BRITISH GENERIC MANUFACTURERS ASSOCIATION

DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION

Response by the British Generic Manufacturers Association (BGMA), interest group registration 52609045913-87, to the European Commission's Concept Paper submitted for public consultation (Sanco.ddg.1.d.3(2011)1342823, dated 18 November 2011)

Friday, 27 April 2012

The British Generic Manufacturers Association represents the interests of UK-based manufacturers and suppliers of generic medicines and promotes the development and understanding of generic medicines in the United Kingdom.

Generic medicines contain the same active ingredient and are as effective as the equivalent brand and cost much less, making the UK National Health Service (NHS) drugs bill affordable. 65% of all medicines dispensed by the NHS are generics yet they cost only 26% of the NHS drugs bill, a saving of around £8.6bn in England & Wales alone. Without generics, the NHS drugs bill would be approximately twice its current level. Competition from generics also stimulates the research based pharmaceutical industry to develop new medicines.

Our 19 members account for around 85% of the UK generics market by volume. Their work keeps medicines affordable for the Department of Health which allows further investment in other healthcare priorities, and promotes innovation in the development of new medicines.

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1. SUMMARY

1.1. We set out our basic conclusions under the different consultation topics in this section with the paragraphs from which they are drawn. Further detail and arguments are presented in the body of the paper.

1.2. CONSULTATION TOPIC NO 1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

1.2.1. The BGMA is generally in favour of manufacturers being allowed to choose their own methods of meeting legislative and regulatory requirements, but the Commission should establish base parameters which would ensure the interoperability of different technical specifications or the operating standards that different technical specifications should meet. (3.1)

1.2.2. We agree the proposed composition of the serial number, but we do not agree the proposed requirement for it to be based on a single existing standard. A multiplicity of accepted open standards would maintain and facilitate competition in the marketplace, consistent with maintaining downward pressure on costs. (3.2.1)

1.2.3. To require manufacturers to add either the batch number or the expiry date to the unique identifier would be beyond the requirements of the legislation. (3.3.1)

1.2.4. There may be supply chain or other commercial benefits in manufacturers choosing voluntarily to include further data on batch number and / or expiry date without the need for the very costly repository systems and anti-tampering features. (3.3.6)

1.2.5. There is no such thing as a pack-specific reimbursement number in the UK. (3.4.1)

1.2.6. No case exists for the cost-effectiveness of RFID in terms of the objectives of Directive 2011/62/EU. (3.5.1)

1.2.7. We see no case to require a change from linear bar codes to 2D codes. Linear and 2D codes and the scanning equipment used should all be compatible and interoperable and relevant rules should give the flexibility to use either. (3.5.5)

1.2.8. The implementation costs for the EU generic industry could be as high as €1 billion and verification costs could be as high as €200 million per year, showing the absolute need for a cost-effective, proportionate and risk based approach. (3.6)

1.3. CONSULTATION TOPIC NO 2: MODALITIES FOR VERIFYING THE SAFETY FEATURES

1.3.1. There is nothing in the Directive that specifically requires a check out process as opposed to verification: this could cause confusion and unnecessarily disrupt the supply of medicines to patients. (4.1)

1.3.2. Directive 2011/62/EU contains no powers to require dispensers to verify the authenticity of products as proposed, and this is not consistent with the objective of Directive 2011/62/EU which is stated to be "specifically to prevent falsified medicinal products from entering the legal supply chain". (4.2.1)

1.3.3. We are advised that the delegated act cannot limit the over-riding requirement of Article 80(ca) of Directive 2001/83/EC which requires that wholesalers "must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging …". (4.3.2)

1.4. CONSULTATION TOPIC NO 3: PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

1.4.1. We believe that more work has to be done before it is possible definitively to favour one option over the others. (5.1.1)

1.4.2. We favour a system of stakeholder governance, but we believe that there must be competition between suppliers to ensure efficiency and cost containment. (5.1.2)

1.4.3. We urge the Commission to apportion costs according to the manufacturer's net ex-factory price of the products deemed to be of high risk and required to carry the unique identifier. (5.1.3)

1.4.4. We agree that all of the information identified by the Commission is commercially sensitive. (5.2.1)

1.5. CONSULTATION TOPIC NO 4: LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES

1.5.1. The general principles set out in the Concept Paper for selecting products for the lists are inconsistent with the requirement that the stated risk criteria should be the guide for formulation of any list. (6.1.4)

1.5.2. We disagree that "A manufacturer cannot decide to apply the unique identifier to medicinal products which do not fall within the scope of the safety feature". (6.1.7)

1.5.3. The inclusion of a medicinal product on the white or black lists should be by its invented name or INN plus MAH as recorded on the Marketing Authorisation and not active pharmaceutical ingredient; a product category may be "generic medicines". (6.1.8)

1.5.4. It is clear that the legislation envisaged "generic medicines" being added to the white list as a category, and we propose that this should be done. (6.1.9)

1.5.5. We seek no exemption from the provisions of Directive 2011/62/EU for generic medicines; merely that the provisions of the Directive should be properly and proportionately applied. If a particular generic medicinal product were to be found to be of high risk, then it should be removed as a product from the white list. (6.1.10)

1.5.6. We propose that the Commission should establish an expert advisory committee comprised of Member States' competent and enforcement authorities to review evidence relating to the risk proposed by

products or categories of product according to the established criteria listed in Article 54a2(b) and available intelligence, and advise the Commission on whether they should be added to or removed from the white or black lists. (6.2.6)

1.5.7. But, if a quantified approach is to be used to judge risk, it must be weighted according to the relative importance of the different factors listed in Article 54a2(b). We believe that the Commission must undertake a study, as we propose elsewhere in this response, of the actual factors behind counterfeited products before reaching a firm conclusion. (6.2.9)

2. INTRODUCTION

2.1. The BGMA, representing UK-based manufacturers and suppliers of generic medicines, is pleased to respond to the Commission's Concept Paper. We have also welcomed the Commission's outreach to stakeholders through meetings, some of which we have been able to attend.

2.2. The BGMA supports all effective and proportionate measures to prevent counterfeit medicines reaching patients. We are acutely aware that the major difficulty appears to lie in the illegal supply chain, frequently accessed by patients via the internet. We are also aware, though not complacent, that no counterfeit generic medicine has been discovered in the legal supply chain in the EU.

2.3. Against this background, and consistent with the objective of Directive 2011/62/EU of preventing "falsified medicinal products from entering the legal supply chain", we are strongly supportive of national measures to enhance the integrity of the legitimate supply chain. It is clear that, for a counterfeit medicine to reach a patient through the legitimate supply chain, someone in that chain must have done business with a criminal: we see, therefore, integrity of the supply chain as the key defence against counterfeit medicines reaching patients.

2.4. As Directive 2011/62/EU recognises, it is appropriate to take a risk based approach to requiring the application of the safety features, and particularly the unique identifier, to medicines since counterfeiters are highly selective of the products they choose to falsify in the EU's regulated and reimbursed markets. We comment below in further detail on the way in which this required risk assessment should be carried out.

2.5. Cost effectiveness of the implementation proposals is also particularly important if the generic industry, based in the UK on a high volume low cost model, is to be able to continue to exert downward pressure on prices, and thus extend the availability of high quality medicines to all European patients. Though we appreciate that the Commission is required to undertake an impact assessment of its proposals, we are concerned that the Concept Paper does not reflect what we feel to be an appropriate level of concern about cost effectiveness at this stage of the process.

2.6. We look forward to the next stages of the Commission's assessment, and were grateful for the Commission's confirmation at its stakeholder meeting on 21 June 2011 that there will be a full impact assessment process. We note that, in paragraph 4 of its Concept Paper, the Commission suggests that the impact assessment need not encompass the impact of the safety feature *[sic]* itself since this is a requirement. We thing that this is an artificial distinction: many of the judgements that are yet to be taken will impact on the cost-effectiveness of the safety features themselves, and we think it necessary to take account of that impact in the impact assessment. We are also aware that data may have changed or have been refined since the original impact assessment was undertaken.

2.7. We stand ready to assist the Commission in any way in which we can. We recognise that there are complex legislative and commercial issues at play here, and are very willing to put our expertise and

understanding at the Commission's disposal, and to discuss any points that may arise from this response.

3. CONSULTATION TOPIC NO 1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

3.1. CONSULTATION ITEM NO 1: BENEFITS AND DISADVANTAGES OF POLICY OPTIONS NO 1/1 AND NO 1/2 (TECHNICAL SPECIFICATION OF THE IDENTIFIER TO BE LEFT TO THE INDIVIDUAL MANUFACTURER, OR HARMONISED THROUGH REGULATION)

3.1.1. The BGMA is generally in favour of manufacturers being allowed to choose their own methods of meeting legislative and regulatory requirements, and believes that this is also consistent with the better regulation principles adopted by the European Commission and many Member States. We take it as read that any technical specification adopted by a manufacturer would need to meet the requirements of Directive 2011/62/EU.

3.1.2. Equally, however, at a practical level, it is important that supply chain operators, where required, are able efficiently to verify the authenticity of a medicinal product carrying a unique identifier. A multiplicity of different technical specifications could make this difficult or more expensive than necessary.

3.1.3. At the least, therefore, we believe that the Commission should establish base parameters which would ensure the interoperability of different technical specifications or the operating standards that different technical specifications should meet. Specific requirements should only be enforced if the Commission's impact assessment of its proposals can show that this would be more cost-effective than leaving the specification to individual manufacturers.

3.2. CONSULTATION ITEM NO 2: ADVANTAGES AND DISADVANTAGES OF THE APPROACH SET OUT IN POINT 2.1.1 (SERIALISATION NUMBER INCLUDING MANUFACTURER PRODUCT CODE AND UNIQUE PACK NUMBER BASED ON EXISTING INTERNATIONAL INDUSTRY STANDARDS)

3.2.1. We agree the proposed composition of the number, but we do not agree the proposed requirement for it to be based on a single existing standard. Different standards are already used in different Member States, and we believe that this degree of subsidiarity should be maintained and open standards adopted or permitted. Indeed, a multiplicity of accepted standards would maintain and facilitate competition in the marketplace, consistent with maintaining downward pressure on costs.

3.3. CONSULTATION ITEM NO 3: ADVANTAGES AND DISADVANTAGES OF POINTS (A) AND (B) IN 2.1.2 (ADDING BATCH NUMBER AND EXPIRY DATE TO THE UNIQUE IDENTIFIER)

3.3.1. The relevant provisions contained in Article 54 of amended directive 2001/83/EC provide for, *inter alia*, safety features to enable relevant parties to "verify the authenticity" and "identify individual packs". This can be done with manufacturer and product codes and nothing more. This sets the limits of the requirement of the new rules and there are no provisions in amended Directive 2001/83/EC that give the Commission powers to require, in the delegated act, manufacturers to add either the batch number or the expiry date to the unique identifier. To do so would, therefore, be beyond the requirements of the legislation, and make the delegated act subject to legal challenge.

3.3.2. That aside, we note that paragraphs 23 and 24 of the Concept Paper make the case for the inclusion of the batch number and expiry date in the serialisation number without discussion of the additional costs or alternative more cost-effective means of achieving the same ends. Article 54a2(a) requires the Commission, in "establishing the safety features" of which the serialisation number is a part, to give "due consideration … to their cost-effectiveness". It may be that the Commission intended to consider this in the future impact assessment, but we find it disturbing that no consideration was given to cost or proportionality in the Concept Paper itself.

3.3.3. It is also noted that Article 54a(3) requires the Commission, when adopting measures under Article 54a(2) to take due account of a non-exhaustive list of factors. This specifically includes the "cost-effectiveness of the measures". This reinforces the need for the Commission to look into these issues across the board which the Concept Paper does not address. We comment elsewhere in this response about the requirement of Article 4 of Directive 2011/62/EU for the Commission to carry out an impact assessment and our concern that cost-effectiveness does not appear to have been considered in the Concept Paper to the extent that it could have been, even short of a full impact assessment.

3.3.4. In this regard, it should be noted that including the batch number and / or expiry date within the unique identifier would be likely to lead to manufacturers incurring additional costs. Some manufacturers, perhaps particularly SMEs, may choose to print the codes and unique identifier where required off-line and associate individual packs with the identifier and, if appropriate, the batch number and expiry date via a reader on the production line. The batch number and expiry date would still be available via a database or repository, and could be read by on-line scanners, even though not within the identifier itself. Where this approach would be more cost effective, particularly for smaller manufacturers, it appears to be inappropriate and discriminatory to prevent those manufacturers adopting it.

3.3.5. Further, applying elements (at extra cost) that are not needed but merely "nice to have" could be disproportionate and act in a discriminatory way whereby these raise the cost of product to a level where some suppliers may not be able to enter or remain in the market. This would potentially damage the resilience of the low cost generic supply chain and reduce the availability of medicines to patients. These are negative socioeconomic impacts which run counter to EU and Member State policies. The extra cost associated with adding these requirements would favour larger and more established suppliers and reinforce market dominance of incumbent suppliers. As well as being discriminatory, this would have cost consequences for member states and possible implications for security of supply to patients across the EU. It should also be pointed out that the batch number and expiry date are required on packaging under current rules and this will remain the case. In this context, any benefit can only be considered as marginal and actors throughout the supply chain can carry out relevant checks as necessary.

3.3.6. We do appreciate that there may be supply chain or other commercial benefits in manufacturers choosing voluntarily to include further data on batch number and / or expiry date, for example as part of commercial arrangements with their customers. This would be outside the delegated act's requirements and without prejudice to the risk assessment required by Directive 2011/62/EU. We also note than any voluntary application of the unique identifier for these sorts of reasons would be done without the need for the very costly repository systems and anti-tampering features.

3.4. CONSULTATION ITEM NO 4: ADVANTAGES AND DISADVANTAGES OF OPTIONS UNDER POINT (C) OF 2.1.2 (REPLACING THE NATIONAL REIMBURSEMENT NUMBER WITH THE UNIQUE SERIALISATION NUMBER, OR ADDING IT TO THE SERIALISATION NUMBER)

3.4.1. There is no requirement in the UK to place a reimbursement number on the pack, and it would clearly be a fundamental national decision to do so. Indeed, there is no such thing as a pack-specific

reimbursement number in the UK. We believe that all decisions of this type are for the national authorities and not the European Commission. We see this as an optional addition, that any system put in place should allow, but not mandate, and we refer to our comments above in this respect.

3.5. CONSULTATION ITEM NO 5: BENEFITS AND DISADVANTAGES OF DIFFERENT CONCEPTS FOR THE TECHNICAL CHARACTERISTICS OF THE CARRIER (LINEAR BAR CODE, 2D-BARCODE, OR RFID)

3.5.1. We believe that no case exists for the cost-effectiveness of RFID in terms of the objectives of Directive 2011/62/EU.

3.5.2. Current UK practice is to apply product information using a linear bar code. Scanners exist at appropriate levels of the supply chain and within the National Health Service (NHS) that can read these codes. A linear code can carry the information required by Directive 2011/62/EU. The objectives of the Directive could therefore be met without additional cost in relation to the carrier by utilising linear bar code technology.

3.5.3. We note too that availability of scanners is not the end of the story – infrastructure needs to be put in place to disseminate software to run all this and then allow access to and / or distribute codes across the system to check all this. This will have a significant cost and given past performance on NHS IT developments is likely to be problematic especially at the point of dispensing. This could lead to the conclusion that simpler is better and mandatory checking out is not going to work

3.5.4. We acknowledge that a 2D code takes less space on the pack than a linear code; and that a change to 2D would be required to include additional information that manufacturers may wish to apply voluntarily (see paragraph 3.3.6 above). We envisage, therefore, that there might be a natural shift from linear to 2D codes. We believe that scanning equipment is available that can scan linear and 2D codes equally effectively.

3.5.5. We see no case, therefore, in terms of the requirements of Directive 2011/62/EU, cost-effectiveness or proportionality for the delegated act to require a change from linear bar codes to 2D codes. Rather, we believe that the Commission should ensure that linear and 2D codes and the scanning equipment used are all compatible and interoperable and relevant rules give the flexibility to use either.

3.6. COSTS

3.6.1. We stress that the costs involved here are considerable. SMEs will have proportionally higher costs than larger manufacturers. With our European association (the European Generic medicines Association, EGA), we have calculated that, based on the production of 10 billion packs per year and assuming a five year life span for a manufacturing line, the implementation costs for the EU generic industry could be as high as €1 billion; and verification costs could be as high as €200 million per year. (Please see the EGA's submission for a further breakdown.)

3.6.2. These numbers show the absolute need for a cost-effective, proportionate and risk based approach if the generic industry is to be able to continue to deliver its prime societal benefit of cost containment and increasing the availability to high quality, lifesaving medicines for the Union's citizens.

4. CONSULTATION TOPIC NO 2: MODALITIES FOR VERIFYING THE SAFETY FEATURES

4.1. PROPOSAL TO "CHECK OUT" PACKS

4.1.1. There is nothing in the Directive that specifically requires a check out process as opposed to verification. The Commission may lack powers to enforce a check out procedure.

4.1.2. Whilst we can appreciate some value in this possible approach, we cannot see it as something that is 100% safe and fear that it would need a lot of effort for everyone across the EU for potentially little benefit. A counterfeit product that has a number that could be accepted could be dispensed before the authentic one is dispensed, and this would flag the authentic as a counterfeit later. There is a possibility that this could just cause confusion and unnecessarily disrupt the supply of medicines to patients.

4.1.3. This would be exacerbated by the range of healthcare professionals who are empowered to dispense medicines. As well as community pharmacists, these include hospital pharmacists and other professionals, doctors, internet providers, homecare services, etc. The scope for confusion and failure of a check out system is considerable.

4.2. CONSULTATION ITEM NO 6: COMMENTS ON CHECK-OUT AT THE POINT OF DISPENSING (POLICY OPTION NO 2/1)

4.2.1. Whilst, under the Commission's proposed system of check-out, we can understand to some extent the logic and thinking behind the proposal that products should be checked out at the point of dispensing to verify them prior to being received by a patient, we feel bound to point out that:

- Directive 2011/62/EU contains no powers to require dispensers to verify in this way. Article 54a2(d) of amended Directive 2001/83/EC merely provides that the "modalities shall allow [our emphasis] the verification", and not that it must be undertaken. In the absence of a specific requirement to check out and additional powers for this in Directive 2011/62/EU, verification by dispensers appears to be a matter for the Member States and not the delegated act.

- Verification by dispensers is not consistent with the objective of Directive 2011/62/EU which is stated to be "specifically to prevent falsified medicinal products from entering the legal supply chain" (Recital 29). By the time they are dispensed, medicinal products have been in the legal supply chain for some time.

4.2.2. Further there are good public health and patient safety reasons for such checks to be made higher up the supply chain. It is clearly in all parties' interests that the earlier a counterfeit product is identified, the more likely that this product will not reach the patient. We believe that falsified products do not enter the supply chain at retail level: they enter at an earlier stage of the supply chain. From a patient safety and security of supply perspective, it is also far better that a product is identified away from the dispensing point so that delays in patients receiving medication at pharmacy level are minimised and identified earlier. Disruption at pharmacy level could mean that patients do not receive medicines when needed.

4.2.3. We can only conclude, therefore, that to require dispensers to verify at the point of dispensing would be *ultra vires* and would risk making the delegated act subject to legal challenge. The only mandated specific requirement to verify in Directive 2011/62/EU arises in Article 80 of amended directive 2001/83/EC and relates to wholesalers and, as noted below, the Concept Paper has failed properly to address this requirement or how it should be fulfilled.

4.3. CONSULTATION ITEM NO 7: COMMENT ON POLICY OPTIONS NO 2/1 (DISPENSER CHECK OUT), NO 2/2 (DISPENSER CHECK OUT WITH RANDOM VERIFICATION BY WHOLESALERS), NO 2/3 (DISPENSER CHECK OUT WITH SYSTEMATIC VERIFICATION BY WHOLESALERS)

4.3.1. Article 80(ca) of amended Directive 2001/83/EC states that wholesalers "must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts referred to in Article 54a(2)".

4.3.2. We are advised that any interpretation of this Article based on the premise that the delegated act could in some way limit the application of the over-riding requirement on wholesalers to verify the medicinal products received are not falsified by checking the safety features would be an incorrect implementation of this specific legal requirement and would go against the specific and general intention of the legislation. A more correct interpretation of the legal requirements would be that the wholesaler must verify all products received which bear the safety features in line with the technology solutions adopted by the delegated act as the modalities are set out. We also note that this is consistent with Directive 2011/62/EU's objective of preventing "falsified medicinal products from entering the legal supply chain".

4.3.3. Any policy option absolving wholesalers from this requirement would fail to implement the legislation and would be *ultra vires* and would risk making the delegated act subject to legal challenge. Even if the legislation were to be interpreted so as to reduce the obligation on wholesalers to some extent, the legislation via Article 80 still clearly envisages that wholesalers "must verify" in some way or other. The Concept Paper fails to address this and makes erroneous assumptions in the policy options set out in item 7. Conversely, there is no specific mandatory legal requirement on other actors in the supply chain to verify the authenticity of the product.

4.3.4. We recognise that wholesalers have argued that it would be practically impossible for them to verify all medicinal products by scanning them on arrival, so they cannot meet the requirements of Article 80(ca). We understand that they have also argued that they need to have batch numbers in the unique serial number to enable them to collect these data. These arguments are, of course, mutually contradictory, and thus lack force.

4.3.5. It must also be pointed out that, as noted above, checks earlier on in the supply chain have significant benefits. Whilst checks at wholesale level will create some extra workload it must also be recognised that checks at dispenser level would also create workload, and that systems at dispenser level will be less likely to cope with this and introduce greater costs overall to systems of medicines supply across the EU.

4.3.6. In fact, the issue is dealt with by Directive 2011/62/EU itself: Article 80(e) of amended Directive 2001/83/EC requires wholesalers to maintain records of the batch numbers "at least for products bearing the safety features"; and the Article 80(ca) requirement to check the safety features can only apply to those products that bear them. The sort of focused risk assessment for which we argue below would result in only those few products of truly high risk of falsification bearing the safety features, thus making the task faced by wholesalers to be reasonable and proportionate.

4.3.7. Paragraph 57 of the Commission's Concept Paper puts forward the argument that verification by wholesalers and dispensers facilitates recall of medicinal products from patients. Indeed, it has been put to us by other stakeholders that Article 117a2 of amended Directive 2001/83/EC requires manufacturers to apply batch numbers to the serialisation number. This is clearly a false argument. That Article places obligations solely on Member States and not on other actors; and the Concept Paper

makes no argument in favour of its assertion in paragraph 57 of the Concept Paper, which we do not believe to be substantiated.

5. CONSULTATION TOPIC NO 3: PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

5.1. CONSULTATION ITEM NO 8: BENEFITS AND DISADVANTAGES OF STAKEHOLDER, EU OR NATIONAL GOVERNANCE

5.1.1. We believe that more work has to be done before it is possible definitively to favour one option over the others. Much will depend upon decisions on other issues canvassed within the Commission's Concept Paper. We look forward in due course to the Commission's further impact assessment when we anticipate seeing these options explored further. Whilst we have had extensive discussions with many systems providers and other stakeholders ourselves, inevitably each seeks to demonstrate the cost-effectiveness of his own system, making it difficult to reach conclusions about the relative value of the claims made.

5.1.2. Instinctively, we favour a system of stakeholder governance, but we believe that there must be competition between suppliers to ensure efficiency and cost containment. We also want a system where the control over the system is fair and where no party using it has undue or unfair influence in how it operates or develops.

5.1.3. We are aware that Article 54a2(e) of amended Directive 2001/83/EC provides that, in the context of the delegated act, the "costs of the repositories system shall be met by the manufacturing authorisation holders of medicinal products bearing the safety features". In assessing its position here and bringing forward the proposed delegated act, we urge the Commission to apportion costs according to the manufacturer's net ex-factory price of the products deemed to be of high risk and required to carry the unique identifier. The generic industry plays a vital role in ensuring the sustainability of healthcare of the EU's citizens by providing large volumes of high quality medicines at low prices. A division of costs on the basis of volume of products would undermine that vital contribution to society.

5.2. CONSULTATION ITEM NO 9: ITEMS OF INFORMATION THAT ARE COMMERCIALLY SENSITIVE

5.2.1. We agree that all of the information identified by the Commission as commercially sensitive – on the number of packs manufactured, the point of dispensing of a pack, the point of re-packaging of a pack – should be protected.

5.2.2. We would go further:

- No data generated by meeting the requirements of Directive 2011/62/EU, or placed on the repository or repositories created for that purpose, or otherwise generated in a way associated with the implementation of the Directive should be allowed to be used for any commercial purpose other than by the supplier supplying these data.

- No data generated by meeting the requirements of Directive 2011/62/EU, or placed on the repository or repositories created for that purpose, or otherwise generated in a way associated with the implementation of the Directive should be allowed to be used by the authorities for any other purpose than that specified or otherwise provided for in law.

- Suitable protections must be put in place to protect and maintain the confidentiality and access to relevant information.

5.3. Consultation item no 10: Other data issues

5.3.1. We agree that no personal data should be associated with the repository or any other data collected for the purposes of implementing the Directive.

6. Consultation topic No 4: Lists containing the medicinal products or product categories which, in the case of prescription medicines shall not bear the safety features, and in the case of non-prescription medicines shall bear the safety features

6.1. Consultation item no 11: Which approach to establishing the white and black lists seems most plausible?

6.1.1. In paragraph 84, the Concept Paper states that "The possibility of exemptions from the general principle laid down by the legislation should be interpreted narrowly. It should not be used as an opportunity to dilute the general principle that all prescription medicines shall bear the safety feature while non-prescription medicines shall not bear the safety feature."

6.1.2. We believe this to be an unreasonable, discriminatory and legally unsustainable interpretation of the provisions of Directive 2011/62/EU which should be applied in line with its wording and provisions, and following the processes it sets out. These clearly do not allow scope for an arbitrarily "narrow" interpretation which prejudges these issues prior to implementation and without following relevant processes.

6.1.3. Article 54a of amended directive 2001/83/EC makes clear that the safety features shall be required to be applied only on the basis of an assessment of "the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products", as the Concept Paper acknowledges in paragraph 82. By insisting on a narrow interpretation from the outset, the Commission has prejudged the risk assessment and fallen short of its normal standards of consultation. This would make any list adopted on this basis at risk of legal challenge.

6.1.4. As well as the risks that need to be considered when drawing up the black and white lists, paragraph 83 also repeats detailed rules set out in legislation on the criteria to be applied when creating these. The general principles set out in the Concept Paper are inconsistent with the requirement that such a detailed list should be the guide for formulation of any list.

6.1.5. Further, if the reference in paragraph 84 to "general principle" is to the sentence in Recital 11 that reads "Medicinal products subject to prescription should as a general rule bear the safety features", this must be interpreted in the context of the sentences which precede and follow it:

- "The scope of these safety features should take due account of the particularities of certain medicinal products or categories of medicinal products, <u>such as generic medicinal products</u>" [our emphasis]; and

- "However, in view of the risk of falsification and the risk arising from falsification of medicinal products or categories of medicinal products there should be the possibility to exclude certain

medicinal products or categories of medicinal products subject to prescription from the requirement to bear the safety features by way of a delegated act, following a risk assessment".

6.1.6. The Concept Paper also argues in paragraph 84 that "The drafting and adoption of the initial delegated act, and of each subsequent amendment, takes around two years" and that thus "Any listing of medicines, in particular as regards the 'white list', has to be carried out with an eye to future developments", seemingly to seek to justify a minimal white list, albeit on spurious grounds. The inability of the Commission to act quickly, particularly in the absence of any effort to find a more effective way in which to operate, is no such justification. This position is also contrary to the provisions of Article 54a2(c) which requires the Commission to adopt in a delegated act a rapid [our emphasis] system for evaluating and deciding on notifications by the national competent authorities of products to be added to the white or black lists. Two years is clearly unreasonable in this context, especially in emergency situations. Other processes in the medicines regulatory system work on much shorter timescales in the order of a number of weeks and with the facility for input from all stakeholders.

6.1.7. Paragraph 85 states that "A manufacturer cannot decide to apply the unique identifier to medicinal products which do not fall within the scope of the safety feature". The Concept Paper makes no justification for this. There is no prohibition of this in legislation – consistent with its major Treaty Base of Article 95 (now Article 114 of the TFEU) – and this is inconsistent with what currently happens across the EU and the transitional provisions of Directive 2011/62/EU. The latter clearly assumes that different systems might currently exist in Member States now that will cross over with the new requirements. It is open, therefore, for manufacturers to apply the safety features even if not required to do so.

6.1.8. In paragraph 86, the Concept Paper debates whether the "medicinal products or product categories" to be placed on the white or black lists should be defined by ATC, brand name, name of the active pharmaceutical ingredient [we assume INN], or by taking a flexible approach on a case-by-case basis. We note that "medicinal product" is defined in Directive 2001/83/EC as a "substance" which is given a name – an invented name or INN plus MAH – as part of its marketing authorisation. "Product category" is not defined, but it is clear from Recital 11 that "generic medicines" is a category envisaged by Directive 2011/62/EU ("categories of medicinal products, such as generic medicinal products"). It is clear, therefore, that the inclusion of a medicinal product on the white or black lists should be by its invented name or INN plus MAH as recorded on the Marketing Authorisation and not active pharmaceutical ingredient; and that a product category may be "generic medicines". There is no evidence to suggest that the legislator intended this to apply to ATC.

6.1.9. We conclude, therefore, that the provisions of Directive 2011/62/EU require an assessment to be made of all medicinal products or classes of medicinal product before a decision is taken on whether they should be added to the white or black lists. We note that Directive 2011/62/EU is concerned solely with "prevent[ing] falsified medicinal products from entering the legal supply chain". We understand from the UK competent authorities that no falsified generic medicinal product has yet been found in the legal supply chain in the EU. We find this compelling evidence that generic medicinal products are of low risk of falsification and should be added to the white list as a category. We believe that it is clear that the legislation envisaged "generic medicines" being added to the white list as a category, and we propose that this should be done.

6.1.10. It should be noted that we seek no exemption from the provisions of Directive 2011/62/EU for generic medicines; merely that the provisions of the Directive should be properly and proportionately applied. If a particular generic medicinal product were to be found to be of high risk, then it should be removed as a product from the white list.

6.2. CONSULTATION ITEM NO 12: COMMENTS ON THE QUANTIFIED APPROACH TO APPLYING THE CRITERIA SET OUT IN THE CONCEPT PAPER

6.2.1. We are concerned that the analysis in the Concept Paper of the impact of the criteria for the assessment of risk set out in Article 54a2(b) of Directive 2001/83/EC as amended apparently fails to demonstrate a full understanding of the drivers of counterfeiting. Counterfeiting medicines is a heinous organised crime which puts people's lives at risk. It is undertaken by the same gangs who counterfeit other products (based on raids and seizures by the enforcement authorities in the UK): for them, the healthcare consequences and moral arguments are irrelevant. Their decisions are based on the identification of a market where there is demand and where they can make the most profit.

6.2.2. The initial creator of the market is demand. As we have seen in illegal internet supply, this is largely for lifestyle, eg erectile dysfunction, drugs which are not available through normal legitimate sources, perhaps due to the patient's embarrassment or healthcare systems' unwillingness to meet the cost. But similar market drivers are likely to apply to other types of product: there will be a market where there is a shortage that creates demand outside of the normal system.

6.2.3. This could be because of shortages of a particular product either through manufacturing or supply issues, or through constraints on the availability of products due to health systems' policies (eg not to reimburse particular products). We believe, for example, that there may have been examples of medicines being counterfeited to order when organised criminal gangs became aware of an impending shortage. Patient demand is also likely to be restricted to recognised brand names and not their INN equivalents which are largely unrecognised by the general public.

6.2.4. It is clear from Parliamentary Answers that the Commission does not have a clear understanding of what circumstances actually create a market and a demand for counterfeit products. Before pressing ahead with the delegated act, it is our view that the Commission should undertake a research project in liaison with the Member States' enforcement authorities better to identify these circumstances so that its implementation of Directive 2011/62/EU is more focused and therefore cost-effective.

6.2.5. We note that the UK MHRA (Medicines and Healthcare products Regulatory Agency) has by common consent a very highly developed and effective anti-counterfeiting strategy, including an intelligence-based system for identifying counterfeit products at risk of being imported to or sold in the UK in the legitimate supply chain or outside of it. The number of products deemed to be at risk is assessed continuously, and is usually fewer than 20. This contrasts uncomfortably with the Concept Paper's theoretical and arbitrary approach.

6.2.6. We propose that the Commission should adopt an EU-wide system based on the MHRA's with the creation of an expert advisory committee comprised of Member States' competent and enforcement authorities. This body could quickly review evidence relating to the risk proposed by products or categories of product according to the established criteria listed in Article 54a2(b) and available intelligence, and advise the Commission on whether they should be added to or removed from the white or black lists.

6.2.7. In any case, it is perhaps moot whether using a "quantified" approach to applying the risk criteria as proposed in paragraph 87 of the Concept Paper meets the requirements of Directive 2011/62/EU to consider the risk by applying "at least the following criteria". A quantified approach may be too inflexible to prevent a full and proper judgement being taken, and could result in a perverse decision being taken (eg, when a product actually counterfeited was shown to be of low risk under all other criteria).

6.2.8. It certainly seems to be a disproportionate and subjective approach to suggest a different threshold for the risk assessment for OTC products and branded and generic POMs when no counterfeit generic has been found in the legitimate supply chain and OTC products have. The argument that OTC products deal with less serious diseases is losing its power as many Member States are reclassifying medicines from POM to OTC as a cost containment measure.

6.2.9. However, if a quantified approach is to be used, it is absolutely clear that it must be weighted according to the relative importance of the different factors listed in Article 54a2(b). We believe that the Commission must undertake a study, as we propose elsewhere in this response, of the actual factors behind counterfeited products before reaching a firm conclusion. However, we list the factors below in order of relevance or importance as we judge it, and comment on the references made to them in the Commission's Concept Paper:

1. *The number and frequency of previous incidents of falsified medicines reported in the Union and in third countries*: The actual falsification of medicines in the Union or in comparable countries is clearly the most powerful evidence that there is a high risk of falsification. Indeed, we cannot agree with the Commission's suggestion that this "may" be an indicator: this must be the overwhelming indicator. However, in assessing this factor, the Commission or its advisory body that we propose (paragraph 6.2.6) should take account of whether the detected falsified medicine was in the Union itself, a comparable regulated and reimbursed country, and in the legal or illegal supply chain. We proposed a phased approach from counterfeit products found in the legitimate supply chain within the Union to one found in the illegal supply chain in an unregulated and unreimbursed third country and ultimately of course to none found anywhere.

2. *The price of the medicinal product*: Price, as we comment above, will be a major driver. However, the Commission's suggestion that €2 per pack is risible. A phased approach from the highest priced product to the lowest should be adopted. Counterfeiters are driven predominately by the price that they can secure for their "goods". The relevant price for this assessment, therefore, is the manufacturer's ex-factory selling price since that sets the market benchmark.

3. *The specific characteristics of the product*: We have commented above on the incidence of problems with branded lifestyle products as opposed the lack of incidents with generic medicines. This is clearly a significant factor when taking account of the characteristics of the product. Further, it is clear that many patients associate with invented brand names, and not with generic and INN names.

4. *The sales volume of the medicinal product*: We believe this to be of low relevance. And we disagree with the Commission's suggestion that low volume products are at greater risk of being counterfeited. We believe the opposite to be the case. Restrictions in supply of products through quotas applied by suppliers or restrictive reimbursement or prescribing policies are likely to create a market demand that could be exploited by counterfeiters. By contrast, the multiple supply sources typified by the generic industry will reduce the risk of counterfeiting by the very availability of the product.

5. *The seriousness of the conditions intended to be treated*: Whilst this will have no impact on the risk of falsification, we appreciate its impact on the risk due to falsification. However, we see this as a secondary feature of the risk assessment since, if a product is not falsified, there can be no practical risk due to its (non) falsification.

6. *Other potential risks to public health*: One other potential risk could be the introduction of lists that are too wide and create too much burden for all. This could increase cost and reduce

availability across EU health systems and this needs to be taken into account when drawing up lists.

7. CONSULTATION TOPIC NO 5: OTHER ISSUES

7.1. CONSULTATION ITEM NO 13: PLEASE RAISE ANY OTHER ISSUE OR COMMENT NOT ADDRESSED ABOVE

7.1.1. The Concept Paper notes in paragraph 89 that Article 54a2(c) requires the Commission to adopt in a delegated act a rapid system for evaluating and deciding on notifications by the national competent authorities of products to be added to the white or black lists. And yet in paragraph 84 the Concept Paper also argues that "The drafting and adoption of the initial delegated act, and of each subsequent amendment, takes around two years". A means of meeting this requirement must be found if the delegated act is to meet the requirements of Directive 2011/62/EU.