RX GPS
THE ALLIANCE FOR GLOBAL PHARMACEUTICAL SERIALIZATION

Patient Level Verification Position Statement

Background

Patient level verification of products has garnered discussion and interest worldwide. In particular, recent proposals in India have included verification by the patient via a mobile phone application. While the benefits of patient level verification may include incremental patient autonomy and peace of mind, there are significantly more challenges associated with patient level verification that must be balanced against any potential benefits.

Patient level verification can create significant security concerns, and the process of serializing primary packaging is extremely complex and costly. Not only does authentication by the dispenser, rather than by the end user (patient), facilitate product checking by professional and informed pharmacists and physicians at the point of dispensation, it ensures the best opportunity for authentication of intact packaging, which might otherwise be destroyed after the patient has received the product. Additionally, patient-level systems are unlikely to be automated and may not include scanning capabilities. In instances where less sophisticated systems are available (*e.g.*, SMS technology), patients may be more likely to manually type in the serial number than to scan it, increasing the level of inaccuracy/errors and inadvertently creating false negatives on patient verification attempts for otherwise good product. For these reasons there has not yet been a market to successfully implement patient level verification of product serial numbers. Some markets, such as Turkey, have implemented scanning technology for the end user, but the patient only gains access to ancillary information about the product (e.g., manufacturer, location of dispense) rather than traceability data for product authentication. Given the numerous challenges with patient-level verification described below, RxGPS supports limiting verification to supply chain entities; if patients are permitted to scan product, the information they receive should only include ancillary product information not related to traceability.[1]

The challenges associated with patient level verification are described in detail below.

Challenges

There are numerous challenges associated with patient level verification. We believe that, together, these challenges outweigh the benefits of patient-level verification. Therefore, any potential approaches to patient-level verification would need to mitigate or eliminate some of the challenges below.

[1] An individual market may identify a specific need for which verification is necessary. While not recommended, if patient-level verification is pursued, it must be done in a way that accounts for the numerous challenges described here.

1. **Utility and Uptake.** To date, there is no evidence to suggest that consumers will see the need for, or actively use on a broad scale, information encoded in a product barcode. Additional research and data is needed to establish the benefits of patient level verification and whether those benefits are recognized by a significant percentage of the patient population. Further, additional research is needed on the impact of verification performed after dispense (as would occur with patient level verification), including whether the information received by the patient corresponds with the safety, security, and quality of the product.[2]

2. Security (data storage and access). Patient-level verification can create significant security concerns because authentication by patients would necessitate a database that is accessible by any person in a country. This would open these secure databases to significant risk of unauthorized access, which would completely undermine supply chain security. Therefore, any database utilized for this purpose would need strict security protocols and infrastructure to protect proprietary serialization data. Further, the database would need to protect against concerns caused by multiple patient verification requests for the same product. A market would need to consider whether to monitor verification attempts/requests, or whether to allow just one verification attempt for a product. And if limited to one attempt, RxGPS believes that should be by the trade (dispenser).

3. Monitoring Patient Activity and Concerns. Patient-level authentication raises important questions, legal and otherwise, about how to handle product that is deemed "invalid" by a consumer, rather than a licensed health care professional. Difficulties in scanning small primary packaging or challenges and inexperience interacting with a verification portal may cause patients to discard medicines that are perfectly good. In addition, patients who are unfamiliar with verification will likely have legitimate questions concerning the verification process and verification responses they receive. Supply chain trading partners should not be obligated to respond to these data or technological concerns expressed by patients. This would require significant time and resources that would best be spent working with other supply chain members and regulators to ensure that product is authenticated before being dispensed to a patient.

4. Education, Communication, and Exceptions Handling. Patient-level verification will necessitate patient education to ensure that the end user understands the verification responses received and the meaning of those responses. Further, any technology implemented would need to allow for the communication of exceptions (e.g., product is expired, damaged, recalled, stolen) to patients in a clear, concise, and understandable way. In addition, if a regulator grants exemptions from labeling requirements for particular products (e.g., the packaging is too small to allow for serialization/labelling), patients will receive products that do not carry a product identifier. It would need to be made clear which products should and should not carry a product

[2] For example, product transactions could occur between individuals once a product has been dispensed, and the quality or authenticity of the product could be compromised. If this is the case, patient-level verification may provide a false sense of security to the patient.

identifier. Thus, clear communication to the end user is necessary to avoid confusion or disruption in the patient level verification process. This adds an additional implementation burden to any network/system for verification.

5. Primary Package Level Serialization or Additional Labelling. Patient level verification would require serialization or additional labelling at the primary package level. There are many different configurations for primary packaging, and the operational impact of encoding many of those configurations would be significant. In some instances, a datamatrix containing static information (*e.g.*, a GTIN) could be added to the package artwork, which would limit the operational impact. But in many instances, it would not be possible to add a datamatrix to the artwork either because the information contained is non-static (*e.g.*, a serial number), or because of the packaging methodology. For example, the foil backing on a blister strip (and therefore any labelling information) is often not applied uniformly to every individual blister cavity. While this approach adds significant efficiency to the packaging process, it also means that a code could not be easily added to every strip or cavity without impacting the size of the package (in order to accommodate individual blister cell serialization) and resulting in increased costs.

6. Dispensing Practices. Across global markets, manufacturers are serializing at the level of the salable unit (utilized here to mean the smallest level of packaging intended to be sold to the dispenser/pharmacy). Certain dispensing practices result in dispensing of products to patients at a level below the salable unit. Not only does this result in a lack of information included in the salable unit product barcode, but it also eliminates key packaging information (e.g., is the packaging in-tact, consistent with packaging from this manufacturer) that is critical to the authentication process performed by dispensers (pharmacists). Therefore, the most appropriate place to authenticate product is at the point of dispense.

Conclusion

Patients should have confidence in the products that they are receiving, but that confidence should be a result of a secure supply chain (manufacturer, wholesaler, pharmacy). Individual markets may identify specific opportunities or a need for patients to have additional product information. However, this information should not be related to traceability (e.g., serial number data), but rather to ancillary product information (e.g., expiration date). RxGPS believes that the challenges of patient-level verification far outweigh the potential benefits. Therefore, RxGPS supports an approach that reserves core traceability to the pharmaceutical supply chain.