ANF Response to the Concept paper submitted for public consultation
Delegated Acts on the detailed rules for a unique identifier for medicinal products for human use, and its verification

A. Consultation Topic nº 1: Characteristics and technical specifications of the unique identifier

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?

ANF is in favour of option number 1/2 "Harmonisation through regulation".

In our opinion a harmonized solution is fundamental to assure the feasibility, cost-effectiveness, technical efficiency and interoperability of a European system of medicines authentication.

The solution adopted must minimize the technical and economic impact in all the agents of the medicines chain.

From pharmacies point of view, if there is no harmonization of characteristics and technical specifications concerning the serialization number and "carrier":

- The complexity of the system will increase;
- The possibility of system failure will be higher (for example, failure in the recognition of the coding system at pharmacy level);
- The economic burden for pharmacies will increase since more complex and expensive solutions related to equipment (for example scanners) and software adaptation will be required.

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

In ANF opinion the technical criteria for "serialisation number" must be flexible in order to assure an easy adaption to different national circumstances. Taking this fundamental principle in account, we consider that "serialisation number" should be based on harmonized standards and specifications for coding serialization established at international level.

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.

ANF supports the inclusion of batch number and expiry date in the serialisation number, in order to increase the efficiency and applicability of the authentication system (for example, medicine recalls and inventory management) and improve patient safety.

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.

Considering the complexity and lack of transparency of the Portuguese legal framework for pricing and reimbursement of medicines, ANF strongly supports the inclusion of the national reimbursement code and medicines price in the serialisation number.

Portuguese pharmacies believe that the implementation of such a system should be viewed as an opportunity to improve other features and procedures related to the distribution, dispensing and reimbursement of medicines. The constant changes on medicines prices and complexity of rules regarding pricing and reimbursement have turned the system chaotic. Hinders patient's access to accurate information on medicines price and causes serious problems in the management of pharmacies stocks. Thus, from the Portuguese pharmacies and patients' perspective, the inclusion of the medicines price is essential to guarantee the system transparency and compliance with the dispensing and reimbursement rules.

In this regard, we refer to a petition launched by the Portuguese Patients Associations, signed by more than 20,000 citizens, currently in discussion in the Portuguese Parliament. The aim of the petitioners is to maintain the practiced retail price on the medicines package in order to improve the transparency and confidence in the medicines distribution system.

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.*

ANF supports the Datamatrix code. We believe the 2dbar code is the most cost-effective carrier to hold the information needed to securely identify a single package and take the maximum benefit out of the authentication system both in terms of quality and safety for patients and transparency and liability of the national medicines distribution and reimbursement systems. We admit that RFID technology can be a possible solution for certain medicines, particularly in the case of high price medicines with higher probability of counterfeiting.

Currently, the vast majority of Portuguese pharmacies are equipped with scanners that only read linear barcode, which implies a significant investment in the adaptation of equipment, software and procedures.

In annex 1 to this consultation response we are sending a very general economic assessment of the main costs for pharmacies. We believe that it is fundamental to conduct an exhaustive economic impact assessment at national level and European level for all the agents in the medicines distribution chain prior to the adoption of the Delegated Acts.

Portuguese pharmacies are available to contribute to the development and implementation of an authentication system at national level. However, considering the current economic scenario in Portugal and the measures established in the MoU, at this moment, any additional cost is unbearable for the Portuguese pharmacies.

Also for the other agents in the distribution chain (pharmaceutical industry and wholesalers) the situation is extremely difficult. Therefore, we believe it is crucial that the European commission takes into consideration the impact of this additional financial burden in countries under financial assistance programmes such as Portugal, Ireland and Greece.

B. Consultation Topic nº 2: Modalities for verifying the safety features

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?

Considering that the safety of patients is the main purpose of a European medicines authentication system, we strongly believe that all the entities involved in dispensing prescription medicines to patients should implement a verification system.

However, it should be noted that the Portuguese pharmacies have high standards and high quality reputation and the confidence of the Portuguese population (pharmacists are one of the professionals with higher levels of citizens' trust). Even without an authentication system, Portuguese pharmacies already have mechanisms in place to assure the safety and quality of the medicines they dispense to the public. Cases of falsified medicines entering the legal supply chain are not known in Portugal.

From the Portuguese pharmacies point of view, an authentication system is an additional tool to maximize the quality and safety of the services they provide.

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 serialisation number;

- number of pharmacies, including hospital pharmacies;

- number of medicinal products dispensed by pharmacies and a hospital pharmacy.

First of all, to assure the integrity of the verification system, ANF believes that all the agents of the medicines chain should implement an authentication system. However, we recognize that the costs and complexity for wholesalers are very significant and can compromise the regular supply of pharmacies. Thus, we support a flexible approach such as random verifications at wholesaler's level.

With respect to the Portuguese pharmacies, our main mission is to guarantee quality and safety in the access to medicines, with the aim to derive maximum benefit for patients and always in their best interest.

Thus, as we mentioned before, we are available and committed with the development and implementation of a medicines verification system in order to improve the safety of the medicines distribution chain in Portugal.

However, there are some key issues that should be addressed in the delegated acts such as:

- Economic impact of the verification system, particularly in a context of economic crisis (annex 1: cost assessment for Portuguese pharmacies)
- Impact on the current pharmacy procedures. The verification procedures should be, as far as possible, integrated in the current practices in community pharmacy. For example, additional scanning must be avoided, and the response time must be considered in order to reduce possible failures or constrains on dispensing activities.
- Pharmacies must be able to verify a medicine prior to dispensing it to the patient in order to guarantee the integrity of the pharmacy stock. For example, verification at the point of entry in the pharmacy.

C. Consultation Topic nº 3: Provisions on the establishment, management and accessibility of the repositories 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).

ANF supports the stakeholder governance model at European level based on the principles agreed by the European stakeholders PGEU/EFPIA/GIRP/EAEPC.

We believe the same model should be discussed and adopted at national level, with the necessary adaptations to the national circumstances and needs. With this objective in mind, ANF and the other Portuguese stakeholders initiated contacts in order to discuss a possible

national authentication system that improves patient safety and prevents the entry of falsified medicines in the legal supply chain.

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?

Each stakeholder in the authentication system owns the data it generates when interacting with the system, thus, data generated by pharmacies is owned by pharmacies that can use and manage such data according to their interests or needs.

Although we consider that the directive is sufficiently clear with respect to the commercial property rights of the different stakeholders that interact with the system, given the commercial sensitive nature there are other issues that should be addressed.

In ANF opinion, besides information that allows the point of dispensing to be established, the following data should also be considered commercially sensitive:

- Geographic origin of the transaction (information that allows the region or country to be established);
- Identification of the product involved in the transaction (the repository system "knows" that a product was transacted but the stakeholders not involved in the transaction do not have access to that information);
- Quantification of the volume of products traded;
- Chronology of the transaction.

For patient safety purposes (e.g. organising recalls) or security alerts, the data in the repository system can be accessed. Even in those circumstances, there would be strict rules for access and data utilization.

Furthermore, the sole purpose of an authentication system is patients' safety. Thus, delegated acts must prevent any attempt to access patient data. It also must guarantee that the system can not to use to access other sensitive data that may jeopardize the commercial activities of other agents in the supply chain, namely parallel trade.

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

In our opinion, there is no need of gathering and recording patient data on the authentication system. However, to maximize patient safety, we believe that the authentication system can be complemented, at pharmacy level, with other instruments, such as electronic patient records. For example, in case of a recall for pharmacovigilance purposes or for falsified medicines alert, these instruments would facilitate the product recall by the community pharmacist from patients who received such products.

D. Consultation Topic nº 4: List containing the medicinal products or product categories which, in case of prescription medicines shall not bear the safety features, and in the case of non-prescription medicines shall bear the safety features.

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?

ANF supports the identification of medicines included in the "black list" and "white list" by International Non-proprietary Name (INN). It is a well established practice in pharmacies across Europe and complies with the current pharmaceutical policies in Portugal and other EU countries regarding prescription and dispensing rules.

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

ANF supports the most comprehensive solution in order to include the widest possible range of prescription medicines, in line with PGEU response.

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.

ANF subscribes PGEU response to this concept paper and also the stakeholders' joint position.

However, given the current economic scenario in Portugal and a severe crisis in the pharmacy sector as a result of the austerity measures taken over the last 5 years, ANF considers fundamental to point out some relevant issues about pharmacies constrains. This is the single reason to submit an individual response to this concept paper.

Portuguese Pharmacies are prepared and available to work on a solution and implementation of a Medicines authentication system. Nevertheless, the implementation of such system implies large initial investments and running costs in the future. The studies on the economic situation of the Portuguese Pharmacies shows that the current remuneration is not sufficient to cover the costs structure and estimate a negative net income of 39,891€ at the end of 2012 for the average pharmacy. These results depict the severe economic crisis of Portuguese Pharmacies, which means that any additional cost at this time would be catastrophic.

For these reasons, ANF supports the implementation of a medicines authentication system that is flexible, easily adaptable to national needs and circumstances and the most cost-effective possible, in order to minimize the economic impact for the state and the agents in the medicines chain.

 Additionally, ANF strongly believes that the European Commission must consider the additional effort that will be made by governments and national stakeholders of countries

under a severe economic crisis in order to comply with the directive and future delegated acts. In our opinion these concerns must be addressed not only under the perspective of costs, but also under the perspective of more flexible procedures and times of implementation.

27th April 2012,

Paulo Duarte, Vice-President of ANF Board

Annex I:

Estimated costs associated with the project for Portugal:

In Portugal exists about 3000 Pharmacies, using about 6 different software solutions. In average, each pharmacy has 5 workstations in the front office.

The medium cost for broad band communications is about 700€ per year, which implies an annual total cost of 2,100,000 €.

Nowadays Portuguese pharmacies are equipped with linear scanners, because our barcode is a linear barcode. The adoption of Datamatrix barcode requires that pharmacies acquire new 2D scanner replacing existing hardware. This involves the overall amount of about 15,000 scanners to read Datamatrix in a estimated total of 3,000,000 €. This is based on a cost of about 200 € for each scanner.

The software pharmacy uses has to be modified to include the new requirements. We estimate a cost of 500,000€ for this operation.

Pharmacy Staff should be trained to understand and use correctly these new features. To get better results, training should also include sessions on site. We estimate a total cost of 1,200,000 € (200€ x 2 persons x 3000 pharmacies).

Summary of identified costs:

- Communications ->	2,100,000 €
- 2D scanners ->	3,000,000 €
- Software modifications ->	500,000 €
- Trainning of staff ->	1,200,000 €
TOTAL :	**6,800,000 €**