



THE ALLIANCE FOR GLOBAL PHARMACEUTICAL SERIALIZATION

RxGPS Digital Labeling Principles

- 1. Digital-only labeling offers significant patient, environmental, and logistical advantages over paper labeling.**
- 2. Digital labeling regulations should be patient-safety focused.**
- 3. Regulations should be grounded in current global technical standards.**
- 4. End-user awareness and adoption are critical components to success.**
- 5. Countries that launch digital labeling must have the software capabilities to support success.**
- 6. RxGPS supports the use of the barcode that is most accessible to the target audience(s) that the material is intended for. The most appropriate barcode to use may also depend upon the pack level and repository system architecture (centralized or distributed) that the nation adopts.**
- 7. If the 2D Datamatrix is the data carrier selected, then the GTIN should be the key on which systems are established. If the QR code is the data carrier selected, then the URL should be the key on which systems are established.**
- 8. The packaging level at which the barcode is applied should align with the intended audience of the digital information.**
- 9. Digital labeling systems should allow MAHs to define the information presented and allow that information to evolve over time.**
- 10. If a nation adopts a centralized-national repository, then that nation should adopt a single consistent format for how information is structured (e.g., XML). Otherwise, nations should give companies the flexibility to decide upon the best format to use.**
- 11. RxGPS recommends digital labeling initiatives include all Rx medications, and, if appropriate, OTC medications and medical devices.**
- 12. Barring unique circumstances (e.g., nations where smartphone access is not widespread), nations that consider adopting digital labeling systems should make such regulations mandatory to replace physical paper labeling.**