EU Consultation Process Document

A response to
Consultation in Preparation of a legal proposal to combat counterfeit medicines for human use – Key ideas for better protection of patients against the risk of counterfeit medicines.

By First Ondemand Ltd
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In response the European Commissions' request for contributions we would like to address a number of specific areas/topics contained within that document.

It is not our intention to provide a highly detailed response to all sections but one that addresses and comments on a number of key issues and topics in our area of interest and technical expertise.

Firstly, if only to put the consultation into context, patient safety must be the overriding principle from which to judge and test any proposals and form any basis upon which to amend the regulatory framework for medicinal products in an effort to combat the counterfeiting of medicinal products.

However, it is generally accepted that in a 'real world' scenario many factors may actually influence an outcome – some of which may be well meaning, but cause unintentional consequences, positive and negative. It is clear the Commission will take great care in its remit.

The pharmaceutical manufacturing sector and its supply & distribution chains are complex and constantly evolve to meet new demands from a variety of stakeholders, be that physician led, advances in treatments such as those delivered by biotech, or in response to global market influences such as state regulation and new technologies. All of which our legislature has limited influence upon.

Therefore it is essential that any proposals must not be considered in isolation. Counterfeiting is a global problem whether it is on our door step or on the other side of the world, and the differentiation between the two is increasingly narrowing in a rapidly growing multinational manufacturing base and global supply chain.

As stated there is clear evidence that Member States are starting to consider taking unilateral action to address the problem of counterfeit medicines (amongst other products) so there is little time to waste in terms of proposing some coherent strategy that might be applied across the EU.

It can also be anticipated that Member States will, in many cases, wish to implement a anti-counterfeiting strategy that aligns with other remits such as combating reimbursement fraud in healthcare provision.

Thus we would propose that any strategy provides a 'framework' around which the core aims can be met and that also allows for additional functionality and business process to be developed. Or to look at it another way, a strategy that does not impede development and innovation.

A fundamental question should be asked – how is it that we are able to consider introducing new regulations to help prevent anti-counterfeiting? The answer at its most basic is that technology and a robust communications infrastructure has provided a catalyst and the tools that enable new solutions to be used. Against that fact, it becomes clear that many aspects being considered are highly dependant on that technology. This, by definition, introduces risk – as many states have found to their cost, with spiralling budgets attached to strategic IT projects not to mention flexible completion dates.

That said, many of the technologies are well proven and we should be confident that they will perform appropriately. What this highlights is that while some elements must inevitably be dependent on leveraging such technology, it vital to frame any legislative requirements against an environment where business process and flow are key drivers – influencing or being influenced by technology solutions.

Against that background, we believe that 'Standards' are mission critical to the success of EU proposals. Indeed that applies to the global arena too.

To that end, we support GS1s approach which recognises the necessity to develop core standards' requirements needed to provide truly interoperable solutions in the pharmaceutical sector. Focusing on two distinct aspects that are seen as critical to securing the pharmaceutical supply chain 1) EPCglobal Drug Pedigree Messaging Standard. 2) EPCIS Standards.

Despite having a US flavour in their original terms of reference these now ratified standards have been developed intentionally to meet a global remit.

They recognise that clear specifications and protocols for securing, recording and communicating 'event/transaction' data must be in place and in this provides the core framework upon which genuine solution interoperability can be delivered.

In the US (and more widely) there is a consultation process with the GS1 Healthcare US Pedigree / EPCIS Assessment Task Force Authorities regarding the appropriate approach for combining the Drug Pedigree Messaging Standard with the Electronic Product Code Information Services (EPCIS). The purpose being to enable a pharmaceutical track & trace system architecture that can meet both the demands of regulatory compliance and the sharing of serialisation data throughout the supply chain. Part of that debate is about the merits of whether pedigree data should be directly embedded into EPCIS event record/reporting structure, rather than just proving linkage between the two distinct pieces (each having been purposely designed to fulfil a particular role and requirement). EPCIS based applications can then be used to locate and share pedigree data with relevant authorised parties in the supply chain.

In our opinion the later is more desirable for a number of reasons – it recognises that EPCIS is the appropriate format and mechanism from which to deliver serial number visibility and, as such, can also be regarded as a logical interface from which to gain access to pedigree data. Although, by definition, the two systems are closely linked, by keeping them independent it also allows for a much more flexible approach to implementing solutions. This is critical since the pharma compliance environment is disparate even in the US where Federal and State law have varying requirements for Pedigree and serialisation combinations.

We believe that the Europe Community has the advantage of the US learning experience and has already taken this onboard. But it is important to stress that there is still active debate in progress – much of it on a global level but with particular focus on those countries where current or pending regulation has created compliance deadlines.

The World Health Organisation WHO IMPACT group and their various committees have been major players in this and have given the debate a sense urgency and purpose by bringing together experts and stakeholders from around the globe.

In essence the key is to put in place a compliance framework without compromising some of the fundamental functionality that each distinct solution focuses on. As such they are core building blocks on which to base any approach – each is clearly identifiable, manageable and interoperable. Crucially these 'blocks' gives scope for solution vendors and pharmaceutical companies to work together to create 'best of breed' solutions with the reassurance that the compliance framework is being adhered too.

In Europe, EFPIA have been working on proposals towards safer medicine supply and their 'A vision for the coding and identification of pharmaceutical products in Europe' Business Case document Version 4.0 January 2008 creates a benchmark against which the Commission should refer too in its deliberations. EFPIA has said that it will submit a detailed response to this public consultation.

There are very many points raised in the EFPIA document which deserve support and consideration. However it is the holistic and realistic approach to the problem that is of key significance. Primarily their proposal is based on delivering enhanced product packaging security through coding and verification – a vision that seeks to deliver an end-to-end (Manufacturer to Pharmacy point of dispensing) solution.

At the heart of this is the need to have an agreed European standards-based codification approach. In the proposal this takes an EPC type approach utilizing a GS1 GTIN or Pseudo GTIN in the product code structure. The content of the code GTIN, Serial Number, Expiry Date and Batch Code provides for totally unique product identification. The batch and expiry data allows for product recall and other alerts.

At this stage it is important to highlight Electronic Product Code (EPC) should no longer be regarded as synonymous with RFID tag only data. A true pervasive computing approach is in essence 'data carrier agnostic' so that any suitable carrier can be considered whether RFID, Data Matrix or other barcode. In the EFPIA proposal the Data Matrix is put forward as carrier of choice.

The key to the system is the secure codification by the manufacturer of the packaged product and the verification process that follows. It becomes obvious that although the EFPIA proposed system is not initially intended to support Track & Trace capabilities it does indeed enhance and facilitate this at the relevant phase.
It is also becomes clear that, in building up Pedigree data and Track & Trace records, that there is a natural and persuasive synergy to be achieved – where the data exchange and code database networks come into play.

It is not a giant leap to see that EFPIA's approach, combined with ePedigree and serialisation in US terms, plus EPC Information Services (EPCIS) based-solutions provide the basis for the coherent framework we have been looking for.

Of course, this should not ignore other elements which are critical to the long term success of an anti-counterfeit and patient safety strategy. There are a variety of other anti-counterfeiting technologies covert or overt, many at packaging level such as special inks and nano particles or holograms, tamper evident seals etc. All still have a role to play.

But fundamentally the solutions that the framework should be built on rely on digital information technologies linked to: business process, making product visible and the applications and data intelligence that helps makes sense of it all.

Aligned to this is the security of these systems such as the databases and the communications networks, and the other vendor technologies. These enable the creation and management of crucial elements such as the serial numbers and the generation of non-repudiable records at every stage from manufactures through to distribution and supply chain.

There is room for many vendors to provide solutions at each level. However standards, and compliance to those standards, at vendor level is as important as the standards that are applied at a regulatory level.

Finally, it is all very well putting in place compliance and regulatory strategies to secure the safe manufacture and supply of medicines but it is the loop holes through which anti-counterfeiters and criminals can exploit weaknesses that present the biggest challenge.

As fast as we design sophisticated solutions to enhance security so too do they and their resources should not be underestimated such is the profit to be made versus the risk. All the more reason why a strategy has to be robust but also allow for evolution.

The risk for profiteers and anti-counterfeiters must be increased - it is patently ridiculous where a drug dealer can get 25 years for supplying cocaine but face only a minimal sentence or even a fine for manufacturing and distributing counterfeit medicines.

Thus it is not only about securing manufacturing and the legitimate supply chain but addressing the illegitimate supply chain. The definition between the two is not as clear as many think and the public are generally unaware of the risks this presents as internet medicine sales increase. This involves considering changes to trading regimes, better customs and border control and the difficult issue of re-packaging which could invalidate some of the most promising solutions.

In conclusion, we support the work done by GS1, EPCglobal, WHO IMPACT and EFPIA and they should be commended for having have laid much of the groundwork for this and initiated wide debate amongst stakeholders. In our view any regulatory framework should seek to take advantage of ePedigree and serialisation based solution approaches and the auditability that are integral to them.

In addition, solutions that enable verification and authentication, whether in the secure supply chain as part of track & trace or direct authentication at point of dispensing, are highly desirable and bring a range of benefits. Product unique identification and chain of custody & ownership when combined with data intelligence brings the visibility needed to show which products are genuine and which are not - with this comes the ability to root out counterfeit goods.

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