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Baxter

European Commission
Unit SANCO D/3, Medicinal Products
BREY 10/114
Falsified medicines consultation
sanco-pharmaceuticals@ec.europa.eu
B-1049 Brussels
Belgium

25 April 2012

Dear Madam, Sir,

Baxter comments to the **"DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION"**

Baxter welcomes the opportunity to comment on the Commission's concept paper. In line with EFPIA and the joint submission with EAEPC, GIRP and PGEU, Baxter is supportive of the move towards the use of 2D Data Matrix Barcoding conform to the internationally recognised GS1 standards. As a diversified healthcare provider with a range of products and services, Baxter also supports the risk-based approach included within Directive 2011/62/EU as regards the application of safety features including unique identifiers.

This contribution to the consultation raises some issues regarding the specific characteristics of certain product groups within our diversified portfolio (e.g. intravenous solutions). For the majority of comments we refer to the EFPIA submission and the joint submission with EAEPC, GIRP and PGEU including more detailed positions and supporting evidence on all the points of the consultation.

As a diversified healthcare provider with a range of products and services, Baxter supports the risk-based approach included within Directive 2011/62/EU as regards the application of safety features including unique identifiers evaluating the actual risk for counterfeiting, reimbursement fraud and patient safety.
As a company we are already implementing such a risk-based approach for our diversified portfolio and e.g. have already safety features including unique identifiers in place for our high-risk products. Regarding unit serialization we believe the labeling needs to be applied from the saleable unit level of packaging for every product group.

We also advocate a flexible approach when it comes to applying the classification criteria to identify the low-risk products. Certain well-defined product groups because of their 'specific nature of the product' as such apply for qualification on the 'white list'.

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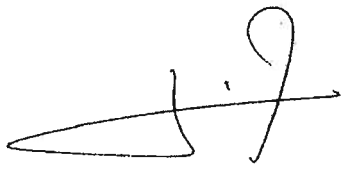
As regards the risk criteria, we believe that criteria going beyond the product as such, should be also taken into account. Hence, authorities should also look into the risks associated with the complexity of the supply chain, in order to obtain a realistic and balanced evaluation of counterfeiting risks for a certain product group. In this respect the evaluation of the complexity of the supply chain plays a role and as such the concept of a 'managed supply chain', whereby products are directly delivered from the manufacturer to the end-user (either hospital or home setting) without involvement of third parties, is an important one to consider.

Yours sincerely,



Toon Digneffe
Director Government Affairs & Public Policy - Europe
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Note

In line with EFPIA and the joint submission with EAEPC, GIRP and PGEU, Baxter is supportive of the move towards the use of 2D Data Matrix Barcoding conform to the internationally recognised GS1 standards. As a diversified healthcare provider with a range of products and services, Baxter also supports the risk-based approach included within Directive 2011/62/EU as regards the application of safety features including unique identifiers.

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A. CONSULTATION TOPIC N°1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Item 1: *Leaving the choice of the technical specification to the individual manufacturer; or harmonisation through regulation*
Baxter sees the Directive 2011/62/EU as an important opportunity to establish a harmonized coding standard all over Europe and as such we support harmonization through regulation (option 2). This policy option will ensure interoperability across EU Member States and thereby optimal security of the system. Given the movement of medicines across national borders, any effective coding and identification system must be able to exchange information between Member States. There should therefore be a harmonised standard coding system across the EU.

Item 2: *Manufacturer product code and pack number*
Baxter is supportive of the use of harmonized and internationally recognized standards for the identification of products encoded with a product code, serial number, batch number and expiry date. In order to ensure that the coding system facilitates other functionalities such as reimbursement, the EU harmonised standards should allow for the incorporation of relevant national codes (included in the product code).

Item 3: *Additional product information (batch number and expiry date)*
Baxter supports including batch number and expiry date in the pack data. Using mass serialisation provides benefits over and above improved counterfeiting prevention. Maximising these should help to encourage widespread use of identification systems and assist all stakeholders. It will also help to future-proof the system thus limiting the need for potentially costly future upgrades.
Healthcare providers such as hospitals can use the data in the 2D data matrix during administration of products to help prevent medical errors and administer short dated products.

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Item 4: *National reimbursement number*
Option 1 replacing the national reimbursement number with the serialization number is preferable, however; where needed, option 2 should be used (so-called "5th element" including the national reimbursement number in the serialization number).

Item 5: *Comments on the three concepts (linear bar code, 2D matrix and RFID)*
Baxter supports a **2D-barcode**, to hold the information relating to each single pack (article number, batch code, expiry date, a unique randomised serial number and, where necessary, the national identification number.
Sufficient transition time for implementation should be envisaged.

B. CONSULTATION TOPIC N°2: MODALITIES FOR VERIFYING THE SAFETY FEATURES

Item 6: *Systematic check-out of the serialisation number at the dispensing point*
To verify the safety features Baxter support a stakeholder-governed system with tight controls on entry and exit points. For security reasons, access to the system should be strictly limited on a needs only basis to those stakeholders who physically handle products in the supply chain.

Item 7: *With additional random or systematic verifications at the level of wholesale distributors*
Policy option 2/2 is preferable, i.e. systematic check-out of the serialization number at the dispensing point with additional random verifications at the level of wholesale distributors.

C. CONSULTATION TOPIC N°3: PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

Item 8: *Stakeholder, EU or national governance*
Baxter supports policy option 3/1 **'stakeholder governance'**?

With regard to the two other options put forth in the EC concept paper, i.e. EU and national governance, Baxter believes that;
EU governance:

- A system run solely by one body, outside the pharmaceutical supply chain, will not be able to integrate and rely on the necessary expertise from key supply chain actors;
- A system in which all interactions are taking place against a core system with no links to any national / regional systems will not be able to ensure the necessary interoperability guaranteeing patient safety.
- One system covering the whole of the EU could form a single point of failure since it would lack the resilience offered by a decentralized system.

National governance:
A national governed system is sub-optimal from two key perspectives:

1) Patient safety – the system clearly impedes harmonization and thereby interoperability, alpha & omega of patient safety;
2) Cost-effectiveness – omitting adaptation to the stakeholders who will be using it, the system is highly burdensome and expensive to run as the interconnection of systems obliges the MAH to be connected to a multitude of national repositories.

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3) Unless national systems are based on a single template, development costs are likely to be much higher than for a set of interconnected systems based around a single set of standards.

Item 9: *Information of a commercially sensitive nature*
Supply chain security cannot be effectively managed without access to data in certain circumstances. In order to maximise patient safety benefits, it is important to ensure that the effectiveness of the system is not compromised by undue restrictions on access to data. The system will not generate any personal data.

Item 10: *Protection of personal data and Re-packaging of medicinal products*
All stakeholders having access to the system will own the product verification data they generate in interacting with the system.
Baxter recognises the sensitive nature of this type of information and propose a system that is highly secured and that permits access to data under strict and defined conditions.

D. CONSULTATION TOPIC N°4: LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES

Item 11: *Identification criteria for listing on white /black lists*
As a diversified healthcare provider with a range of products and services, Baxter supports the risk-based approach included within Directive 2011/62/EU as regards the application of safety features including unique identifiers.
We believe a risk-based approach is needed regarding the implementation of safety features including unique identifiers evaluating the actual risk for counterfeiting, reimbursement fraud and patient safety.
Regarding unit serialization the labeling needs to be applied from the saleable unit level of packaging for every product group.
As a company we are already implementing such a risk-based approach for our diversified portfolio and e.g. have already safety features including unique identifiers in place for our high-risk products.

Item 12: *Applying the classification criteria*
Baxter advocates a flexible approach when it comes to applying the classification criteria to identify the low-risk products.
Certain well-defined product groups because of their 'specific nature of the product' as such apply for qualification on the "white list". One example is the product group of intravenous solutions, which is already included in existing legislation under the term 'Solutions'. Below you will find a more detailed definition of this product group as per existing legislation:

According to the US e-pedigree Bill N° 1307 "solutions" are exempted and means any of the following:
(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

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(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.
(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.
Going beyond the classification criteria listed below, these products are also subject to a 'managed supply chain' (i.e. direct delivery from the manufacturer to the end-user without involvement of third parties).

The *price of the medicinal product*: It is assumed that medicinal products at a very low price are, for economic reasons, less at risk of being falsified.
Regarding price, in view of the risk of channeling falsified medicines into the legal supply chain at wholesale distributor level, the gross manufacturer price (i.e. the price to be paid by wholesale distributors) would have to be considered.

Moreover, 'high price' being a relative term, it would need to be established against the costs for falsifying a medicinal product. These costs are typically very low. Therefore, a manufacturer's gross price of more than 2 EUR could be considered as a 'high price'. **(High price 5 Points, low price 1 Point)**

The sales volume of the medicinal product: It is assumed that medicinal products placed on the market in very low volumes are, for economic reasons, less at risk of being falsified. 'Sales volume' being a relative term, it would need to be established against the typical sales volume of medicinal products *per annum* in the EU. **(High volume 5 Points, low volume 1 Point).**

- ***Comment***: Sales volume is not the only criterion to be considered, but also the actual physical volume of the product (e.g. 'Solutions' of 1 liter and more render these products unattractive to counterfeiting given e.g. cost of distribution).

The number and frequency of previous incidents of falsified medicines reported in the Union and in third countries: The number of incidents of falsified medicines detected within the EU, at its borders or in third countries, may be an indicator that a product or a category of product entails a higher risk of falsification. Regarding product categories, point 1 may apply. **(Several incidents 5 Points, no incident 1 point)**

The specific characteristic of the product: Medicinal products may have specific characteristics which make the risk of falsification unlikely: One example might be products that are delivered direct from the manufacturer to hospital pharmacies **(Risk of falsification 5 Points, no risk 1 Point).**

- ***Comment***: The example of 'products that are delivered direct from the manufacturer to hospital pharmacies' or to patients at home concurs with the definition of 'managed supply chain' given above.

The seriousness of the conditions intended to be treated: Falsified medicines usually do not have the same efficacy as the original product: For example, the active substance may not be contained in the falsified medicine, or it may be contained in a higher or lower dosage

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than the original. Therefore, falsification of these products may have very serious consequences for patients, who will not receive the correct treatment. Examples may include oncology medicines and medicines for cardiovascular diseases. **(Conditions severe 5 Points, not severe 1 point)**

Other potential risks to public health: Other criteria may be identified in the future for consideration in the assessment. **(Max 5 points)**

In conclusion, Baxter advocates a flexible approach when it comes to applying the classification criteria to identify the low-risk products. Certain well-defined product groups because of their 'specific nature of the product' as such apply for qualification on the 'white list'.

Secondly, instead of solely focusing on product risks, authorities should also look into the risks associated with the complexity of the supply chain, in order to obtain a realistic and balanced evaluation of counterfeiting risks for a certain product group. In this respect the evaluation of the complexity of the supply chain plays a role and as such the concept of a '**managed supply chain**', whereby products are directly delivered from the manufacturer to the end-user (either home or hospital setting) without involvement of third parties, is an important one to consider.

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Annex: About Baxter.

Baxter is a global diversified healthcare company that develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions.

As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

The company operates in two segments: *BioScience and Medical Products.* *BioScience* manufactures recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders; plasma-based therapies to treat immune deficiencies, alpha 1-antitrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions; products for regenerative medicine, such as biosurgery products; and vaccines.

Baxter's Medical Products business manufactures products used in the delivery of fluids and drugs to patients. These include intravenous (IV) solutions and administration sets, premixed drugs and drug-reconstitution systems, IV nutrition products, infusion pumps and inhalation anesthetics. The business also provides products and services related to pharmacy compounding, drug formulation and packaging technologies. In addition, Baxter's Medical Products business is a leader in Renal home-based therapies, such as peritoneal dialysis, and offers other products and services for people with end-stage kidney disease.

Global diversified healthcare company

Baxter is truly an international company with a strong global brand and broad geographic reach.

- Approximately 48,500 employees and 250 facilities worldwide.
- Products are sold in more than 100 countries and manufacturing presence in 27 countries.
- In Europe Baxter has within its EMEA (Europe, Middle East and Africa) region over 15,000 employees operating in more than 35 markets. As a region, it represents more than one-third of Baxter's global turnover and manufactures products that are distributed in all our markets around the world. Baxter EMEA counts 22 manufacturing plants (UK, Ireland, Belgium, Germany, Switzerland, Austria, Italy, Spain, Malta, Tunisia, Poland, Czech Republic, Turkey, Saudi Arabia) and 3 major research centres located one in Belgium and two in Austria.

Diversified portfolio and expertise

Baxter is a different kind of healthcare company. Our diversified healthcare model furthers our ability to innovate.

- We specialize in biotechnology, medical devices and pharmaceutical products and therapies.
- We leverage our diverse technology platforms across our organization to address unmet medical needs and to expand options for physicians and patients (e.g., medical plastics, isolation technology, regenerative technology, PD solutions).

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- Our core technical competencies include drug delivery, hardware and software, medical plastics, protein development and manufacturing, separation and purification, and sterilization.

Innovation is the driving force behind Baxter's successes

Our heritage has been built on more than 80 years of innovation in healthcare, including a long history of firsts.

- First manufactured intravenous solutions.
- First commercial kidney dialysis system.
- First factor VIII concentrate to treat hemophilia.
- And many other medical breakthroughs.
- More recent firsts include the first recombinant factor VIII processed with no blood-based additives and the first cell culture-derived pandemic influenza vaccine.

In 2011 Baxter invested in R&D $946 million.

Throughout 2011, Baxter introduced a number of new products, expanded indications of existing products and advanced approximately 20 key R&D programs in late-stage clinical development, many of which have the potential to profoundly improve the treatment and delivery of care for chronic diseases like hemophilia, immune deficiencies, Alzheimer's disease and end-stage kidney disease.

Sustainability is integral to our business

Part of being a great company is being a responsible corporate citizen.
Baxter gives back to the communities it serves through environmental stewardship, employee volunteerism, corporate giving and other initiatives. Baxter has been recognized for its commitment to sustainability, the company's long-term strategic approach to including social, economic and environmental considerations and opportunities to achieve its business objectives and contribute to a more sustainable world.