PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

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PGEU Response to 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

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 31 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

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?

PGEU favours option n°1/2. It is essential in our view that the selected system is both cost effective and technically efficient from the point of view of all the actors in the supply chain (not only manufacturers).

Harmonisation through regulation will both provide economies of scale for manufacturers; thereby reducing cost, but also will help to avoid technical barriers through the use of incompatible coding systems within the same market.

For example, allowing manufacturers to select their own coding technology may significantly impact on the cost and technical efficiency of pharmacy level authentication, since it would require both pharmacists and the software systems in pharmacies to 'recognise' different incompatible coding systems (which given the range of manufactures in any given market, could be extensive).

Nonetheless, regulation should be kept to the necessary minimum, leaving sufficient space for

national flexibility.

For further observations on the options we refer to the PGEU/EFPIA/GIRP/EAEPC Joint Response.

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

We refer to the PGEU/EFPIA/GIRP/EAEPC Joint Response on this point.

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.

PGEU strongly supports the inclusion of batch number and expiry date in the serialisation number in machine readable form.

We believe that given the substantial investment required to establish and run the authentication system, (particularly on the part of pharmacists and manufacturers), opportunities to increase the added value of the system from the point of view of patient safety, even where these require a marginal additional expense, should be embraced.

As the Concept Paper correctly notes, inclusion of the batch number in the code will facilitate recalls and serve as a second line of defense preventing the dispensing of recalled products. The recall system currently tends to rely on dissemination of information to pharmacies by email, fax or pharmacy intranet, and pharmacists manually checking the stock. Despite the best efforts of pharmacists to avoid recalled products reaching patients, the inefficiency inherent in such a system is obvious. Therefore we suggest that a machine readable batch number is included on the individual pack code to allow second line checking by pharmacy software (on or offline) for recalled products before dispensing it to the patient.

Similarly, the inclusion of the machine readable expiry date will contribute significantly to the efficient management of pharmacy stock and ultimately will prevent the dispensing of expired products (on or offline). It is notable that the possibility of checking expiry dates is one of the added value features highly regarded by pharmacists in the established Belgian authentication system.

It is essential that **all four** coding elements are also included in the pack in human readable form. This will allow, for example, manual entry of numbers to the system if electronic reading

is not possible as a result of system downtime, or printing errors.

With regard to the possibility of preprinting serial numbers on packaging and making batch number and expiry date available on the database, we believe that, while possibly allowing some savings, overall cost effectiveness would be impaired through the inevitable possibility of security breaches.

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.

PGEU supports Option Number 2, for the reasons given in the PGEU/EFPIA/GIRP/EAEPC Joint Response. National reimbursement numbers, where they exist, are part of a complex and legally established system. It must remain Member States' competence to regulate these aspects. Technical options to include national reimbursement numbers into the coding standards exist (cf. Joint Response).

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.

PGEU supports 2D- Barcode, for the reasons given in the PGEU/EFPIA/GIRP/EAEPC Joint Response.

We have included some comments on cost in the Annex to this consultation response.

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?

Community Pharmacies are the key points of dispensing for medicines, authorised and recognised in all the EU 27. There are approximately 154.000 community pharmacies in the EU. In addition, hospital pharmacies exist in the vast majority of EU Member states.

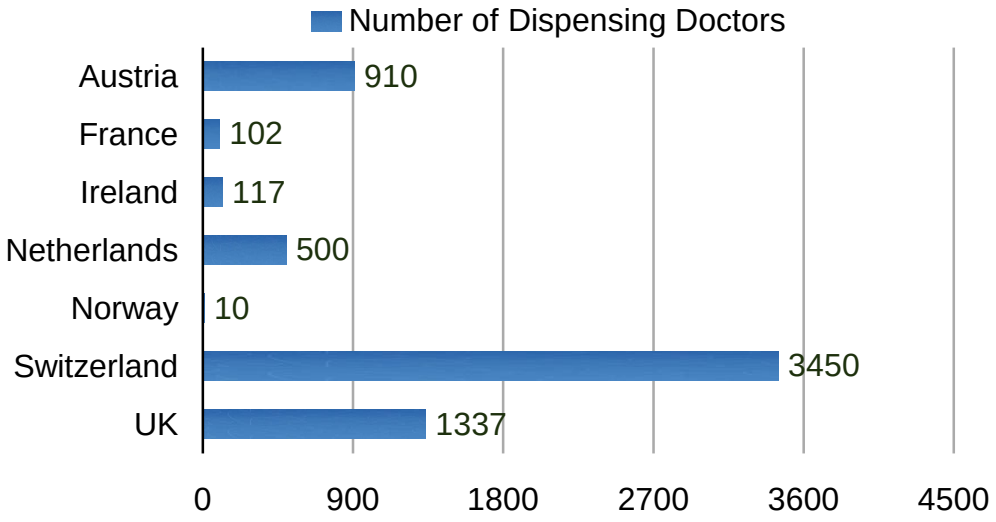
There are two other points of dispensing in some countries –namely, authorised internet or mail-order pharmacies, and dispensing doctors.

The sale of medicines through the internet is not authorised in all Member States, and only four Member States currently permit the sale of *prescription* medicines through the internet. In terms of logistical requirements, internet sellers are able to verify at the point of 'dispatch', rather then, strictly speaking, the point of dispense. In theory this should present no particular difficulties from a technical point of view, since authorised internet sellers would be permitted to access the repository system in the same way as Community Pharmacies, and would simply need scanners at their dispatching points.

Discussion is ongoing with colleagues in the hospital sector with regard to the particular contingencies of authentication at point of dispense in hospitals (e.g. at ward level or at point of entry to the hospital pharmacy), although again there is no reason to suppose that hospital pharmacy participation in the authentication system is problematic from a technical point of view. The European Stakeholder Model (ESM) foresees hospitals as an integral constituency within the authentication system.

Dispensing doctors exist in only a small number of Member States (*Figure 1: Number of Dispensing Doctors in Europe (Source PGEU Database 2011)*. Again there is no reason from a technical perspective why dispensing doctors should not be included in the system. In the interests of patient safety, dispensing doctors should under no circumstances be granted exemption from the obligation to authenticate the medicines they dispense.

Figure 1: Number of Dispensing Doctors in Europe (Source PGEU Database 2011)



As a final comment it is worth recalling that 80% of medicines in Europe are dispensed in ordinary Community Pharmacies. We would strongly oppose measures which gave undue

weight to other points of dispense, increased costs and complication for the great majority, and impacted in a prejudicial way on the role and contribution of the Community Pharmacy network.

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.

The Community Pharmacy is the last point in the distribution chain where the quality, security and authenticity of the medicines dispensed to the patient can be ensured. The quality, safety, security and authenticity of medication is part of our professional mission as pharmacists. We believe that patient safety should in no circumstances ever be compromised.

We are therefore committed to the implementation of pharmacy level medicines authentication.

There are substantial costs for the sector in adopting authentication, and an initial quantification of these is included in the Annex.

We believe that in addition to authentication at point of dispensing, pharmacists should have the option to verify medicines at any point prior to dispensing, without changing the status of the product in the repository system (this position is supported by our ESM colleagues). This is particularly important for e.g. Italian pharmacies, which are legally obliged to secure pharmacy stock from counterfeit products.

It is absolutely essential that the process of authentication at point of dispensing can be smoothly integrated into current dispensing procedures. This means that any additional scanning processes must be avoided, and response times (that is, the time taken for the pharmacists to receive the response message from the repository following the scan), should be virtually instantaneous. In the authentication systems currently operating in Turkey and Belgium, the response time is less than 200 milliseconds. Anything longer will seriously prejudice the efficiency of pharmacy processes and impose additional costs on pharmacies in terms of, for example, additional staff time. Slow response times will inconvenience patients,

and may lead to a loss of confidence in the authentication system itself.

PGEU supports option N°2/2 for the reasons given in the PGEU/EFPIA/GIRP/EAEPC Joint Response.

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).

PGEU supports the stakeholder governance model and the repository structure proposed under the ESM, for the reasons given in the PGEU/EFPIA/GIRP/EAEPC Joint Response. Note that the subsidiarity based approach favored by the ESM is not exactly captured by the three options put forward in the Concept Paper.

It is essential that the system adopted in Europe is cost effective, flexible and reflects the professional practice and rights of the stakeholders. We believe this is in the best interests of Europe's patients.

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?

Note that the Directive also requires the Commission when adopting measures under the Delegated Acts to take account of *'… the legitimate interests to protect information of a commercially confidential nature …and the ownership and confidentiality of the data generated by the use of the safety features'* (Article 54a para 3). We believe therefore that ensuring confidentiality and ownership of data, both from the legal and technical point of view, is essential when constructing the system.

PGEU believes each stakeholder in the authentication system owns the data generated when that stakeholder interacts with the system (subject to the provisions in the Directive relating to government access to data). This view is supported by our ESM colleagues, and is of course consistent with the view of the Directive that commercial property rights must be respected.

We believe however that data should be made available within the system where patient safety would be thereby enhanced. This should be in a fixed range of 'Exceptional Events', such as negative verification scans. The process whereby data would be released, which data, and to whom, would also need to be predefined. This process is currently being elaborated in discussion with our ESM partners.

For further comments on this aspect of the authentication system please refer to the PGEU/EFPIA/GIRP/EAEPC Joint Response.

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

PGEU strongly believes that no patient data should be kept on the authentication systems, and there is currently no legal basis for gathering patient data as part of authentication process. We draw attention to the Article 117a of the Directive which requires the system to facilitate recall of medicinal products from patients. Pharmacists are committed to helping implement such a possibility through the use, for example, of electronic patient medication records, established with patient consent, and with read and-write access rights for pharmacists.

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?

PGEU strongly supports the inclusion of the widest possible range of medicines within the scope of the safety feature.

From the point of view of the pharmacy profession, identification of medicines by the name of the active pharmaceutical ingredient (or INN) is the most favorable, supported by the brand name in certain circumstances, as these approaches are well established in daily pharmacy practice. In addition it is important to note that identification by INN is in line with current policies of many national governments with regard to the promotion of generic substitution by pharmacists.

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

PGEU strongly supports the inclusion of the widest possible range of medicines within the scope of the safety features. We support the quantified approach set out in the Concept Paper. We believe exceptions from the obligation to use safety features should be truly exceptional.

A narrow scope would simply encourage the counterfeiting of 'White List' medicines, without the flexibility of an immediate response (particularly if the Commission's view that voluntary serialisation is not permitted, is sustained).

Filtering out prescription medicines which do not need to be authenticated will present additional costs for pharmacists, as this will need a software enhancement (at least) and will require manual screening of products. This will potentially undermine the overall effectiveness of the system.

Unlike other stakeholders, the fixed costs for pharmacists in implementing authentication in the pharmacy are not contingent upon the range of medicines bearing the safety feature (such costs will be more or less the same for a narrow or wide scope), and this needs to be borne in mind when assessing the overall cost effectiveness of the system.

PGEU also believes that the interpretation of the Directive put forward in the Concept Paper with regard to the right for manufacturers to place safety features on the packs voluntarily is open to question. This position seems to lack a rationale, and can only ultimately add to the costs and complexity of the system.

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.

No additional comments.

The END

Annex

Pharmacy Costs

Medicines Authentication – Estimated Costs of implementation for Community Pharmacies

1 Unlike all other actors in the supply chain, costs at pharmacy level are the same once point of dispensing authentication is assumed irrespective of the overall organisation of the system and even if the scope of the obligation to place safety features is limited.

2 The costs for community pharmacies for implementing medicines authentication fall into four principal categories – (I) the cost of an internet connection, (II) the costs for scanners, (III) the costs of software extension and , (IV) , the cost for pharmacy staff training and support.

3 It is assumed for the purposes of the following calculations that:

(1) There are approximately 154,000 pharmacies in the EU, including Croatia.

(2) 99% European community pharmacies have a computer and use point of dispense-software in their daily operations.

(3) Database response times are in line with current practice of one fifth of a second or less. Delays in the dispensing processes would entail additional overhead costs for pharmacies.

(4) Changing existing scanners to the appropriate capability, if 2D barcode is the chosen carrier, would be fully attributable to the requirements of the Directive. In practice, some normal recycling cost should be assumed, but we have not been able to quantify this at this stage.

4 **Internet**

Access to broadband internet connections from pharmacies is subject to national coverage. Following the European Commission's own figures, there is a significant disparity within the EU with regard to rural and urban broadband coverage[1].

PGEU's own figures (*Figure 2: Availability of broadband connection in pharmacies in Europe (Source: PGEU Database 2011)*) suggest disparities between the number of pharmacies with broadband internet connections within the EU. PGEU data is limited to 10 EEA countries and

[1] http://ec.europa.eu/information_society/digital-agenda/scoreboard/docs/pillar/broadband.pdf

excludes eastern European countries and Greece that where it is understood that there are lower coverage rates, in particular in rural areas. The Portuguese Pharmacy Association reported as few as 55 % community pharmacies having broadband in the country. Experience suggests that broadband connection will be a pre-condition for the efficient running of the system at Community Pharmacy level. Therefore it is important to note that establishment of the broadband connection may imply costs, in particular in areas where broadband is not currently available.

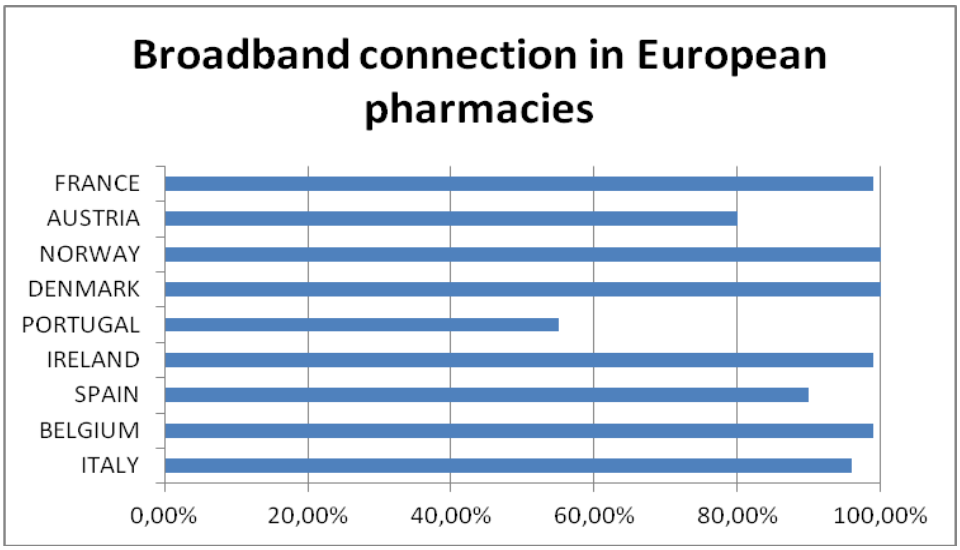


Figure 2: Availability of broadband connection in pharmacies in Europe (Source: PGEU Database 2011)

The costs of upgrading internet connections where they are not yet available are difficult to predict and are not included in our calculations. A solution for pharmacies which do not have access to broadband connections will presumably need to be developed during implementation of the Delegated Acts at national level.

The relevant costs for the purposes of this paper are the incremental cost for those pharmacies which have an available broadband connection, but which do not currently connect. The average price for a broadband connection in the EU is 40 Euros per month (although this does not necessarily reflect the cost in those regions where connection is currently low).

PGEU figures suggest that where broadband connection is available, on average 80% of pharmacies are connected.

It is assumed that 10% of European pharmacies have no available connection. We suggest that

approximately 27000 pharmacies would need to connect to the internet at first instance. This therefore represents a significant costs attributable to the implementation of the Directive.

5 Point-of-Dispense (PoD) Software extension

In order to implement authentication systems at point of dispensing, the existing point of dispensing software needs to be adapted in order to ensure that authentication function is integrated into existing dispensing processes. This is a key requirement of pharmacists – anything else would significantly increase the burden of authentication and potentially limit its effectiveness and acceptability by main end users of the system. We assume that the vast majority of European community pharmacies have at least one computer and use point of dispense software. For those pharmacies that do not fall under the scope of this assumption, the initial cost will be much higher.

The range of point of dispensing software solutions varies significantly between EU pharmacies, as does the number of software providers according to PGEU data (Figure 3: Number of Pharmacy Software Providers in Europe (Source: PGEU Database 2011)).

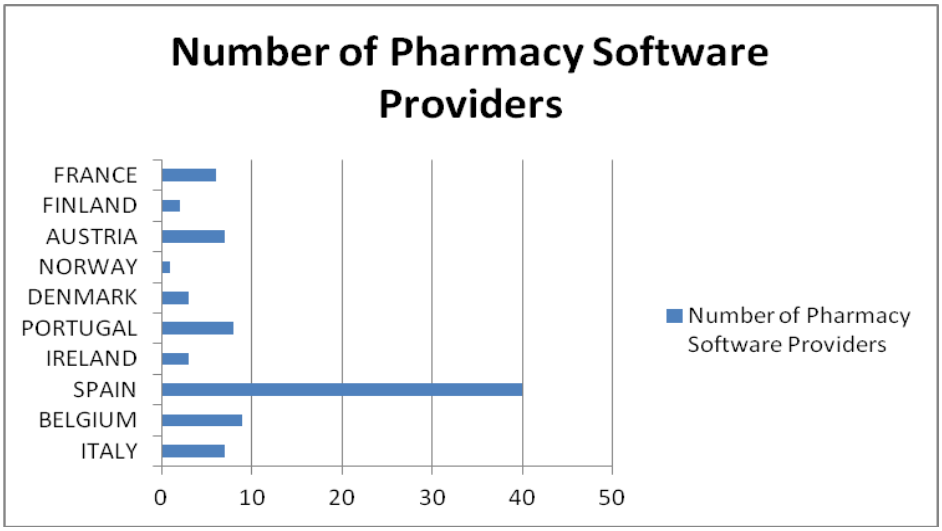


Figure 3: Number of Pharmacy Software Providers in Europe (Source: PGEU Database 2011)

The costs of adapting software may be sensitive to the following factors:

(i) Complexity of existing point of dispense software solutions.

(ii) Complexity of the authentication system and even the scope of unique identifier

(additional functionality to alert pharmacist which products should bear safety feature, etc).

(iii) The number of point of dispense software providers operating in the relevant market. This may have cost effects by (i) the operation of economies of scale where adaptations can be implemented for a large number of pharmacies (this in turn would be greater in larger markets) (ii) markets with a greater numbers of providers will have an incentive to minimise costs through the effect of competition.

Examples

In the pilot project undertaken by EFPIA in Sweden, costs per pharmacy of software adaptation were 1230 euros per pharmacy. Note that (i) there was only one software provider and the system was piloted in the pharmacies that at that moment belonged to the pharmacy chain owned by Swedish government, which would tend to simplify the process of software integration and staff training and therefore reduce costs (ii) the figure does not reflect economies of scale because of the limited size of the pilot (the total cost was divided over the number of participating pharmacies).

In Portugal, estimated costs for software adaptation are 172 euro per pharmacy, based on the calculation of one software provide which covers approximately 98% of the market, so economies of scale are maximised.

In Belgium, under the Aegate system, the costs of software adaptation were not passed on the pharmacies as part of the agreement undertaken to set up the system – this may be a possible outcome in some national markets where competition between providers is strong.

Given the widely diverse landscape of pharmacy software solutions in Europe and taking into account yearly maintenance cost for point of dispense software per pharmacy (Figure 4: Pharmacy software yearly maintenance cost (Source: PGEU Database 2011), which may increase as a result of the required software adjustemnts, we estimate that average costs for pharmacy may range from €0 up to €4000. Therefore total cost may range from 0 to €616.000.000. It is important to remember that this costing is based on the assumption that the pharmacy is equipped with necessary hardware and already operates pharmacy software.

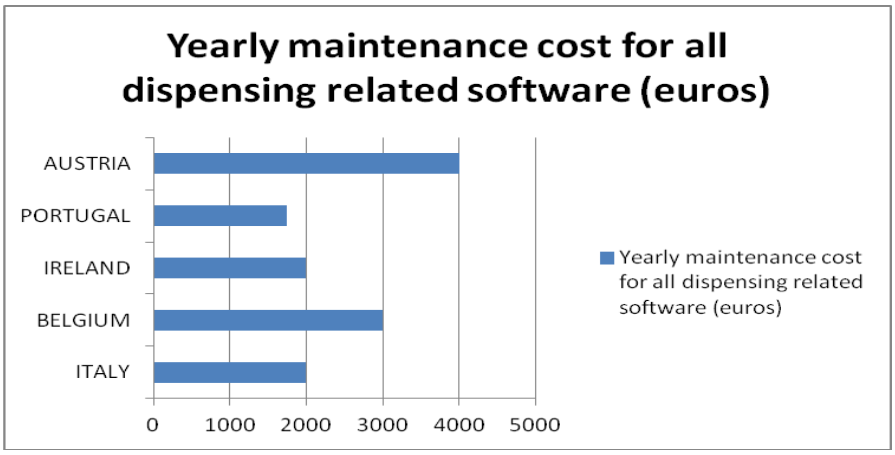


Figure 4: Pharmacy software yearly maintenance cost (Source: PGEU Database 2011)

6 Scanners

We assume that for the purpose of authentication an optical scanner will be required. The majority of EU pharmacies currently scan products, but only a minority of these scanners would currently be capable of reading a 2 Dimensional Bar Code. No data is currently available on the number of pharmacies in the EU already equipped with appropriate scanners.

We assume an average of 5 scanners per pharmacy would be required. In addition to the scanners at the point of dispense there is usually a scanner at the reception of goods area in the pharmacy. Currently optical scanners cost €250-300. We use the €250 figure for the purpose of our calculation giving a cost for scanners of €192.500.000 for all European Community Pharmacies. (N.B the assumption above regarding recycling)

7 Staff Training and Support

To train the staff how to use the software and ensure smooth running of the system initial training will be needed. This is assumed at €500 per pharmacy and also includes staff costs. It may vary depending on the number of staff needing to be trained and complexity of the system. This gives a total of €77.000.000 for all European community pharmacies.

In addition it is worth noting that full time support from pharmacy management will be required to ensure smooth running of the system at the level in the pharmacy, especially during the first months of implementation. This will require additional labour costs. In addition, we anticipate

that the help line will be needed to support pharmacists and ensure smooth running of the whole system. We do not attempt to quantify these fore present purposes.

In conclusion, broadband Internet connection, scanners and staff training are fixed costs which are not expected to vary greatly. The total cost for the sector for implementation of a medicines authentication system largely depend on the costs for software extension, and may vary from € 269,500,000 to € 885,500,000 for all 154.000 European community pharmacies (see table below). This estimate excludes additional running costs such as internet connections.

The estimate is highly speculative at this stage, and further enquiry is required in order to fully understand the financial implications of system implementation. PGEU is currently undertaking this work.

OPTION I – no cost for software extension:

Cost Item	Per Pharmacy	Total
Software extension	0	0
Scanners	€ 1.250	€ 192.500.000
Staff Training	€ 500	€ 77.000.000
TOTAL	€ 1.750	€ 269.500.000

OPTION II – average cost for software extension € 2.000:

Cost Item	Per Pharmacy	Total
Software extension	€ 2.000	€ 308.000.000
Scanners	€ 1.250	€ 192.500.000
Staff Training	€ 500	€ 77.000.000
TOTAL	€ 3.750	€ 577.500.000

OPTION III – highest expected cost for software extension € 4.000:

Cost Item	Per Pharmacy	Total
Software extension	€ 4.000	€ 616.000.000
Scanners	€ 1.250	€ 192.500.000
Staff Training	€ 500	€ 77.000.000
TOTAL	€ 5.750	€ 885.500.000