GHP Guild of Healthcare Pharmacists

13th July 2016

ESM
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65 Gresham Street
London
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UK consultation on the User Requirement Specifications
For the UK Medicines Verification System

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,500 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

Please find our duly completed word document response form attached to this letter. However, as there is no section to make additional comments in the response form, we would like to make the following additional comments:

It is positive that an open consultation on the UK's medicines verification user requirements is being conducted. However 4 weeks has been short time span within which to conduct consultation on wide ranging technical matters. The Guild of Healthcare Pharmacists (GHP) believes that 12 weeks would have been more acceptable period in respect to such a consultation.

We wish to again raise our concern about the system's cost allocation/governance model, according to the Falsified Medicines Directive the costs of the product verification system will be borne by the manufacturers of medicines. The EMVO/NMVO model has it that central operating costs of the system are shared by the "stakeholders". Subsequent subscription fees to cover this are then set at a level that excludes very many impacted stakeholders from participating in that governance, which marks a governance problem requiring redress, otherwise it is not so much a "stakeholder model" as a "stakeholders that can afford the model.

It is the view of GHP that the UK medicines verification systems must take account of, and reflect, the particular use needs of the hospital pharmacy sector. While there are a number of responses within the consultation document that cover our views and concerns, we would particularly wish to highlight the following issue: Hospitals typically receive a significant amount of medicine in large bulk containers or

packs, the GHP believes that verification systems provide the possibility for hospitals to check out medicines on arrival via a scan of an aggregated barcode on the bulk container. This will save significant time and resource compared to the need to break large containers into individual package components for the purposes of scanning. We believe that the UK verification system designers must look to provide this functionality within the system. Use of aggregated barcodes in this manner can go a long way towards creating a verification system that is fit for purpose from day one.

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

Graeme Richardson
Vice President
Guild of Healthcare Pharmacists

Barry Corbett
Professional Secretary
Guild of Healthcare Pharmacists

UK consultation on the User Requirement Specifications for the UK Medicines Verification System

Consultation response form
This consultation will close at 23:59 on Wednesday 13th July 2016

Consultation Questions

1. Do you believe that the systems proposed meet the requirements of the EU legislation?

Yes ☑
No ☐
If no, please describe how you believe they fail to do so, or feel free to provide any further comments.

2. Do you support the core principles underpinning this approach?

Yes ☑
No ☐
If you have said no, please select which of the principles you do not support from the list below (you may select as many as you wish – *see final section, 'Evaluating the Overarching principles'*).

3. Do you agree that the system architecture and the UKMVO's main tasks as described in the URS are appropriate to the needs of the system?

Yes ☐
No ☑
If no, please describe why not, or feel free to provide any further comments

While we agree that the system architecture and the UKMVO's main tasks as described in the URS are appropriate to the needs of the system, there are some issues that we feel need to still be included especially with respect to functionality in the hospital environment: 1) Section B.11 describes the decommissioning of a pack, by the party that physically takes a pack out of the supply chain e.g. a pharmacist sends a product back to the wholesaler who himself sends it back to the manufacturer for destruction following a recall. In this case it would be the manufacturer as the last party in the reverse logistics process who sets the pack as "decommissioned" by setting an appropriate pack indication. However, in a hospital environment, when the medicine is checked and its status changed at the point of entry to the pharmacy to 'Decommissioned' obtaining a new indication "Supplied". Then in the case of a recall the pack returned to the wholesaler who then sends it back to the manufacturer for destruction, the party that physically takes a pack out of the supply chain in this case the manufacturer, could not decommission the pack as it has already been decommissioned at the point of entry to the pharmacy. Unless the recall occurred within 10 days of

decommissioning the point of entry to the pharmacy, the pharmacy would be unable to undo the decommissioning process.

2) There are a number of sections in the document where the decommissioning/checking of a bulk of packs by a user who connects to a national system (it is a use case that is envisaged to be used by wholesalers). The wholesaler system will not send one decommissioning request per pack to the national system, but transmit within one transaction the product code and the entire set of serial numbers to be decommissioned. We believe that this must also be possible in the hospital environment and to support this there should be the facility to utilise aggregated barcodes on bulk packs to allow more rapid data entry. The aggregated bar codes must be available on all the various outer packaging from a cellophane pack of 10 to say a pallet of product.

3) Section 4.3.1.5 describes the functionality that occurs when a pack is scanned in a market that was not its originally intended market for sale. In these scenarios, the Delegated Regulation is clear that the scanned pack shall not be immediately reported to the user as 'unknown' by the connected National repository but instead a query will be sent to the European Hub and the Hub will then send a directed query to the market originally intended for the sale of the pack scanned. It is acknowledged that this extended capability will now mean that the response to a genuine unknown pack will now take longer than originally specified (because the system cannot initially differentiate in all cases between a genuinely unknown pack and one that requires an inter-market query), this will cause issues in hospital pharmacy where we regularly have such packs that have been imported either due to supply chain shortages in the UK or due to the product not being available on the UK market.

4) Section 4.2.5.4.2 describes the case where a product pack or multiple product packs are identified as stolen, this use case provides the manufacturer and/or Parallel distributors the ability to mark the product pack(s) as stolen. Once a product pack has been identified as stolen the pack must be reported as such to the European Hub which will transfer the new product pack status to the National System(s). At National system the stolen pack gets decommissioned and obtains a new indication "Stolen". We are unclear how useful this function is, if the pack(s) are stolen the product identification code etc. and a serial number would not be available to be used to identify the pack(s) on the system to allow decommissioning to the "Stolen" status? i.e. how would anyone know which packs to decommission as "Stolen" as there would be no record of the relevant details. Additionally it is common that stock disappears, only to be rediscovered at a later date (put away in an incorrect location etc.) in such cases if there is only a 10 day grace period for the same party to return the pack(s) from their "Stolen" designation, then this may not be sufficient time. Also if packs are stolen once decommissioned within a hospital, it is unclear how this would be handled by the UK MVS.

5) Section B.14 describes the functionality to transmit information concerning product recalls in addition to the established recall procedures. For that purpose, the European Hub will propagate the recall information to the concerned national systems. There, the status of the affect batch (or for those packs that have an "Active" status) is set to "recalled" – the status of all other packs remains unaffected. While this is extremely useful where packs are checked out at the point of dispensing, this will be of little value if in a hospital environment, when the medicine is checked and its status changed at the point of entry to the pharmacy, to 'Decommissioned', obtaining a new indication "Supplied". In this case the functionality must exist to alert that hospital that they have had packs affected by the recall and the date the packs had their status being changed to 'Decommissioned'.

6) The pack/product identification code (including national code where relevant), the expiry date, the batch number, and a serial number should be made available for use within the hospital system at the point when the medicine is checked and its status changed at the point of entry to the pharmacy, resulting in the status being changed to 'Decommissioned' and obtaining a new indication "Supplied". If the hospital pharmacy system can then use the information to record future issues to facilitate product checks, expiry date monitoring and to support recalls post eventual dispensing to patients.

7) There is a real opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), the name, form and strength should also be incorporated in the 2D barcode to enable identification checking within electronic dispensing and medicines administration systems. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

8) There continues to be no facility for patients to check their own products, there must be an add on environment on a read only basis to allow patients to check they the pack they have been supplied is not counterfeit, by simple entry of the product code and the serial ID, the patient could them be provided with appropriate information informing them of the pack status and then provide advice in the case of it being marked as unknown.

9) There is a real opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), a link to allow patients to access the Patient Information Leaflet (PIL) could be included so that they could use apps on their smart phones to access the PIL. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

10) It is not clear how hospital manufacturing units and prepacking units will decommission the original packs and upload the new packs/products onto the system. It would be assumed that it would be as described 4.2.5.4.1 Repack by Parallel Distributor, where the hospital unit would unpack the original product packs (supported by decommission pack use case), produce repacked product packs and mark them with a data matrix code. The information about the original product code and batch used for repackaging and the new product code and batch for the repacked product packs is then transmitted from the hospital system to the European Hub (supported by upload product pack data use case).

4. Do you believe that there are any gaps in major functions or additional requirements as outlined in the URS?

Yes ☑
No ☐

If yes, please specify any additional functions or additional requirements that you think should be added

We believe that there are any gaps in major functions or additional requirements as outlined in the URS especially with respect to functionality in the hospital environment:

Functional Gaps

1) Section B.11 describes the decommissioning of a pack, by the party that physically takes a pack out of the supply chain e.g. a pharmacist sends a product back to the wholesaler who himself sends it back to the manufacturer for destruction following a recall. In this case it would be the manufacturer as the last party in the reverse logistics process who sets the pack as “decommissioned” by setting an appropriate pack indication. However, in a hospital environment, when the medicine is checked and its status changed at the point of entry to the pharmacy to ‘Decommissioned’ obtaining a new indication “Supplied”. Then in the case of a recall the pack returned to the wholesaler who then sends it back to the manufacturer for destruction, the party that physically takes a pack out of the supply chain in this case the manufacturer, could not decommission the pack as it has already been decommissioned at the point of entry to the pharmacy. Unless the recall occurred within 10 days of decommissioning the point of entry to the pharmacy, the pharmacy would be unable to undo the decommissioning process. It is unclear how the recall process would work in such circumstances.

2) There are a number of sections in the document where the decommissioning/checking of a bulk of packs by a user who connects to a national system (it is a use case that is envisaged to be used by wholesalers). The wholesaler system will not send one decommissioning request per pack to the national system, but transmit within one transaction the product code and the entire set of serial numbers to be decommissioned. We believe that this must also be possible in the hospital environment and to support this there should be the facility to utilise aggregated barcodes on bulk packs to allow more rapid data entry. The aggregated bar codes must be available on all the various outer packaging from a cellophane pack of 10 to say a pallet of product.

3) It is not clear how hospital manufacturing units and prepacking units will decommission the original packs and upload the new packs/products onto the system. It would be assumed that it would be as described 4.2.5.4.1 Repack by Parallel Distributor, where the hospital unit would unpack the original product packs (supported by decommission pack use case), produce repacked product packs and mark them with a data matrix code. The information about the original product code and batch used for repackaging and the new product code and batch

for the repacked product packs is then transmitted from the hospital system to the European Hub (supported by upload product pack data use case).

Additional Requirements

1) Section B.14 describes the functionality to transmit information concerning product recalls in addition to the established recall procedures. For that purpose, the European Hub will propagate the recall information to the concerned national systems. There, the status of the affect batch (or for those packs that have an "Active" status) is set to "recalled" – the status of all other packs remains unaffected. While this is extremely useful where packs are checked out at the point of dispensing, this will be of little value if in a hospital environment, when the medicine is checked and its status changed at the point of entry to the pharmacy, to 'Decommissioned', obtaining a new indication "Supplied". In this case the functionality must exist to alert that hospital that they have had packs affected by the recall and the date the packs had their status being changed to 'Decommissioned'.

2) The pack/product identification code (including national code where relevant), the expiry date, the batch number, and a serial number should be made available for use within the hospital system at the point when the medicine is checked and its status changed at the point of entry to the pharmacy, resulting in the status being changed to 'Decommissioned' and obtaining a new indication "Supplied". If the hospital pharmacy system can then use the information to record future issues to facilitate product checks, expiry date monitoring and to support recalls post eventual dispensing to patients.

3) There is a real opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), the name, form and strength should also be incorporated in the 2D barcode to enable identification checking within electronic dispensing and medicines administration systems. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

4) There continues to be no facility for patients to check their own products, there must be an add on environment on a read only basis to allow patients to check they the pack they have been supplied is not counterfeit, by simple entry of the product code and the serial ID, the patient could them be provided with appropriate information informing them of the pack status and then provide advice in the case of it being marked as unknown.

5) There is a real opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), a link to allow patients to access the Patient Information Leaflet (PIL) could be included so that they could use apps on their smart phones to access the PIL. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

5. Do you see the need to add additional user requirements specific to the needs of a UK verification system?

Yes ☑
No ☐

If yes, please specify them

We see the need to add additional user requirements specific to the needs of a UK verification system especially with respect to functionality in the hospital environment:

1) Section B.11 describes the decommissioning of a pack, by the party that physically takes a pack out of the supply chain e.g. a pharmacist sends a product back to the wholesaler who himself sends it back to the manufacturer for destruction following a recall. In this case it would be the manufacturer as the last party in the reverse logistics process who sets the pack as "decommissioned" by setting an appropriate pack indication. However, in a hospital environment, when the medicine is checked and its status changed at the point of entry to the pharmacy to 'Decommissioned' obtaining a new indication "Supplied". Then in the case of a recall the pack returned to the wholesaler who then sends it back to the manufacturer for destruction, the party that physically takes a pack out of the supply chain in this case the manufacturer, could not decommission the pack as it has already been decommissioned at the point of entry to the pharmacy. Unless the recall occurred within 10 days of

decommissioning the point of entry to the pharmacy, the pharmacy would be unable to undo the decommissioning process. There will need to be additional requirement to allow such a recall to be processed according to the rule that the party that physically takes a pack out of the supply chain is responsible for decommissioning the pack.

2) There are a number of sections in the document where the decommissioning/checking of a bulk of packs by a user who connects to a national system (it is a use case that is envisaged to be used by wholesalers). The wholesaler system will not send one decommissioning request per pack to the national system, but transmit within one transaction the product code and the entire set of serial numbers to be decommissioned. We believe that this must also be possible in the hospital environment and to support this there should be the facility to utilise aggregated barcodes on bulk packs to allow more rapid data entry. The aggregated bar codes must be available on all the various outer packaging from a cellophane pack of 10 to say a pallet of product.

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4) The pack/product identification code (including national code where relevant), the expiry date, the batch number, and a serial number should be made available for use within the hospital system at the point when the medicine is checked and its status changed at the point of entry to the pharmacy, resulting in the status being changed to ‘Decommissioned’ and obtaining a new indication “Supplied”. If the hospital pharmacy system can then use the information to record future issues to facilitate product checks, expiry date monitoring and to support recalls post eventual dispensing to patients.

5) There is a real opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), the name, form and strength should also be incorporated in the 2D barcode to enable identification checking within electronic dispensing and medicines administration systems. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

6) There continues to be no facility for patients to check their own products, there must be an add on environment on a read only basis to allow patients to check they the pack they have been supplied is not counterfeit, by simple entry of the product code and the serial ID, the patient could them be provided with appropriate information informing them of the pack status and then provide advice in the case of it being marked as unknown.

7) There is a real opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), a link to allow patients to access the Patient Information Leaflet (PIL) could be included so that they could use apps on their smart phones to access the PIL. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

8) It is not clear how hospital manufacturing units and prepacking units will decommission the original packs and upload the new packs/products onto the system. It would be assumed that it would be as described 4.2.5.4.1 Repack by Parallel Distributor, where the hospital unit would unpack the original product packs (supported by decommission pack use case), produce repacked product packs and mark them with a data matrix code. The information about the original product code and batch used for repackaging and the new product code and batch for the repacked product packs is then transmitted from the hospital system to the European Hub (supported by upload product pack data use case).

‘Evaluating the Overarching Principles’

Please tick yes or no if you support the below core principles. If you can please describe why you do not support these particular principles:

A.1. The original pack unique identifier must be cancelled in the database by the parallel distributor and a new number provided. The new unique identifier must be linked to the original product number at the batch level in the European Hub to enable the product to be identified in case of recalls or other safety issues.

Yes ☑
No ☐

This should reduce the time talen to decommission the pack as the relevant information will be available in the national system, in this case the UK MVS.

A.2. All national database systems must be able to work together through the European Hub in order to allow any Member State to check on whether the pack has been decommissioned before, irrespective of its country of origin. The European Hub provides this functioning of interoperability between the national systems.

Yes ☑
No ☐

A.3. Without this interoperability, counterfeiters would be able to exploit gaps between national systems to insert falsified medicines into the legitimate supply chain.

Yes ☑
No ☐

A.4. There should be sufficient flexibility to implement national solutions within the European Medicines Verification landscape. EMVO has assessed that the blueprint concept and all its aspects is expected to be the most cost efficient model. The cost allocation model as described in Appendix A is a core element of the blueprint concept.

Yes ☐
No ☑

We wish to raise our concern about the system’s cost allocation/governance model, according to the Falsified Medicines Directive the costs of the product verification system will be borne by the manufacturers of medicines.

The EMVO/NMVO model has it that central operating costs of the system are shared by the "stakeholders". Subsequent subscription fees to cover this are then set at a level that excludes very many impacted stakeholders from participating in that governance, which marks a governance problem requiring redress, otherwise it is not so much a "stakeholder model" as a "stakeholders that can afford it model

A.5. National database systems should meet appropriate quality assurance requirements.

Yes ☑
No ☐

We believe that they **must** meet appropriate quality assurance requirements rather than should.

A.6. The unique serial number can only provide protection against falsification if it is routinely or systematically checked out and the status changed on the database to "decommissioned" before the product is handed to the patient or when it is processed in repackaging/ relabelling (as examples only).

Yes ☑
No ☐

A.7. Systems should be configured so that pharmacists can undertake checks when medicines enter pharmacy stock as well as at point of dispensing.

Yes ☑
No ☐

Systems **must** be configured so that pharmacists can undertake checks when medicines enter pharmacy stock as well as at point of dispensing.

A.8. The process of verification in the pharmacy should be virtually instantaneous. The process of verification at all levels (i.e. pharmacies, wholesalers, manufacturers, and parallel distributors) should allow products to be checked without changing the status on the database.

Yes ☑
No ☐

There are a number of sections in the document where the decommissioning/checking of bulk of packs by a user who connects to a national system (it is a use case that is envisaged to be used by wholesalers). The wholesaler system will not send one decommissioning request per pack to the national system, but transmit within one transaction the product code and the entire set of serial numbers to be decommissioned. We believe that this must also be possible in the hospital environment and to support this there should be the facility to utilise aggregated

barcodes on bulk packs to allow more rapid data entry. The aggregated bar codes must be available on all the various outer packaging from a cellophane pack of 10 to say a pallet of product.

A.9. Verification systems are for preventing falsifications, not for accessing individual stakeholder data.

Yes ☑
No ☐

This is a must.

A.10. Manufacturers do not seek, and will not have access to, individual patient/prescribing profile information.

Yes ☑
No ☐

This is a must.

A.11. Transactional data belongs to the pharmacist, or in relation to wholesaler verification, to the wholesaler or, in relation to manufacturers and parallel distributors, to the manufacturing authorisation holder who performs this activity. For the avoidance of doubt, information relating to pack status changes (for example dispensing, decommissioning for repack) belongs to the operator who performs this activity and must not be visible for any other party. However, relevant stakeholders may need to see certain data to help investigate when there is a verification failure, a product recall or a level of unusual activity related to a specific serial number, in accordance with national circumstances.

Yes ☑
No ☐

We would support this, but believe that there must be safeguards in place to prevent stakeholders accessing data for other reasons. One suggestion would be that there is a formal request process to allow access to the data being requested and that there is a robust governance process in place to monitor this on an EU and national basis.

A.12. Any additional use of transactional data would need to be agreed by the stakeholder owning the data on a case-by-case basis in light of national circumstances and in compliance with relevant legislation.

Yes ☑
No ☐

Also see A.11

A.13. The product verification solution proposed should meet the criteria of being practical, affordable and accessible.

Yes ☑
No ☐

The product verification solution proposed must meet the criteria of being practical, affordable and accessible. There is a very real risk that meeting the requirements of the UKMVS will cost the NHS from both software development and additional staffing resources to operate the additional processes.

A.14. Only the manufacturer can enter serial numbers into the system (in the case of parallel distributed products, the relabelling/repackaging entity will inevitably be a manufacturer).

Yes ☑
No ☐

It is not clear how hospital manufacturing units and prepacking units will decommission the original packs and upload the new packs/products onto the system. It would be assumed that it would be as described 4.2.5.4.1 Repack by Parallel Distributor, where the hospital unit would unpack the original product packs (supported by decommission pack use case), produce repacked product packs and mark them with a data matrix code. The information about the original product code and batch used for repackaging and the new product code and batch for the repacked product packs is then transmitted from the hospital system to the European Hub (supported by upload product pack data use case). We would thus expect suitably licenced hospital manufacturing units and prepacking units to have the status of a manufacturer for the purposes of the UKMVS and FMD.

A.15. There will be a requirement for an “undo” capability within the system where, for example, a serial number has accidently been “checked out” or a patient no longer requires the medicine.

Yes ☑
No ☐

In a hospital environment, when the medicine is checked and its status changed at the point of entry to the pharmacy, resulting in the status being changed to ‘Decommissioned’ and obtaining a new indication “Supplied”. Then in the case of a recall the pack returned to the wholesaler who sends it back to the manufacturer for e.g. destruction, the party that physically takes a pack out of the supply chain in this case the manufacturer, will not be able to decommission the pack as it has already been decommissioned at the point of entry to the pharmacy. Unless the recall occurred within 10 days of decommissioning the point of entry to the pharmacy, the pharmacy would be unable to undo the decommissioning process.
We believe that the 10 day limit will prevent hospitals meeting some requirements of the FMD and the UKMVS.

A.16. The code to be affixed to each pack should include the data elements required by the Commission Delegated Regulation (EU) 2016/161 i.e. product identification code (including national code where relevant), the expiry date, the batch number, and a serial number.

Yes ☑
No ☐

There is a real opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), the name, form and strength should also be incorporated in the 2D barcode to enable identification checking within electronic dispensing and medicines administration systems. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

There is an additional opportunity to use other information (other than the product identification code, the expiry date, the batch number, and a serial number), a link to allow patients to access the Patient Information Leaflet (PIL) could be included so that they could use apps on their smart phones to access the PIL. This would improve safety by ensuring the safety features are also used to reduce dispensing and administration errors in the hospital environment.

There continues to be no facility for patients to check their own products, there must be an add on environment on a read only basis to allow patients to check they the pack they have been supplied is not counterfeit, by simple entry of the product code and the serial ID, the patient could them be provided with appropriate information informing them of the pack status and then provide advice in the case of it being marked as unknown.

A.17. It is necessary to make a link at the level of the originator's batch between (a) the number of newly commissioned packages (and their dose count) and (b) the originator's batch as well as the list of decommissioned and newly commissioned serial numbers. The number of decommissioned packages (and dose count) will enable the system, in a timely manner, to reconcile parallel distributed products by verifying that the number of doses "decommissioned" does not exceed the number of doses subsequently checked in or "commissioned" into the system (see also A.1 above). This link needs to be maintained over the lifespan of a batch.

Yes ☑
No ☐

Again it is not clear how hospital manufacturing units and prepacking units will decommission the original packs and upload the new packs/products onto the system. It would be assumed that it would be as described 4.2.5.4.1 Repack by Parallel Distributor, where the hospital unit would unpack the original product packs (supported by decommission pack use case), produce repacked product packs and mark them with a data matrix code. The information about the original product code and batch used for repackaging and the new product code and batch for the repacked product packs is then transmitted from the hospital system to the European Hub (supported by upload product pack data use case). We would thus expect suitably licenced hospital manufacturing units and prepacking units to have the status of a manufacturer for the purposes of the UKMVS and FMD.

A.18. Data ownership is determined by the party who generates the data (see also A.11 above)

Yes ☑
No ☐

A.19. The system should be highly secured and permit access to data only under strict and defined conditions.

Yes ☑
No ☐

A.20. In very simple terms, a serialisation system holds the information in accordance with Commission Delegated Regulation (EU) 2016/161 Article 33(2).

Yes ☑
No ☐

A.21. Negative verification results are reported according to the defined escalation procedures, e.g. “The data elements that are scanned do not match the database information – e.g. the batch number or the expiry date.”

Yes ☑
No ☐

A.22. In a product recall scenario, relevant stakeholders would require access to the status of all impacted serial numbers, including details of which impacted serial numbers have been decommissioned (e.g. dispensed or repacked). For that purpose, the European Hub will provide information in aggregated form (directly or via the national system).

Yes ☑
No ☐

Section B.14 describes the functionality to transmit information concerning product recalls in addition to the established recall procedures. For that purpose, the European Hub will propagate the recall information to the concerned national systems. There, the status of the affect batch (or for those packs that have an “Active” status) is set to “recalled” – the status of all other packs remains unaffected. While this is extremely useful where packs are checked out at the point of dispensing, this will be of little value if in a hospital environment, when the medicine is checked and its status changed at the point of entry to the pharmacy, to ‘Decommissioned’, obtaining a new indication “Supplied”. In this case the functionality must exist to alert that hospital that they have had packs affected by the recall and the date the packs had their status being changed to ‘Decommissioned’.

A.23. Data in the system shall not be used for quantitative analysis of flow of goods in the supply chain. Should Member States decide to use the information contained in the repositories system, for the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology, the system shall provide them with the necessary reports.

Yes ☑
No ☐

We believe that this is a valuable feature but again as in A.11, but believe that there must be safeguards in place to prevent stakeholders accessing data for other reasons. One suggestion would be that there is a formal request

process to allow access to the data being requested and that there is a robust governance process in place to monitor this on an EU and national basis.

A.24. The governing principles described in this document will be reflected in the contractual arrangements between EMVO and the National Medication Verification Organizations.

Yes ☑
No ☐

About you

1. What is your name?

Graeme Richardson

2. What is your email address?

Email: graeme.richardson@stft.nhs.uk

3. What is your organisation?

Organisation: Guild of Healthcare Pharmacists

Are you responding as...

Are you responding as:

- A member of the originator industry ☐
- A member of the generic industry ☐
- A parallel trader ☐
- A prescriber ☐
- A wholesaler ☐

- A dispenser ☐
- Other ☑

If you have selected 'Other', please specify

Trade Union Organisation representing Pharmacists working in the managed sector (this will include prescribers, wholesaler, dispensers and manufacturers).

For those answering as a dispenser

- Are you a dispenser ☐
- In the community ☐
- A dispensing doctor ☐
- In a hospital ☐
- In a healthcare institution ☐

Thank you for taking the time to take part in this consultation.

Confidentiality and data protection

The contact information that you provide will be used to perform internal checks to ensure the validity of responses, such as identifying a duplicate response where responses have been submitted via several routes. We may also use this information to inform respondents of any key updates of the consultation.

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOI), the Data Protection Act 1998 and the Environmental Information Regulations 2004.

Under the FOI, there is a statutory Code of Practice with which public authorities must comply and which deals with our confidentiality obligations among other things.