Consultation Response sheet

Instructions

- If possible, please send responses electronically to falsified.medicines@mhra.gsi.gov.uk using the following table. Even if you reply in hard copy, please use this table.

- Please also complete and return the confidentiality template

Respondent details

Please provide your details as requested below. The second and third pieces of information would assist us in delivering the Government's commitment to engage with small, medium and micro businesses.

- Please provide your name and (if relevant) the organisation or body you represent:

- Please tick this box if you or the body you represent are in the NHS or public sector: ☐

- If you represent a private sector company, please indicate the number of employees in the company by ticking the relevant box below:

9 or less ☐ 10-49 ☐ 50-249 ☐ 250 or more ☐

Question Number	Question	Response
1	**Are there any other additional costs or savings that should be identified?**	
2	**Have we missed any impacts? If so what are they and what are the costs?**	The impact on the UK economy if the integrity of the UK legitimate supply chain is doubted by overseas traders and existing opportunities for overseas trade diminish.
3	**Are the assumptions we have made in the Impact Assessment considered reasonable?**	
4	**Are there areas in which you consider the proposals for transposition of this Directive "gold plate" the EU requirements – either by inappropriately retaining pre-existing higher requirements or by establishing a requirement that is more onerous than required by the Directive?**	None. The RPS believes the UK Government must take this opportunity to introduce other relatively low cost initiatives that will further enhance patient safety that, without this system, would prove too cost-effective. There is the opportunity to add the requirement to display details of the drug being prescribed, to assist the pharmacist and facilitate a further accuracy check, reducing the number of dispensing errors, further reducing harm to patients and saving the costs of further treatment to rectify the potential harm done.
5	**Do you support the proposed approach to collecting the necessary information for registration from Wholesale Dealers who also broker**	Not Applicable

	medicines? If not, why not?	
6	**Is the proposed transitional period for existing brokers to register with the MHRA reasonable? If not, why not?**	Not Applicable
7	**Brokers will need to spend time throughout the year complying with good practice. However, because brokering does not involve physical handling of products, compliance will be a paper exercise. We have assumed that each broker will spend 80 hours a year complying with good practice, at an hourly cost of £24 (see assumptions section). These assumptions yield annual costs of £0.097 million. Is our assumption reasonable?**	Not Applicable
8	**Brokers of medicinal products will only be able to negotiate trade in medicinal products that are subject to a valid authorisation issued by the European Medicines Agency, or by the Competent Authority in an EEA Member State. How will this affect your business? Can you estimate the proportion of activity you may lose or gain,**	Not Applicable

	and its impact on revenue?	
9	**UK registered brokers will need to have a permanent residence and contact details in the UK. Will this impose an extra burden upon you? If so, can you provide an estimate any additional cost?**	Not Applicable
10	**How much time would you estimate it to take to prepare the information required in the application for registration? What is the estimated cost of this preparation time to your business?**	Not Applicable
11	**Brokers will need to notify the MHRA where changes occur in their trading circumstances, particularly in relation to the information provided in the application for registration. How often would you anticipate needing to make such registration variations? Can you provide an estimate of any additional costs in establishing and maintaining a system to track such changes?**	Not Applicable
12	**Brokers will also need to maintain an emergency plan,**	Not Applicable

	ensuring that recalls of medicines are effectively implemented when required by the MHRA, manufacturers or marketing authorisation holders. Can you provide an estimate of the costs involved in setting up and maintaining such a system?	
13	**Brokers will need to record certain information on the products they broker. These records must be kept for five years, and may be subject to MHRA inspection. Can you provide an estimate of annual cost for keeping such records?**	Not Applicable
14	**Brokers may be inspected at their premises by the MHRA. Straightforward inspections are assumed to last one working day. How much do you anticipate it will cost you to prepare for and facilitate an inspection?**	Not Applicable
15	**Brokers will need to comply with the principles of EU Good Distribution Practice. How much do you estimate this will cost you annually, over and above any established operating costs you may have?**	Not Applicable

16	**Brokers will be expected to maintain a quality system setting out responsibilities, processes and risk management measures taken. Do you currently operate a quality assurance system (such as ISO accreditation)? If so, what is your estimated annual cost of maintaining the quality system? If not, can you estimate how much extra cost you consider would be involved (on an annual basis)?**	Not Applicable
17	**How many other brokers do you know of? Can you estimate how many brokers there are in the UK?**	Not Applicable
18	**Do you know if there are UK or European trade associations representing brokers?**	Not Applicable
19	**Can you provide an estimate of the current annual cost to your business of compliance with the current requirements of EU Good Distribution Practice and UK legislation?**	
20	**Can you provide an estimate of the number of different products**	Not Applicable

	you import from another EEA Member State annually? Can you provide an estimate of the quantities and wholesale value of those products?	
21	**Can you provide an estimate of the number of individual packs of UK authorised POM products you handle in a year?**	Not Applicable
22	**Can you provide an estimate of the time it would take your organisation to verify that a tamper evident seal was intact on an individual pack? Can you provide an estimate of the hourly cost of undertaking such a check?**	Not Applicable
23	**Where recording of batch number is required for a product with a safety feature, would you use a manual system for capturing this information, or would you look to capturing the information automatically (by barcode scanning or RFID signal)?**	Not Applicable
24	**Can you estimate the time it would take your organisation to capture the batch number of an individual pack?**	Not Applicable

25	**Can you give an indication of the scale of capital investment you may require to capture batch numbers, based on your current business model and preferred method of batch number capture (for example, an estimate of the number of bar code scanners you would need to purchase)?**	Not Applicable
26	**Can you describe any other essential systems changes you would need to make as a consequence of recording and then supplying batch number information (for example, automated stock control or accounting systems)?**	Not Applicable
27	**Do you export medicinal products to third countries? Could you estimate the total quantity of product(s) exported and the value (in Pound Sterling) of this part of your business? Could you identify the main countries to which you export?**	Not Applicable
28	**Does your quality system already incorporate documented elements of risk management (for example by incorporating concepts from ICH Q9)? Can**	Not Applicable

	you estimate any additional costs for your business to incorporate risk management into your quality system?	
29	**Is the new requirement for ensuring bona fides of brokers of medicinal products likely to add a significant burden to your business? Can you estimate any additional costs, introduced by Article 17(d) of the FMD, in ensuring the bona fides of your suppliers?**	Not Applicable
30	**Can you estimate any additional costs arising from the requirement to immediately inform the MHRA of any medicinal products you receive or are offered which you identify as or suspect to be falsified?**	Not Applicable
31	**MHRA Good Distribution Practice (GDP) Inspectors have provided information on staff costs. For staff who (will) have direct responsible for ensuring good distribution practice firms that trade medicines, we have assumed that the average annual salary cost is £30,000. Assuming further that non-salary costs add another 30%, that the working year is 215**	Not Applicable

	days and that the working day is 7.5 hours, we estimate the staff cost per hour is £24.	
32	**Other staff will also be involved indirectly in good distribution practice activities. We have assumed that the salary costs for these staff range between £15,000 (for a van driver) to £35,000 (for a warehouse manager). The estimated hourly staff cost is between £12 and £28. Are these costs a reasonable or true reflection of costs in the supply chain?**	Not Applicable
33	**The MHRA has been advised that the cost of informing MHRA of suspicious transactions and products is estimated to be between £15 and £20. Given that these events are, we believe from available evidence, extremely rare we estimate that the incremental cost of this provision is insignificant. Is this a correct assumption to make?**	Not Applicable
34	**We believe that the vast majority of UK wholesalers already diligently check the bona fides of suppliers. Currently they do this by securing a notarised translation of the registration**	Not Applicable

	documents of their suppliers. The introduction of the EU central database of suppliers will remove the need to secure notarised translations of documents. Each notarised translation costs approximately £125. MHRA believe that there are 100 UK firms that currently import from EEA suppliers, that each supplier has on average 20 suppliers and that the annual turnover of suppliers is 5%. These assumptions yield annual cost savings of £12,500 (present value of £107,596). Is this assumption correct?	
35	**Given that UK wholesalers are expected to experience no other changes to their activities as a result of the parts of the FMD that we are analysing in this Impact Assessment, we do not expect there to be any incremental health benefits. Is this a correct expectation to make?**	Not Applicable
36	**The annual cost of contracting a "Responsible Person" (RP) is on average £7,000. The alternative would be to assign the RP role**	Not Applicable

	to an existing member of staff. We anticipate that the RP role requires one third of a full time employee – an estimated £13,000. Is this a correct assumption to make?	
37	**How many wholesale dealers that export medicines to a non EEA country, or import medicines from a non EEA country for export to a non EEA country, do you know? Can you estimate how many such wholesalers there are in the UK?**	Not Applicable
38	**Do you know if there are any trade associations representing such importers and exporters?**	No
39	**Do you agree with the approach proposed to include information in the application form for registration of manufacturers those who also manufacture active substances?**	Not Applicable
40	**Can you estimate the cost of applying for a UK manufacturers licence, taking account of time to prepare the relevant information and preparation for inspection?**	Not Applicable

41	**Do you use third party auditors for the assessment of active substance suppliers (manufacturers or distributors)? If so could you provide an estimate of the annual cost to your business of using such auditors, and the number of man-hours for which they audit on your behalf? Could you provide an estimate of the cost savings to your business that such an approach brings?**	Not Applicable
42	**Do you undertake any audits of active substance manufacturers or distributors in third countries? Could you estimate the annual cost of such audits?**	Not Applicable
43	**Do you already undertake a risk-based approach to assessing your excipient suppliers? If so, could you provide an estimate of the annual cost of such an approach?**	Not Applicable
44	**Do you anticipate that verification of the registration for your active substance suppliers will be a significant burden? If so, could you elaborate on why you consider this to be the case, and provide**	Not Applicable

	an estimate of cost to your business?	
45	**How many active substance suppliers do you routinely use? Can you estimate the annual cost (including man-hours) of auditing these suppliers?**	Not Applicable
46	**How many excipient suppliers do you routinely use? How do you anticipate ensuring compliance with good manufacturing practice (identified through the risk assessment)?**	Not Applicable
47	**Can you estimate the annual cost to your business of ensuring compliance of excipient suppliers with the requisite good manufacturing practices?** *Specific questions for suppliers of active substances*	Not Applicable
48	**Do you operate a quality system (e.g. ISO accreditation)? Please specify the quality system you work to.**	Not Applicable
49	**Are you audited by your customers? How frequently?**	Not Applicable

	Can you estimate the annual burden (cost and man-hours) in hosting audits by manufacturers of medicinal products?	
50	**Using the current requirements of Part II of the EU GMP guidelines as a basis, can you estimate the annual cost of compliance?** **Do you export any active substances to countries outside of Europe (please specify which countries)? Are these active substances manufactured to the same GMP standards as material destined for Europe? If not, can you estimate any additional costs to bring manufacture into compliance with EU GMP standards?**	Not Applicable
51	**Can you estimate how often significant changes are made to your business (e.g. types of materials manufactured/distributed, quantities manufactured, manufacturing and storage facilities)?**	Not Applicable
52	**Do you supply "atypical actives"? Can you describe the impact of the requirements of**	Not Applicable

	the Falsified Medicines Directive on your business in this area?	
53	**The biggest incremental costs will come from the requirement to maintain GDP. Each firm will need to comply with the requirement of GDP for active substances. Estimating these costs is not straightforward. The annual cost of contracting a specific GDP staff member is on average £7,000. The alternative would be to assign these responsibilities to an existing member of staff. We anticipate that the GDP staff role requires one third of a full time employee – an estimated £13,000. The effect of the Falsified Medicines Directive is likely to be to increase substantially the demand for contractor GDP staff and hence the cost will probably rise. To account for this likelihood, we have chosen the full £7,000 to £13,000 range to represent the annual cost to firms. These assumptions yield total annual costs of between £0.455 million and £0.845 million. Have we got the costing right?**	Not Applicable

54	**How many GDP qualified staff do you currently need? How many of them are contracted and how many of them are full-time employees? Will you need any additional GDP qualified staff to meet these new commitments? If so, how many will you need?**	Not Applicable
55	**Do you know of any active substance manufacturers in the UK? How many do you estimate that there are as a whole?**	Not Applicable
56	**Do you know of any active substance manufacturers in the EU? How many do you estimate that there are as a whole?**	Not Applicable
57	**Do you have any dealings with third country active substance manufacturers? Do you know of any cost that they will incur as a result of getting certification from their domestic competent authorities and increasing the quality of their GMP?**	Not Applicable
58	**Do you operate a quality system (e.g. ISO accreditation)? Please specify the quality system you work to. Could you estimate the**	Not Applicable

	annual cost of maintaining the quality system?	
59	**Are you audited by your customers? How frequently? Can you estimate the annual burden (cost and man-hours) in hosting audits by manufacturers of medicinal products?**	Not Applicable
60	**We have been unable to estimate the cost to the UK of implementing these measures. Our current expectation is that the costs will not be substantial. If you are legally entitled to sell medicines to the public at a distance, via the internet, how much will it cost you to have your website amended to include the common logo and to be linked to the EMA website.**	Not Applicable
61	**How many other distance selling pharmacies do you know of? Can you estimate how many distance selling pharmacies there are in the UK?**	Not Applicable
62	**Do you agree with this approach to the development of offences and sanctions?**	Yes
63	**Do you agree with the approach**	Not entirely.

	we have take to the transposition of the Falsified Medicines Directive? Please explain why, or why not.	The RPS believes the emphasis in this consultation is almost solely on the cost to business, rather than the effect it will have on patients. This Directive has been brought forward solely to increase patient safety but this term isn't used in the consultation document.
64	**Do the draft regulations inadvertently introduce any unforeseen changes?**	Snipping etc
65	**Have you identified any potential errors in the draft regulations?**	
66	**Are there any provisions that you do not understand, or that could be made clearer?**	
67	**Are you able to comply with the requirements of the legislation? If not, why not?**	Nor suitable for UK volume
68	**Are there any other benefits and/or costs arising from the way that we propose to transpose the Falsified Medicines Directive?**	
69	**Are you a micro (<10 employees), small (10-50), medium (50-250) or large (250+) business? Can you estimate the proportions of the sizes of the businesses within your sector?**	

Further comments (please use a separate row for each comment and insert more rows if necessary)

Number	Further comment
General	The RPS understands this Directive enhances patient safety by reducing the potential for counterfeit drugs to enter the legitimate drug supply chain. The costs of introducing this measure are an important factor, but patient safety is at least as important. We are surprised that that patient safety isn't mentioned once in any of the 69 questions above and there are no questions relating to the potential for the introduction of this Directive to enhance patient safety. The RPS believes that the cost of implementing this directive will be substantial and unless features are installed to increase patient safety through minimising dispensing errors, there will be no patient benefit at community pharmacy level. Counterfeiting would be better addressed by increased scanning at wholesale levels because the current frequency of counterfeits entering the chain at dispensary level are negligible
General	Adoption of the Directive in the form set out by the MHRA does not recognise current pharmacy practice. It offers no benefits to those responsible for using the system and it appears there is little potential to police the system, to ensure that packs are scanned at the point of dispensing. There appears to be little reason why this Directive is implemented if none of the patient safety benefits are realised.
General	The RPS is concerned that the UK will be exposed as the only member state with a different system and a perceived weak link in the legitimate medicines supply chain. This will have a negative impact on the UK's ability to trade, as the medicines traded from the UK will be considered at a greater risk of patient harm than those traded between member states who fully adopt the measures included in the Directive. Those exporting medicines, either as a broker or wholesale dealer, will be required to prove their integrity very much in the same way as medicines originating from less secure parts of the world. It is highly likely that this activity will result in incurred costs, time and resources that will remove some of the UK's competitive advantage. On balance, the RPS believes that implementation at the individual pharmacy level will be disruptive to patient safety through additional workload. Implementation of the directive should therefore include the creation of safety checks to reduce dispensing errors, operated

	by using the data encoded in the barcode.
General	The RPS believes that counterfeiters will pass their counterfeit products on, into markets with the weakest security checks, rather than face the challenge of trying to sell to member states who are benefiting from enhanced protocols that drive up standards of patient safety. The UK is in danger of being recognised as an opportunity, where it may be possible to sell into the medicine supply chain with potential follow-on sales into member states that employ the new measures set out in the Directive. As such, the UK may face increased levels of counterfeits medicines being sold into the legitimate medicines supply chain.
9.1	New safety features are an essential aspect of the new system to be introduced via the Falsified Medicines Directive. Sections 9.1 – 9.3 provide an outline of possible new safety features, to be introduced by a delegated act. These safety features must be fully implemented for patient benefits to be realised. Before implementation, the UK must also amend current pharmacy practice to ensure that whole packs of medicine can be dispensed wherever possible. This issue usually arises where prescriptions are received for multiples of 28 or 30 tablets when packs are of a different size to the prescribed amount. The result is that sealed packs will be opened and two or more tablets are snipped from a blister pack. The result carries patient safety issues in that the two remaining tablets are unlikely to have the expiry date and possibly even the batch number on them. . Patients are likely to suspect the integrity of the resulting opened pack. The RPS believes this practice is unnecessary and whole packs must be dispensed, similar to the system used in Scotland, where prescriptions can be adjusted to either include or exclude 10% of the number of tablets on the original prescription. This single addition allows pharmacists to be able to dispense whole packs, with the tamper-proof seal intact.