single time investment cost based on data provided by global manufacturers
7 Figures reflecting an average of the single time investment cost based on data provided by global manufacturers

The practical implications of this are a costly two-step production process, where the manufacturer first has to order the packaging material well in advance of the actual manufacturing, and second is the manufacturing step itself after goods receipt and QA release of the serialized packaging material. This not only considerably increases the planning time and the manufacturing costs but, requires specific stock monitoring of packaging material as well. For some Chinese manufacturers, this imposition requires additional dedicated resource and processes to manage this *exceptional* local process requirement compared to *normal* production processes. The proprietary nature of the product coding means that the product codes are neither globally standardized nor globally recognizable which is both disruptive and inefficient.
Ongoing cost in paying the carton print vendor to print the EDMC code, additional man hours in downloading and sharing EDMC serialisation codes between various manufacturing sites, managing stock level of serial numbers, etc. is on average US$600,000 per year for a global manufacturer[8].

Finally, it is important to mention that barcode equipment providers confirmed that no additional cost will occur by **transitioning to implementation of GS1 codes**. Indeed, this will only involve the format change of barcode currently used and current barcode equipment can still generate the new format of GS1 barcodes without modification.

Use of GS1 standards for pharmaceutical traceability

The traceability of medicinal products is a key objective of regulations around the world to fight against counterfeiting. More and more regulators are requiring the use of unique identifiers to be encoded into data carriers on the secondary packaging and linked to relevant information in a database. Increasingly, regulators are recommending or requiring the use of GS1 standards to implement these traceability requirements.

For example, GS1 standards for drug coding are followed in regulations of the U.S.A., Argentina, Turkey, Saudi Arabia, the United Kingdom, Australia, Korea, Japan and India.

Although some countries in Europe (*see Fig. 1 – countries highlighted in red*) are currently still using a national coding system for pharmaceuticals, mainly due to historical reasons and the use of national reimbursement numbers, this situation will change by 2019. Indeed the EU Directive on Falsified Medicines (FMD)[9] is setting up requirements for a harmonised approach across Europe, using global standards to efficiently address the issues surrounding falsified medicines and to enable cross-border traceability.

8 Figures reflecting an average of the as ongoing life-cycle costs based on data provided by global manufacturers
9 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:en:pdf

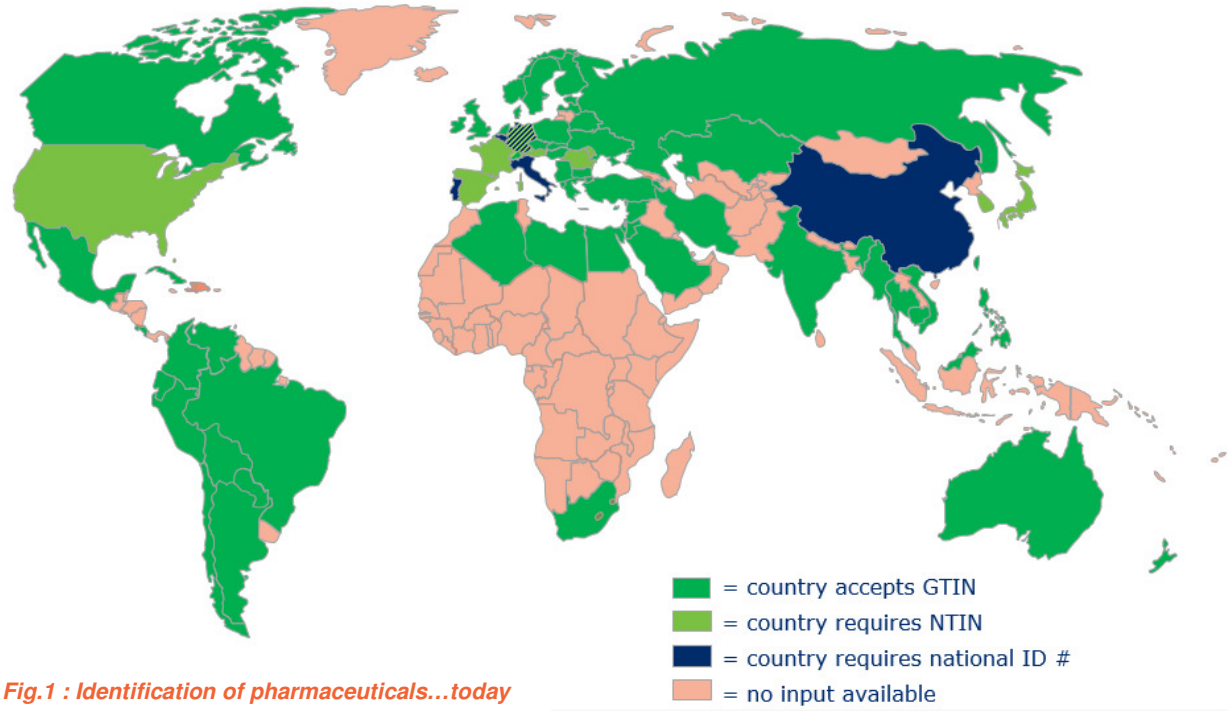

Fig.1 : Identification of pharmaceuticals…today

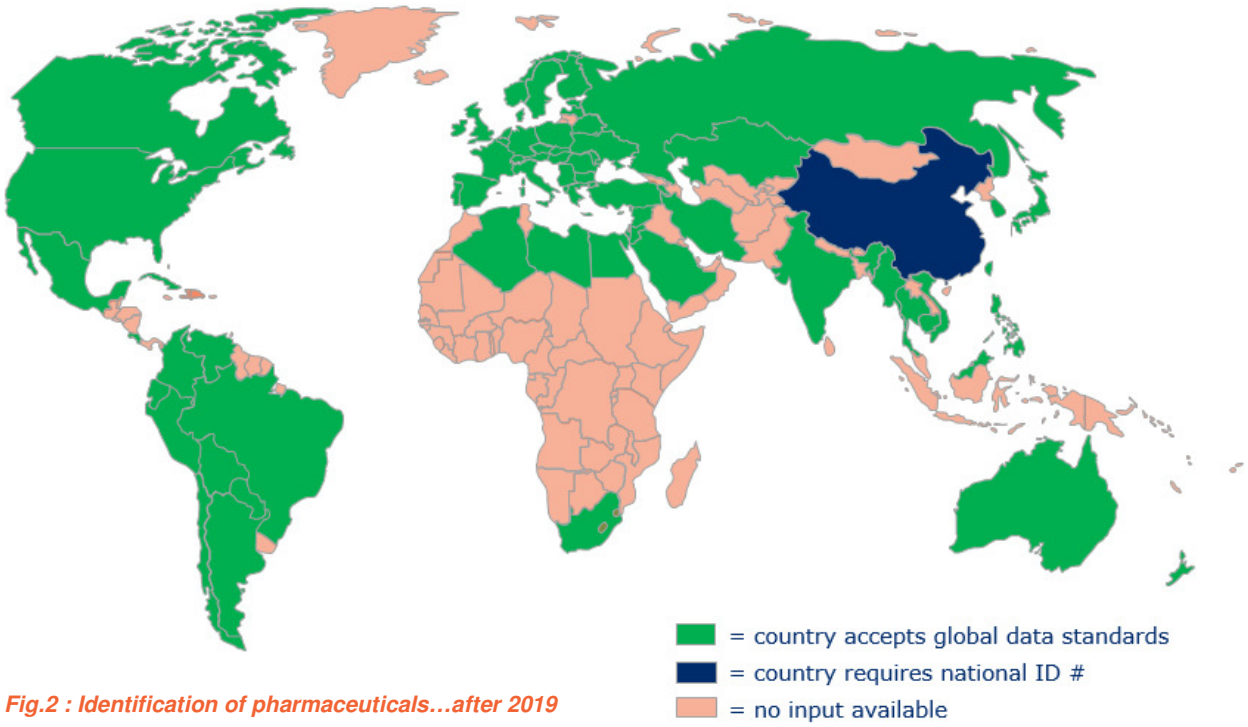

Fig.2 : Identification of pharmaceuticals…after 2019

It is expected that as of 2019, China will remain the only country across the world using a national coding system for pharmaceuticals (*see Fig. 2 – country highlighted in red*).

As the pharmaceutical industry becomes more global, managing the labelling and packaging in so many countries globally and having to adapt their processes to meet the specific requirements of only one country, becomes more and more challenging and will significantly impact the competitiveness of Chinese manufacturers

In addition, the limits of having a purely national system for drug traceability is also limiting the benefits in regards to patient safety and supply chain security in an increasingly globalised context.

APEC moving towards alignment on Global Data Standards (GDS) for drugs integrity and supply chain security

The APEC (Asia-Pacific Economic Cooperation) work group on track and trace systems for drugs (TTWG) is one of ten work groups working on the APEC Roadmap for Global Medical Product Integrity and Supply Chain Security. The TTWG, which is comprised of regulatory authorities and industry members, has identified and evaluated current traceability best practices with the overall goal to ensure that pharmaceutical products moving in international commerce are not falsely represented in any way nor diverted from secure supply chains or distribution channels.

Common themes and practices have emerged through the APEC dialogue and the TTWG have developed three key overarching recommendations. The third of these recommendations is the use of global data standards (GDS) for implementation of the traceability system for drugs.

The APEC Committee on Trade and Investment (CTI) summary of the Third Senior Officials Meeting identifies the lack of common data standards for product verification and serialization as the first barrier to trade in healthcare products and recommends addressing these barriers as a priority.

In November 2014, a Joint Ministerial Statement was issued at the APEC Ministerial Meeting in Beijing China. The Statement officially details “new actions for deepening Asia-Pacific partnership to navigate the changing regional and global landscape and boost economic recovery.” Article 24 of the Statement supports the development of

Global Data Standards Pilot projects as well as a further study and policy recommendations on the topic.

Benefits of using GS1 standards compared to the Chinese Electronic Drug Monitoring Network

GS1 standards	Chinese Electronic Drug Monitoring Network
Manufacturers create their own serial numbers following GS1 standards. Management of serial numbers becomes simple and manageable. No need to check for validity of the serial numbers since they are generated and printed internally. Avoid complexity of using dedicated computers outside the company network.	Serial numbers (EDMC serialisation codes) are provided by CFDA. Third party allocation of numbers: implies manual intervention and opens the door to errors in aggregation, traceability, etc. Need a special IT set-up which needs to be used on a dedicated computer. Need to download from CFDA and transfer numbers to the manufacturing sites and carton print vendors. Serial numbers are (a) generated a long-time before they are used in manufacturing and (b) transferred to a third party. Both are a security risk because undetected theft of the numbers could lead to usage of valid numbers on falsified products.
Industry recommendations can be followed: use of two-dimensional GS1 DataMatrix encoding the serial numbers along with product identifier, batch/lot and expiration date.	Codes have to be captured in a linear barcode with specific format prescribed by CFDA.
Each product and package level has a GTIN which is unique globally across all products and manufacturers.	Extremely complex master data: many data elements such as product code, resource code, subtype code, version number, code level etc. need to be maintained None of these complexities exists if GTIN is used as the product identifier and GS1 standards are followed.

	The lack of a way to automatically upload commissioned serialized data to the CFDA website requires extra work which will dramatically increase on January 2016 when all drug products will be subject to the requirements. The requirement to provide two reports about commissioned product – once at packaging and once upon shipping from the warehouse – deviates from other regulated markets' requirements. Reporting both commissioning and shipping separately is duplicative, complicated and provides little usable information.
GS1 standards on data exchange enable interoperability and compatibility using Internet-based, interconnected network.	Reporting of EDMC serialisation codes to CFDA needs to be done manually via predefined file formats using a dedicated computer with the specific software installed.
Any software systems throughout the supply chain (including hospitals) will be able to recognise and decode the data captured into a GS1 barcode and that all barcode scanners will be able to do the same, which reduces complexity.	
Benefits to the caregivers: need to have a system working and understood beyond borders in order to ensure drug integrity. The use of a GTIN to provide links to additional product information to support other patient care initiatives and increased product visibility in both warehousing and pharmacies. Single code links to all product information, GS1 standards would allow this to be shared.	The effectiveness of China's serialization system is quite limited given that dispensers do not have to authenticate the product provided to the patient. This also considerably limits the impact of anti-counterfeiting policies in China.

Export benefit: product will meet more than one local requirement for traceability and be compliant with global traceability requirements. Common systems and process for domestic as well as export markets	
Alignment with other products such as medical devices, food etc.	
GS1 standards aligned with global requirements.	The Chinese National Coding system is not aligned with the work carried on by APEC on the use of Global Data Standards.

Conclusion

It is recognised that in order to combat counterfeiting across borders, global traceability is necessary. The use of global data standards, namely the GS1 standards, is recommended by inter-governmental organisations (e.g. WHO) as well as by key trade associations across the world. The GS1 standards are used and implemented by at least 65 countries worldwide.

GS1 Healthcare recommends a transition to GS1 standards in China in order to ensure harmonisation and alignment with healthcare regulators across the world; in particular EU countries will have transitioned to a global solution by 2019. *(Refer Fig. 2).* GS1 Healthcare recommends:

- To transition from the national numbering scheme to the GS1 numbering scheme (GS1 Global Trade Item Number (GTIN) with the relevant Application Identifiers)
- To transition from linear barcodes to two-dimensional barcodes (GS1 DataMatrix) due to the increase of information in the code and speed/security in production

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Recommendation from GS1 Healthcare: use of GS1 GTIN with relevant AIs captured into a GS1 DataMatrix

To ensure China's **global competitiveness, growth and future prosperity**, alignment on a suite of global standards as outlined, will have a significant and positive outcome on reducing supply chain complexity, cost and risk for all stakeholders while enhancing the potential for much desired supply chain optimisation and interoperability and ultimately, improving patient safety outcomes.

Annex – Standards comparison grid

	GS1 Standards	National codes
Availability of high information density data carriers	Yes (GS1 DataMatrix and RFID)	Generally not (linear barcodes)
Comprehensiveness of the standard in terms of identification definitions	10 identification keys (incl. GTIN, GLN)	Product code only
Master data synchronization	GDSN (Global network)	No
Includes traceability standard	Global Traceability Standard for healthcare	No
Interoperability with national ID numbers	National numbers compatible with use of GS1 standards	Not intended to be used outside country
Used in all global geographies	Yes	Only in country
Span across product types	Pharmaceuticals and medical devices	Pharmaceuticals only
Global organization infrastructure andsupport	Global infastructure and support (global office and 111 member orgs)	Within relevant country
Additional industry coverage	Core sectors in Retail, Healthcare, Transport and Logistics; 20 others	Pharmaceuticals only
Regulatory agencies / jurisdictions accepting use of standard	65	China, Germany, Italy, Belgium, Portugal

McKinsey report "Strength in Unity" presents a Comparison grid highlighting the benefits of using GS1 standards.