EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Medical products – quality, safety and innovation

STAKEHOLDERS' WORKSHOP ON THE DELEGATED ACT ON SAFETY FEATURES FOR MEDICINAL PRODUCTS FOR HUMAN USE

26 FEBRUARY 2016

SUMMARY OF THE WORKSHOP

List of participating organisations annexed

1. Welcome

The Commission (COM), chair of the meeting, welcomed participants and explained that the aim of the meeting was to inform stakeholders of the recently published delegated Regulation detailing the safety features for medicines for human use.

COM informed the audience that COM will draft minutes of the workshop, circulate them with stakeholders for comments and publish them on COM public health website.

2. Presentation of the delegated Regulation detailing the safety features for medicines for human use

COM explained that the Delegated Regulation (DR) on the safety features was adopted on 9th February 2016 and the new rules will apply as of 9th February 2019. Belgium, Italy and Greece have the possibility to defer the application of part of this Regulation for up to 6 years. Belgium has informed COM that they are not going to use this additional period.

COM further explained that the DR was part of the implementation of the Falsified Medicine Directive (FMD, Directive 2011/62/EU) and presented the key elements of the Regulation, in particular the background and scope of the DR, the technical characteristics of the unique identifier (UI), the verification of the safety features, the repositories system, the list of exceptions from bearing/not bearing the safety features.

COM presentation is publicly available:
(http://ec.europa.eu/health/files/falsified_medicines/201602_stakeholders_workshop_final.pdf)

3. Questions and Discussion

EMVO asked whether, in the case of smaller countries such as Luxembourg, it was necessary to implement the whole verification system or it is sufficient to have a platform connected to other national repositories.
COM replied that the DR does not require each Member State to have a national repository system, so possible for Luxembourg to use other Member State repositories through a platform. The platform needs however to be in line with the requirements of

the DR, i.e. hospitals and pharmacies need to be connected to the platform and transaction data should be kept within the platform.
EMVO confirmed this is the case.

In the context of the possibility for Member States to extend the scope of the safety features, **EGA** asked the Member States whether they would allow manufacturers to decide on the extension so that it can be done on a voluntary basis.
COM replied that, although it is for the Member States to decide how they want to extend the scope of the safety features, this has to be done within the limits of the legislation.

EAHP expressed its discontent with the process leading to the publication of the DR, in particular the insufficient consultation and transparency, the quality of the impact assessment and the lack of requirements for aggregated codes, which engendered anger in hospital sectors in many Member States. EAHP asked about how the provision allowing Member State access to the repositories system for the purposes of pharmacovigilance should be interpreted and whether COM will monitor the implementation of the DR.
COM pointed out to the public consultation which took place in 2012 and to the stakeholders' workshops of 2011, 2012, 2013 and 2014. The draft DR was also notified to the WTO in 2015. Intermediate consultations took place on targeted areas. In addition, there were extensive consultations of Member States through the meetings of the Member State expert group on the safety features.
COM further explained that aggregation is permitted by the DR, but not required – such a requirement may come at a later stage.
COM will facilitate the implementation of the DR by continuing organising meetings of the Member State expert group. Discussions with Member States on their access to repositories for the purposes of reimbursement, pharmacovigilance and pharmacoepidemiology are ongoing. COM drew the attention of the stakeholders to the limits to Member State use of repository data set out by the FMD.

PGEU asked whether the safety features rules apply when, as it is the case in some Member States, pharmacies import unlicensed medicines from other Member States and these medicines have a different legal status or are not classified as medicines (e.g. food supplements).
COM explained that it depends on the legal basis used to authorise the entry of non-authorised medicines. If the legal basis is Art. 5(1) of Directive 2001/83/EC, then the rules on the safety features do not apply. Pharmacists are however kindly invited to voluntarily decommission any UI present on those products.

EGA commented that EMVO favours a pragmatic approach concerning the regulatory requirements (i.e. variations/notifications) for the implementation of the safety features, in view of the about 250,000 products potentially requiring variations.
COM pointed out that the implementation plans for both centrally- and nationally-authorised products that are in place include much pragmatism from COM side as they encourage the use of regulatory procedures that would have been needed/done anyway.

EIPG pointed out that the verification/decommissioning of the unique identifier may become a big burden when the point of dispense does not coincide with the point of verification and that aggregation would have been nice. EIPG further asked whether expired products need to be decommissioned one by one or it can be done automatically.

COM clarified that the DR does not regulate such issue but such mechanism can be voluntarily put in place by the entities managing the repositories.
EMVO added that, in the system they are developing, an expired product will be barred from dispense.

GIRP congratulated COM for the work on the DR and asked how the legitimacy of wholesalers connecting to national repositories can be properly verify since many Member States do not have public registries listing authorised wholesalers.
COM replied that Member States have a legal obligation to populate EudraGMDP, including with names of wholesalers authorised on their territory. COM will be firmer in monitoring that this requirement is respected, as the proper population of EudraGMDP is essential to identify legitimate wholesalers.
EMA further explained that some Member States have had technical problems to upload data in EudraGMDP but that EMA is providing further training and bilateral discussions to try and solve those difficulties.

AEGATE supported GIRP's congratulations for the DR, stressed the importance for the security of the system that only verified users (wholesalers, hospitals and pharmacies) are allowed to connect to the repositories system and asked who is responsible to identify verified users. AEGATE further asked whether the receipt of an alert (e.g. by a pharmacy) should be recorded in the audit trail.
COM clarified that every single operation in the system concerning the UI has to be recorded in the audit trail, including the receipt of alerts. COM further agreed that verification of users is a key issue and that repositories managers will need to work jointly with national competent authorities to identify legitimate users.

EGA explained that the generic industry runs on small profit margins and on a large sale volume (generics represent 56% of products marketed in the EU). The estimated costs of implementing the safety features are high - €1 billion for the whole sector, including the costs of upgrading the manufacturing lines and running/using the repositories system. The EGA doesn't have a representation in every Member State (only in 18 Member States). In order to improve effectiveness and reduce the costs, harmonisation of key aspects of the national repositories is necessary, in particular concerning the application of the blue print system and the cost allocation model. EGA wondered whether COM and the Member States could help achieving this harmonisation.
COM replied that the legislation leaves (national) stakeholders the choice of which system to use at national level (e.g. blueprint or not) and the Commission cannot replace national discretion. COM will continue fostering discussions among Member States on the implementation of the legislation with the aim of promoting/sharing best practices and working towards harmonisation.

IFA Gmbh asked whether the reply to question 27 of the Q&A document is binding, since placing the UI in the blue box is complicated for manufacturers.
COM clarified that the Q&A document is non-binding guidance document. It further clarified that the recommendation to place the UI in the blue bow only applies in case of extension of the scope of the UI in accordance with Article 54a(5) of Directive 2001/83/EC.

ARVATO System Gmbh mentioned that, when dispensing a product, it is necessary to have in the system an exact list of which products have or do not have to bear the safety features and further asked who should provide such list.

COM replied that such information will be provided by national competent authorities upon request, in accordance with Art. 43 of the DR.

EAHP asked whether COM has a view on what is a reasonable subscription fees (for the repositories system).
COM replied that it is left to stakeholders to decide.

EFPIA congratulated COM for the DR and commented that new legislation unavoidably means changes and stakeholders have to be forward-looking and work to take the best out of those changes. EFPIA further mentioned that, in their experience, COM has had a good dialogue with stakeholders and that stakeholders' views have been considered when drafting the DR. EFPIA also informed that EAPH and HOPE had been invited to participate in the EMVO but establishing a constructive dialogue has proved difficult.

AEGATE Ltd asked whether the Commission has guidance on when the repositories system should be in place and which penalties would apply if repositories are not in place on 9 Feb 2019.
COM replied that the repositories system should be put in place as soon as possible so that it can be properly tested and people trained to use it. Concerning penalties, COM informed that penalties are national competence. COM trusts companies to put products on the market only if they are compliant with legislation.

EFPIA mentioned that national awareness of the new rules is quite low in some Member States and encouraged COM and Member States to do more to inform manufacturers, marketing authorisation holders, wholesalers and pharmacies on their territory.
COM confirmed its availability to attend, in person or via video-link, national information events organised by Member States and stakeholders to present the new rules.
PGEU supported the point raise by EFPIA and mentioned that PGEU may organise an outreach event and will contact COM to ensure its participation.

COM concluded the workshop with a take-home message for the stakeholders: the responsibility is now with you to set up the system and make it work within the required timeframe. COM will do its best to facilitate the process.

COM reminded participants that the COM presentation and workshop minutes will be published on COM website.

The workshop was closed.

ANNEX
LIST OF PARTICIPATING ORGANISATIONS

Organisation
ACS PharmaProtect GmBH
AEGATE Ltd
AESGP
Arvato Systems GmbH
Costeff e.V
EAEPC
EAHP
EALTH
ECHAMP
EDQM
EFPIA
EGA
EIPG
EMVO
EQPA - ECA
EUCOPE
EuropaBio
GIRP
GS1 Global office
HOPE
IFA GmbH
PGEU
secuPharm e.V
Solidsoft Reply

Member State	Competent Authority
AUSTRIA	Federal Office for Safety in Healthcare
BULGARIA	Bulgarian Drug Agency
DENMARK	Danish Medicines Authority
FINLAND	Finnish Medicines Agency FIMEA
FRANCE	Représentation permanente de la France
	Ministère des Affaires sociales, de la santé et des droits des femmes
HUNGARY	Ministry of Human Capacities
GERMANY	Ministry of Health
	Ministry of Health
GREECE	National organisation for medicines _EOF
IRELAND	Health Products Regulatory Authority_HPRA
LATVIA	State Agency of Medicines of the Republic of Latvia
MALTA	Medicines Authority Malta
NORWAY	Norwegian Medicines Agency
POLAND	Ministry of Health
PORTUGAL	INFARMED
ROMANIA	National Medicines Agency
SLOVENIA	JAZMP
SPAIN	Spanish Agency of Medicines and Medical Devices (AEMPS)
SWEDEN	The Medical Products Agency
THE NETHERLANDS	Dutch Ministry of Health
	Ministry of health Welfare and Sports
UNITED KINGDOM	Department of Health

Member State	Competent Authority
	MHRA
EU	DG SANTE
	EMA