Annex A – Consultation questions and how to respond

Summary of questions

Question 1: What form of sanctions regime do you think would be the most effective to enforce the regulations across the UK medicines supply chain?

We support the approach Government has indicated they are minded to implement (see below). This would be proportionate and reserve criminal sanctions for instances of wilful disregard for patient safety. It would allow a more lenient approach for inadvertent breaches which were corrected on notification that they had occurred. We would also expect the pharmacy regulator to to take note of compliance with the new legislation as they do with any other aspects of pharmacy practice during routine inspections. There should also be a period of grace after the implementation date to allow for new processes and procedures to be embedded into daily routines.

"Government is minded to move to an approach that would use a mixture of both criminal and civil sanctions. Such civil sanction might include written warnings, stop notices and civil fines, before the application of criminal sanctions which would only be used for the most serious (intentionally fraudulent) breaches"

Question 2: Can you provide any additional evidence or comment on the existing impact analysis to develop the cost benefit analysis in the impact assessment?

N/A

Question 3: Do you agree with the Government's proposed approach not to extend the requirements for the unique identifier or anti-tampering device to any additional products at this time?

Yes we agree at this time but this requirement will need to be reviewed regularly to ensure that the safety features are aligned with any new trends in counterfeiting which might appear at a later date.

Question 4: Do you agree with the Government's proposed approach not to require a reimbursement number, or other national number identifying the medicinal product, to be placed on products bearing the safety features?

In the UK there is at present no need for any additional numbers.

Question 5: Do you agree that manufacturers should be allowed to include information other than the unique identifier in the 2D data matrix code?

Yes. We agree that there should be no restriction on manufacturers to allow any future advances in technology to be incorporated should the manufacturers wish to do so. In the longer term the potential for additional information could be developed to support pharmacy practice and patient information.

We therefore welcome allowing the flexibility for extra information which provides commercial opportunity for innovation by the pharmacy software supplies and manufacturers to enhance their PMR systems using new bar code technology.

Question 6: Do you agree with the Government's proposal to put in place provisions requiring wholesalers to verify and decommission medicinal products bearing the safety features before supplying them to any Article 23 provider authorised to supply medicines to the public?

Yes having considered the impact assessment, the complexity of the UK supply chain and consulted with our members we agree this is the best option available.

We are assuming that the term nursing home in this instance will also encompass both care homes and nursing homes as in Scotland these are classified separately but both need to be accommodated in a similar manner.

We have had feedback from Wales requesting that it would be more practical for ambulance trusts not to be classed as healthcare institutions but to be included in the Article 23 list instead. Do we need clarity on how different ambulance trusts work across the UK to ensure all systems are categorised in the most pragmatic way, to allow efficient work flow and facilitate timely patient access to emergency medicines.

Question 7: Do you agree that there is no practical benefit to exempting persons operating within a healthcare institution in the UK from the obligations of verification and decommissioning under the conditions set out in chapter 5

Yes we agree that there is no advantage to making this specific exemption.