Pharmaceuticals: Appendix B- Case Studies of innovative projects

1. **American Academy of Pediatrics & GS1 Healthcare, US - Project on 2D barcoding**

GS1 is a neutral, not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 111 countries, with the Global Office in Brussels, Belgium.

GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

The American Academy of Pediatrics (AAP) has chosen to work with GS1 to provide the standards around 2D barcoding because of GS1's experience and involvement in healthcare delivery systems. GS1 has developed standards that are followed throughout the world and recognized by many manufacturers. DataMatrix and GTIN are used as the delivery system for 2D barcoding on vaccines. The GS1 Data Matrix is one type of 2D barcoding. It uses the Global Trade Identification Number (GTIN) which integrates the NDC.

The specific standards referenced in this GSI guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- GS1 General Specification – Available in the Solutions Center through the GS1 US website at www.gs1us.org/solutionscenter
- ISO/IEC 16022 Information Technology – International Symbology Specification – DataMatrix
- ISO/IEC 15416 Information technology – Automatic identification and data capture techniques – Barcode print quality test specification – Linear symbols
- ISO/IEC 15415 Information Technology – Automatic identification and data capture techniques – Barcode print quality test specification – 2D symbols
- ISO 1073-2 Alphanumeric character sets for optical recognition – Part 2: Character set OCR-B – Shapes and dimensions of the printed image
- AAP Clinician Guidance.
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- *Additional considerations and resources specified*
- 2D barcodes require camera-based scanners. Traditional laser barcode scanners cannot read the 2D barcode. As a result, it is important for supply chain partners to communicate prior to implementing 2D barcodes to ensure that the appropriate scanners are in place.
- Prior to purchasing barcode scanning equipment, it is recommended that the purchaser consult the Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria and the AAP Clinician Guidance.
- There are many reasons why a barcode may not scan. Many times it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US prepared another document entitled Procedure for Responding to Troublesome Barcodes to help resolve barcode

scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users.

2. **Promoting Pharmaceutical Medicine Training Programme :'PharmaTrain' - Ireland**

The main objective of the PharmaTrain project is to build and implement a new modular Master level programme for advanced studies in Pharmaceutical Medicine and Drug Development Sciences. The programme is based on the Bologna credit and title system and builds on the new PharmaTrain syllabus 2010 of the European Federation of Courses in Pharmaceutical Medicine (EFCPM).

The modular concept of the training programme also provides an opportunity to professionals to select courses for accredited Continuing Professional Development (CPD), as well as individualized training à la carte. The PharmaTrain consortium has identified 6 base courses and 13 master level programmes at European universities that will be standardized at the same quality level. PharmaTrain sets, maintains and constantly improves the standards and quality management of the training schemes and practices for pharmaceutical professionals

The programme will encourage exchanges between the industry, regulators and academia, produce and promote distance e-learning programmes, and will enable increased flexibility, transferability and mobility. A uniform high-level training in Europe will make the drug development process faster, more economical, and more tailored to patients' needs, and will give Europe a global advantage in developing new innovative medicines. PharmaTrain is a collaboration of 20 EFCPM university training programmes, 13 learned societies including 3 competent authorities, several partner training organizations and 15 pharmaceutical companies. One year after its start, May 1, 2009, PharmaTrain has gained full momentum and has met basically all milestone deliverables in the 'Prepare Phase' and now launches the next two years of the Learn/Execution Phase.

First year results include:

- Creation of new postgraduate training curricula with syllabus standardised modularisation and related learning outcomes providing increased mobility

- Unified examination principles

- Different mixes of blended e-learning for comparative testing during the programme

- Combined with a new concept of cooperative training among new EU member states as well as a pan-European accreditation system

- A continuing Professional Development (CPD) Platform and a comprehensive quality management process