Shire

Shire Specialty Pharmaceuticals
725 Chesterbrook Blvd
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02 April 2012

Dear SANCO,

Shire is a global specialty biopharmaceutical company with major operations in Basingstoke, UK, Wayne, PA and Lexington, MA, and a network of offices and distribution channels throughout Europe, South America, Canada, and the Pacific Rim. Shire employs some 4,000 people in more than 25 countries with a global 2011 revenue of approximately $4 billion. We are organized into three divisions: Specialty, Human Genetic Therapies, and Regenerative Medicine. Our products are marketed in over 50 countries worldwide.

We welcome the opportunity to submit the comments in response to the consultative document on Unique Identifier for Medicinal Products for Human Use, and Its Verification.

Sincerely,

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Shire

To: European Commission
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09 April 2012

SHIRE'S RESPONSE TO SANCO'S CONCEPT PAPER ON DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION

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Shire welcomes the opportunity to submit the following questions and comments, in response to the consultative document on Unique Identifier for Medicinal Products for Human Use, and Its Verification.

Consultation item 1: An advantage to leaving specifications to the manufacturer would include being able to piggy back off of existing platforms, which would reduce time and cost for implementation. However, having a harmonized regulation would result in an alignment of standards and create the possibility to leverage one approach within a manufacturer and between manufacturers /Contract Manufacturing Organizations (CMO's).

Consultation item 2: While this approach is low in complexity it does not include enough information to enhance patient safety nor aid with recalls, pricing or reimbursement.

Consultation item 3: It would be advantageous to include this additional information to facilitate supply chain activities such as identify expired product, aid in recalls, traceability within the supply chain and enhance patient safety. In addition, the approach is in alignment with other countries current barcode formatting, and we see this as more of a global approach.

Consultation item 4: Our preference would be option 1 whilst using a 2D barcode, due to space limitation on packaging. The reimbursement number should be eliminated and replaced by a Marketing Authorization (MA) or Mutual Recognition Procedure (MRP) number. Thus when the product is scanned by the pharmacist at the dispensing point the product is approved to be reimbursed regardless of the country. Country software should be amended to allow reimbursement against the numbers.

Consultation item 5:
Linear barcode:

- Advantages: Widely used and proven technology.
- Disadvantages: Large barcode size would likely require artwork redesign.

2D barcode:

- Advantages: Increasingly used for pharmaceutical products. For the supply chain, 2D is likely to be the best data carrier. It can contain a large amount of data within a small space and therefore use will result in minimal impact to packaging components/ artwork.

- Disadvantages: For manufacturers without current capability there would be a moderate cost to obtain equipment. Downstream customers (e.g. pharmacists and hospitals) would need to have the necessary equipment and procedures to scan the barcodes.

RFID:

- Advantages: The non line of sight access to information can enhance supply chain activities, such as material handling and inventory management.
- Disadvantages: High cost for implementation and only a limited number of manufacturers currently have the capability. Downstream customers (e.g. pharmacists and hospitals) would need to have the necessary equipment and procedures to scan. The reliability of RFID tags is not proven and there is no data recovery if the tag fails to be read. In addition, RFID technology is not approved for use with biologics and may have impact to API.

Consultation item 6: No additional dispensing points have been identified.

Consultation item 7: Only option three meets the full objective to protect patient safety through - out the supply chain.

Option 1 does not validate the dispensing of the original medication to the patient. If an original is copied in the supply chain, the counterfeit drug will be back in the distribution channel and not the original. It will be too late and the damage would have been done before knowing a counterfeit drug was sold.

- Number of wholesale distribution plant- No impact.
- Costs for adapting such plants- No impact.
- Duration of scanning such plants - No scanning, therefore no impact.
- Number of pharmacies, including hospital pharmacies- No scanning at receiving only when dispensed, thus may slow down the reading.
- Number of medicinal products dispensed by pharmacies and a hospital pharmacy- Volume may impact scanning speed and if the repository is down for maintenance it may prevent the product to be dispensed.

The concept of option 2 is similar to prioritization risk assessment, but the goal will not be met as a counterfeit drug can be identical from a packaging standpoint and be read the same as the original.

- Number of wholesale distribution plant- Random scanning will slow down the wholesale process and would not provide evidence that it is not a counterfeit drug that was scanned.
- Costs for adapting such plants- Minimal to none as wholesalers have all the necessary scanning equipment.
- Duration of scanning such plants - Will slow down the process for incoming product.
- Number of pharmacies, including hospital pharmacies- No scanning at receiving, only when dispensing. May slow down the reading.
- Number of medicinal products dispensed by pharmacies and a hospital pharmacy- Volume may impact scanning speed and if repository is down for maintenance, may prevent the product from being dispensed.

Preference is for Option 3, systematic verification by the wholesalers. The prioritization risk assessment concept should apply here in order to progress a full chain of custody across all partners in the supply chain and should include progressive introduction of more products, starting with products that are most attractive to counterfeiters. This would facilitate introduction

of the legislation gradually, giving time to evaluate areas for improvement and technology enhancement.

- Number of wholesale distribution plant- Aggregation would be required to help wholesalers to transfer product from point A to point B and update the central repository accordingly.
- Costs for adapting such plants- After picking a customer order the person responsible for checking the order accuracy will need to scan the aggregated box and /or individual packs. Once the order is verified and approved a 2D barcode, aggregating all items in the order, can be printed and applied to the shipping box. One printer of approximately $125,000 USD would be required by the warehouse.
- Duration of scanning such plants - May need to double the number of personnel in the warehouse inspecting the orders.
- Number of pharmacies, including hospital pharmacies- May facilitate the receiving by scanning the 2D barcode on the shipping box to confirm if shipment matches the PO. Other than that, it would be the same scenario as option 2, no scanning at receiving only when dispensed. May slow down the reading.
- Number of medicinal products dispensed by pharmacies and a hospital pharmacy- Same as option 2, the volume may impact scanning speed and if the repository is down for maintenance it may prevent the product to be dispensed.

Consultation item 8: If option 1 was used it would lead to difficulty for pharmacists to read data from multiple pharmaceutical manufacturers when it is not standardized.

The preference is to use option 2, EU Governance, which would standardize data transmission. It is estimated that for each specification to meet the EU governance requirement for data transmission the cost would be approximately $25,000 per brand.

Consultation item 9: The system would need to be configured to prevent any information from being extracted and exported. Confidential company information such as markets, distribution channels, product SKU mix, manufacturing partners and pricing information would need to be protected.

Consultation item 10: We are in agreement with section 4.3 with regards to applying equivalent safety features after repackaging. The manufacturer's unique identifier would need to be decommissioned. The repackagers would need to demonstrate that they are authorized repackagers by providing all necessary documentation, since there needs to be adequate controls in place to ensure this in not a potentially weak point for counterfeit drugs to enter the supply chain.

Consultation item 11: Several manufacturers have different brand names thus making it cumbersome to be identified by the brand name. In addition, a manufacturer may have a distribution agreement with other companies to sell the product under their name. This also applies to the API. The case-by-case approach would not be preferred as it opens variability in the process therefore lack of standards. Thus our preferred option would be to use the SKU number combined with the manufacturer number as identification of the product.

Consultation item 12: We agree with approach that all prescription drugs should be listed on the "black list". In regards to OTC products it would be preferable that they are not identified with a unique identifier as it might create a major issue for data transmission and substantially slow down response time when a product is scanned at point of sale due to high volume of OTC products on the market.

Consultation item 13: When the expiry date of a product is reached and there are still products that remain unsold, they should be decommissioned in the central data base and moved into a static database for reference purposes. Doing so will minimize further introduction of duplicate number or a counterfeit drug in the market.

Also, the use of multimarket packs should be considered, for example when deciding if the technical specifications will be harmonized (e.g. consultation item 1) and what information will be included in a bar code (e.g. consultation item 3).

Sincerely,

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