Consultation: Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal products for Human Use, and its Verification

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Comment from ABDA (Federal Union of German Associations of Pharmacists)

The ABDA – Bundesvereinigung Deutscher Apothekerverbände (Federal Union of German Associations of Pharmacists) is the umbrella organisation of all German pharmacists and perceives and promotes the common interests of this free health profession, representing the Chambers of Pharmacists and the Pharmacists' Associations. On European level, the ABDA is a member of the Pharmaceutical Group of the European Union (PGEU). The ABDA's European Transparency Register ID is 04294287173-30.

The ABDA endorses the positions of its fellow stakeholder associations, namely securPharm (the German stakeholder association for medicines' authentication), PGEU, and the common answer of the European stakeholders EAEPC, EFPIA, GIRP and PGEU. These comments by ABDA should be read as supportive and complementary to this common approach, written from the special perspective of the German pharmacists.

Note: As well as EAEPC, EFPIA, GIRP and PGEU, the ABDA would like to draw the attention of the European Commission to a lack of clarity in the terminology used in the Concept Paper. When referring to a "serialisation number" it is often the "pack code" as a whole (i.e. product code, serial number, batch number and expiry date) which is being referred to in the Concept Paper. For consistency, the stakeholders use the term "pack code" for these four data elements (instead of 'serialisation number'), and for technical accuracy we would stress that the "unique identifier" feature referenced in the Falsified Medicines Directive (FMD) and envisaged in this submission would equate with a "serialised product code" (i.e. serial number + product code).

Consultation item n°1: Please comment on points 1 and 2 (policy options n°1/1 and n°1/2). Where do you see the benefits and disadvantages of each policy option?

Option no. 1/2 (harmonisation through regulation) is preferred. However, in accordance to the European principle of subsidiarity, this should only take place to the required extent. Furthermore, operators as well as the national systems themselves should be granted as much flexibility as possible to enable the most appropriate implementation of medicines' authentication in all Member States. Especially, ISO standards should be used for the standardisation of pack code, product code and carrier. The existing identification systems (IFA, GS1) must comply with those standards in a way that different codes like e. g. the IFA code (PPN), the GS1 code (GTIN, NTIN) or others can be used interoperably.[1] The ABDA calls on the European Commission not to establish a system based on non-open standards of certain providers, as this would lead to an economically inappropriate monopoly.

Option no. 1/1 is rejected by ABDA, as the system as a whole would be too complex and expensive if every manufacturer could perform his own technical solution. This might even lead to a fragmentation of the European market, because interoperability could not be ensured.

Consultation item n°2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.? Please comment.

Consultation item n°3: Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2? Please comment.

Consultation item n°4: Which of the two options set out under point (c) of point 2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment.

It is highly recommended to generalise the term "manufacturer product code" to "product code" to preclude an ex-ante assumption of the GS1 code as a solely mandatory standard (the term "manufacturer product code" is usually related to GS1). Furthermore, only the product code is the identifying feature of a product, which should be distinguished more clearly. In association with the serial number, the serialised product code (product code + serial number) is generated, with which an individual pack can be identified. Batch number and expiry date are not necessary for identification, but add value to patient safety (e. g. in cases of recalls, expired medicines …) and for pharmacies (easier warehouse management).

[1] Example for IFA/PPN: The code specification follows ISO/IEC 16022; to identify the PPN in the Data Matrix Code an explicit data designator following ANSI MH10.8.2 referring to ISO/IEC 15418 is used.

Using international standards is crucial for interoperability. However, these standards must be usable license free. Under this principle, for example the GS1 standard cannot be foreseen as the exclusive coding standard in Europe (though manufacturers may choose this standard, which can be available besides other standards, e.g. IFA/PPN in Germany). As already mentioned in item 1, certain requirements of the European Commission concerning the serialised product code are appropriate (e. g. regarding length or randomness of the serial number). Beyond that, flexibility should be granted to allow the implementation of national characteristics or pharmaceutical demands (like the use of the national reimbursement/identification number PZN in Germany). Linking the different national systems, the European Hub[2] must be designed in a way that allows the usage of all currently known coding methods in Europe, especially GS1 (GTIN/NTIN) and IFA (PPN).

To provide a higher safety of medicines, batch number as well as expiry date should be printed on the pack. But again it has to be stated that only product code and serial number are the identifying features of a pack which should be used obligatorily for verification, while batch number and expiry date are not necessarily required for this purpose.

Anyway, if no connection to the audit database can be established, expiry date (towards system time) and batch number (towards publicly reported recalls) can still be checked by the pharmacy-internal system. Thus, already existing recall systems are maintained.

Based on German legal provisions, the only product number for pharmaceuticals is the Central Pharma Number (Pharmazentralnummer - PZN) which is allocated based on central registration by IFA (Informationsstelle für Arzneispezialitäten). The PZN serves for all logistic practices and is embedded into all IT systems and business processes. The allocation rules, which must be demand-orientated and influenceable by market stakeholders, follow the specific characteristics of pharmaceuticals. This means, if e.g. the composition of a medicine changes, it gets a new PZN. In addition, the German reimbursement system requires the use of the PZN by law. Therefore, replacing the PZN as pointed out in option 1 would require the abolition and re-construction of the whole German reimbursement system. The so-caused impacts would be drastic, require a high use of resources – of all stakeholders, but especially the public Health System – and need significantly more time than an alternative option.

A parallel existence of two product identifications as pointed out in option no. 2 would mean increased complexity and risks associated with the ambiguous declaration of pharmaceuticals. The existence of two parallel product identities (new manufacturer product code and existing national product and reimbursement numbers) in the market would mean:

- potential source of error due to use of the wrong primary key,
- two product identifiers that follow different allocation rules,
- additional costs of maintaining two product identifiers,

[2] The European Hub is a system element described in the common paper by EAEPC, EFPIA, GIRP and PGEU.

- additional costs due to possible double license fees for the product codes,
- potentially additional costs due to higher volume of data (increased code size),
- potential error through inaccurate timing of synchronization during the update of the product code.

The ABDA supports the use of harmonised and internationally recognised ISO standards for the identification of products. But instead of being replaced by a new manufacturer product number, existing national product numbers should be made globally unique and thereby become applicable across Europe.

Several ways exist by which national product numbers can be made globally unique. The IFA, serving as an ISO-certified issuing agency as well, has already transformed the German PZN into the globally unique PPN (pharmacy product number). The PPN in combination with a unique identification number of the pack will be perfectly able to meet the verification requirements set out by the Commission.

In conformity with the third option, being proposed in the statements of securPharm and EAEPC/EFPIA/GIRP/PGEU, the following option would be preferable for Germany:

Mandatory information (to identify a pack; jointly the „serialised product code“)		*Additional information * (not essential to identify a pack)*	
product code (contains the *national reimbursement number* / PZN) **	***serial number* (pack number)**	**Expiry date**	**Batch number**
XXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX
The four elements together form the ISO standardised „pack code“ that is printed on the pack.			

* In this context, “additional” means that indeed this information is not necessary to identify a pack, as the serialized product code meets the requirements. But in any case, expiry date and batch number ought to be printed on the pack.

** This globally unique product code contains the national product number as well as the national reimbursement number, provided it exists in the affected country.

The implementation of the above-mentioned pattern is possible via PPN (pharmacy product number) as well as via NTIN (national trade item number). In both options, the national reimbursement number is embedded into the product code. On the other hand, the use of a GTIN would require the implementation of a fifth element which the ABDA rejects for the German market, considered being too complicating. The parallel use of two mutually-independent identification numbers (PPN and GTIN) in one pack code provides an excessive risk of confusion, while parallel usage of PPN and NTIN is unproblematic. An adaptation in other national systems may lead to the choice of another pattern (e. g. via a national reimbursement number as an additional optional information feature) if circumstances so require. In summary, the member states should be granted sufficient flexibility. The only important

arrangement that must be made are interoperable interfaces for data exchange, which GS1 (GTIN/NTIN) and IFA (PPN) can comply with.

Consultation item n°5: Please comment on the three concepts described under point 2.2. Where do you see the benefits and disadvantages of each of the three concepts? What are the costs for each concept? Please quantify your reply, wherever possible, by listing for example:

- costs for reading devices for the different carriers;

- costs for adapting packaging lines of medicines packaged for the EU market.

Considering technical standards the ABDA clearly prefers concept no. 2 (2D DataMatrix code). A lot of information can be machine-readable lodged in a relatively small space (see item 4). The concept of the 2D barcode is technically thoroughly proven and many vendors for printing as well as reading devices are present in market. Even if a determination on one certain standard takes place, the plurality of suppliers is warranted and no risk of monopolisation or oligopolisation emerges.

Concept no. 1 is rejected due to reasons of space. Regarding the capacity of information, a 1D barcode is depending on the available room. As medicine packs normally afford only a limited free zone for the pack code, a linear barcode is ineligible.

Concept no. 3 is as well rejected by the ABDA. Presently, RFID is relatively untested. Moreover, no long-term studies concerning effects of radio waves on the efficacy of pharmaceuticals exist. Therefore, RFID is ruled out regarding a higher drug safety. Furthermore, estimations indicate that the costs would probably be significantly higher.

The determination of a pan-European compulsory carrier format is important to ensure compliance between the member states and to limit necessary investments of pharmacies and manufacturers to a minimum.

As the concept of the linear barcode disappears due to practical reasons and RFID is expensive and possibly unsafe, retrofitting costs incurred by concept no. 2 are considered appropriate, particularly in view of the fact that pharmacies as well as producers have to retrofit their printers and readers anyway after considerable time (e. g. due to old or broken devices or technical innovation).

Consultation item n°6: Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered? How can these be addressed in this policy option?

Pharmaceutical packs are not only dispensed in pharmacies, but also – for example – in hospitals. In this context, packs likewise will have to be checked there. Attention should be paid to international differences in the right to dispense (e.g. in some countries doctors may dispense medicines under certain circumstances), which cannot be harmonised at European level. National regulations regarding the authentication of medicines at the point of dispense and ensuring drug safety will suffice.

Consultation item n°7: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible. This applies in particular to the:

- **number of wholesale distribution plants;**
- **costs for adapting such plants;**
- **duration of scanning of the serialization number**
- **number of pharmacies, including hospital pharmacies;**
- **number of medicinal products dispensed by pharmacies and a hospital pharmacy.**

In respect of the expressions in the consultation papers' footnote no. 20 and marginal no. 46 – which both preclude wholesalers to mandatorily check the pack code – it has to be mentioned that the directive itself does not compellingly profess this exclusion. Rightly, even wholesalers should be involved into the obligation to check, but in reduced circumference. Checking packs on returns of pharmaceuticals shall be compulsory, while verifying the authenticity can be omitted on direct purchase from the manufacturer. Above, randomized checks on wholesalers' level add value to drug safety through a comparatively minor use of resources.

Option 2/2 is preferred. To realize the end-to-end concept within EU, an authentication at the point of dispense suffices. Though every stakeholder of the legal distribution chain should have the – optional – possibility to prove the genuineness of a drug.

Option 2/3 is rejected by ABDA. The establishment of a full track-and-trace system with systematic verification by wholesalers would be extremely complex and costly, while bringing no added value compared to an end-to-end system.

Consultation item n°8: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, wherever possible. This applies in particular

to the estimated one-off costs and running costs for a repositories system. Where possible, please provide information on past experiences with a repositories system at individual company level and at national level (taking into account the experiences of Member States and companies).

Option no. 1 is preferable. Since the – simultaneously directing – market participants bear the costs, cost effectiveness is ensured. Besides, the daily involvement of the stakeholders into the process of drug distribution grants much expert knowledge. An interoperable EU-wide system guarantees drug safety on European as well as on national and regional level.

A system of a European Hub connecting different national systems is desirable. As long as an interface for the Europe-wide System is provided, the choice between option no. 3/1 and 3/3 can be made quite flexibly on national level.

Consultation item n°9: Please comment on point 4.1. Are there other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act?

In Germany, this task is solved within the frame of the stakeholder securPharm project that follows the concept of data ownership. Every stakeholder remains the owner of his own data. The physical separation of the national repository by use of two servers (pharmaceutical industry server and pharmacies server) warrants maximum data protection, especially because a superior authority (securPharm) checks suspected cases and at no time any stakeholder involuntarily forfeits sensitive information to another stakeholder. Anonymising the authentication queries of the pharmacies provides data protection even beyond the abovementioned facts. We call on the Commission to shape the Delegated Acts to allow for the establishment of this particular model in Germany (national flexibility).

Consultation item n°10: Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?

The proposed system of drug authentication works without any patient data, therefore a maximum of data protection is granted. In the case of a suspicion of falsifying of medicines the pharmacy and its

staff shall inform the potentially affected patients. Storing patient data in the verification system would contain a tremendous risk of abuse and is thus strictly rejected by ABDA.

Replacing serial numbers while re-packaging is a very sensitive process. The EU stakeholder model provides that re-packagers have to sign out the original numbers from the database, assign own new numbers to the re-packed medicines and link those two numbers on batch level in the database. Hereby it is ensured that in the case of recalls or suspicion of falsifying the affected pharmaceuticals can be identified without disproportional effort.

Consultation item n°11: Which approach seems the most plausible from your view? Can you think of arguments other than those set out above? Can you think of other identification criteria to be considered?

Basically, from a practical point of view a serialisation of all drug packs is advantageous. Thus no different handlings are necessary and the process in pharmacies is standardised and simplified.

Concerning identification criteria for the white-list and black-list, the ABDA abstains.

It is important that all products affected from serialisation are known and can be deposited in the pharmacy software. Only then the pharmacy certainly “knows” which products have to be checked and which not. If the absence of the pack code alone would mean a product does not have to be serialised, falsifiers could easily utter packs without pack code.

Consultation item n°12: Please comment on the quantified approach set out above.

The ABDA abstains on this item.

Consultation item n°13: Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

The risk of faulty practice increases if more than one pack code is printed on a pack. Then, packs could possibly not be correctly identified any more. That is why only one pack code – which must also

match given criteria regarding the national reimbursement number (PZN) in Germany – may be printed on a pack.