Dear Sir/Madam

I would like to take the opportunity to thank you for the opportunity to comment on the "Delegated Act On The Detailed Rules For A Unique Identifier For Medicinal Products For Human Use, And Its Verification" – "Concept Paper Submitted For Public Consultation" (Sanco.ddg1.d.3(2011)1342823).

Solgar UK Ltd is the Holder of a number of Traditional Herbal Remedy approvals in the UK and has submitted a number of others.

Note that the responses are my personal views and do not necessarily reflect those of Solgar UK Ltd.

Consultation Point 1
I would suggest that Policy Option 2, would be more beneficial due to a smoother implementation especially for SME.

Consultation Point 2
No comment

Consultation Point 3
I would have to question whether pharmacists and/or retailers, other than large multi-shop groupings, would take advantage of having expiry dates on individual packs, especially if not all products would have this coding.

Consultation Point 4
No comment

Consultation Point 5
No comment, however I have also addressed this in my response to Consultation Point 12

Consultation Point 6
Dispensing doctors, ships captains, military bases.
I would presume that medicines used by paramedics and the such like would be checked when collected or issued.

Consultation Point 7
I would suggest that in order to achieve the aim of the directive, it would be important to ensure that the products are checked at each stage of the process. However, I would also say that for premises with GDP or equivalent practices it would only be necessary to check at receipt. This would ensure that each incoming package is genuine, while minimising any disruption due to the need to check a small number of items from a large number of different outgoing shipments.

Consultation Point 8
Any decision on this needs to take into consideration the results from Consultation Points 1 and 2. However, the ability for third parties to re-packing product with these features (see 4.3 of document) would suggest that a Pan European system would be more applicable.

Consultation Point 9

No comment

Consultation Point 10
I would expect that any company engaged in repackaging would be required to “check out” the original serialisation number(s).

Consultation Point 11
I believe that it is important to consider products on a case by case basis, with any listing based on the ingredient, pharmaceutical presentation and indication. This would allow some company flexibility in branding, while ensuring that any latter generic products would be covered by the same criteria, whilst concurrently ensuring that less enticing ingredients/presentations are not subject to onerous checking.

Consultation Point 12
I am extremely concerned at the proposed target and scheme.

Based on the proposed scheme it would be very easy to classify Traditional Herbal Medicinal Products as being included in the scope of the requirements. Consider:

Criteria	Rating	Notes
1 Price	5	A simple clear capsule containing a powder – cheap and simple to copy
1 Volume	3	Partly as unknown
2	2	As not known
3	3	As product is sold as a GSL, so not always under Health Care Professionals control
4	1	
5	0	
TOTAL	14	

Even if Criteria 1 Volume, and Criteria 2 are set to the minimum value of 1, then a Total score would be 11 which would result in a non-prescription range of products being considered within the scope.

I would therefore maintain that either the proposed value for a non-prescription product to be considered under the scope is too low, or that the Rating values suggested are too high

Consultation Point 13
I am pleased that the issue of falsification of Medicinal Products has been positively and actively approached. However, I am concerned that the result may be a set of requirements that are not only overly onerous to the majority of stakeholders, but would result in a system that could be more easily bypassed as people come to trust “the system” rather than consider the origin of the product.

It is also important to consider that General Sales List (GSL) items may be sold at locations which would not be in a position to invest in any required hardware or connection to the registry. This could result in the falsification of GSL products becoming more attractive to criminals and concurrently result in a situation whereby it is harder to trace or recall a product in cases of public safety.

Once again I thank you for the opportunity to comment on this document.

David

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