Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and its Verification **BCGA Comments**	
	General comments
	The BCGA is a UK based Association representing the manufacturers and distributors of industrial, medicinal and food grade gases and related equipment and services in the UK. It is a technically based organisation which aims to improve both the safety and quality of the goods and services provided by its member companies. *It specifically represents those companies that supply medicinal gases and services in the UK, working through a dedicated Medicinal Gas Technical Standards Committee (TSC7), with representation from most of the major companies who operate in the UK. The member companies closely co-operate on safety, quality and technical matters to achieve the highest level of patient safety with the gases and services that are supplied for medicinal use and work closely with the MHRA.* *The BCGA Medicinal Gas Technical Standards Committee (TSC7) have reviewed the Concept Paper submitted for Public Consultation (Sanco.ddg1.d.3(2011)1342823) on the proposals for including a unique identifier on all medicinal products for human use. We have reviewed the document from a medicinal gas manufacturer's perspective and the comments made reflect how we see the proposals impacting on our products. In some instances, the comments made are of a more general nature and could apply to all medicinal products.* *Although we fully understand the need to control the supply of counterfeit medicines, we believe that medicinal gases should be exempt from the proposals (as 'white list' products), We do not believe that there is a significant risk with medicinal gases due to the integrated supply chain which is under the control of the manufacturer and due to the high costs of supplying the medicinal gas packages and the filling system relative to the value of the gas.* *The comments made against each of the consultation points endorse this opinion and provide the arguments why medicinal gases should be exempt.* *When reviewing the document we made the following assumptions:* • *We assumed that the proposals for adding a unique identifier would not apply to bulk medicinal products supplied direct to the hospital – especially for bulk medicinal oxygen which is supplied directly into a storage tank without any packaging or batch labelling.* • *some medicinal gases are supplied directly to the patient, based on the prescription supplied by the doctor, without passing through any Wholesale Dealer, Pharmacy or other retail outlet. In these circumstances there is no opportunity for the any responsible person to make any checks with the repository prior to patient use – hence these regulations would not be applicable to a significant proportion of our activities.* • *The supply model for supplying medicinal gases is based around renting the gas*

	packages to the customer and the implications for customers to not control their holdings of cylinders. Hence it would not be possible for a counterfeit supplier to supply the product in a cost effective manner without utilising the legitimate supplier's containers.
1	***Please comment on points 1 and 2 (policy options n°1/1 and n°1/2).*** ***Where do you see the benefits and disadvantages of each policy option?***
	Policy Option No. 1/1 is seen to be the better option for the pharmaceutical industry as it will allow the manufacturer to find the most appropriate solution for their operation and allow the costs to be controlled in line with the risks associated with the product. *The advantages of this option is that the additional costs can be kept commensurate with the identified risk.* *The disadvantages of allowing the manufacturer to determine how the unique identifier is applied to the finished product is that there may not be consistency across the business, specifically with the repository systems that will be set up to store the data. This may be possible to mitigate for specific sectors of the industry (such as medicinal gases) if they were allowed to adopt their own agreed standards for their specific types of products.* *Due to the diversity of products that this legislation will control, it is difficult to see how the approach of providing a unique identifier could be harmonised.* *Although it may be an advantage to have a harmonised approach, the disadvantage to this approach is that it is likely to impose a greater financial burden on smaller companies.* *The best approach would be to set out the basic rules centrally but allow an element of freedom as to how the information should be presented.*
2	***Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.***
	We do not see any adverse issues with the proposals set out in 2.1.1. *Our only point would be clarification as to the term 'Manufacturer's Product Code' and whether this is meant to apply to each individual pack size or only related to the overall product.* *Care needs to be taken as to the number of digits allocated to each field so as to allow for all products to be covered.* *It is assumed that when defining the Manufacturer's Code that the use of leading zeros will be defined.*
3	***Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2.***
	As an industry, we see including the batch number and expiry date with the serialisation

	number as a benefit to the end user in being able to manage their stock. *However we do not believe that adding the expiry date would have any significant benefit from an identification of falsified medicines perspective.* *We can not comment as to whether this would be a benefit to the regulated pharmaceutical supply chain for other medicinal products.*
4	***Which of the two options set out under point (c) of point 2.1.2 is in your view preferable.*** ***Where do you see advantages and disadvantages?***
	Option 2 appears to be the only sensible way of including the National Reimbursement number.
5	***Please comment on the three concepts described under point 2.2.*** • ***Where do you see the benefits and disadvantages of each of the three concepts.*** • ***What are the costs for each concept?*** ***Please quantify your reply, wherever possible, by listing for example:*** • ***costs for reading devices for the different carriers;*** • ***costs for adapting packaging lines of medicines packaged for the EU market.***
	From the medicinal gas industry's perspective, the appropriate choice for the method of identifying the product needs to take account the fact that the primary packaging is reusable. *Currently the unique identifier for the container is associated with the cylinder and / or valve serial number allocated by the manufacturer and are human readable. This unique identifiers is retained with the package and is not a randomised number (and hence would not comply with the requirements specified in Para 12.)* *To enable the industry to comply with the requirements of the proposals, a separate unique identifier would have to be printed and applied to the package. The prime issue if this was adopted as the way of uniquely identifying the package is that it would be difficult to control the reconciliation between the two unique numbers applied to the package, with a significant risk that the wrong label would be applied.* *If it were considered necessary to provide a randomised unique identifier to medicinal gas cylinders, it would be beneficial if the current unique identifier for the container could be retained and any additional number (which could be used as the batch number), displayed as a separate bar coded label using a randomised code. Although this would overcome the issues of reading in the information, it is not clear how multiple labels would be read into the*

	reader without introducing additional costs to all systems. *It is assumed that the unique identifier label would need to be fitted to the shoulder of the cylinder / container. As this part of the packaging is three dimensional, a linear bar code would need to be restricted in length(due to the difficulty of reading bar codes on a curved surface). An alternative would be to put the bar code label down the length of the cylinder but in this location it is difficult to see when containers are stacked and vulnerable to damage.* *Currently 2D barcodes are not generally used but this is seen as an appropriate way forward as and when additional information needs to be displayed.* *RFIDs are used by some companies but there can be some difficulties reading the device due to the mass of metal being close to the RFID. As the medicinal gas containers are reusable, the current RFID systems utilises a read / write facility. Having the RFID rewritable is seen as a security risk from a counterfeit perspective and systems would need to be developed to ensure that the rewriting process was secure. Alternatively the RFID could be replaced for each fill but this would add significant cost.* *From a cost perspective, the linear bar code would be the cheapest and simplest option for the medicinal gas industry to adopt as most customers in the regulated supply chain have access to a compatible type of bar code reader. There would be dependant on the bar code being an applied to the packaging in a way that it can be read easily. However, there is a move towards bar code readers being able to read both linear and 2D bar codes.*
6	***Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered*** ***How can these be addressed in this policy option***
	For medicinal gases, the regulated supply chain is normally very short. and the majority of products are supplied directly from the manufacturing site directly to the pharmacy either in the hospital or to the retail pharmacist in rare circumstances. *Small amounts of product are supplied to Wholesale Dealers but most of these are controlled by the manufacturers. It is only under very rare circumstances where product is supplied to the customer through another Wholesale Dealer.* *However, medicinal gases are supplied directly to either the patient (for use in homecare type applications) or directly to the Healthcare Professional end user (such as dentist, GP and Emergency Services) where there is no pharmacist control.* *Hence, where the manufacturer directly supplies the end user, the requirements to control of the product from falsification should be exempt from these requirements.*
7	***Please comment on the three policy options set out in points 1 to 3. Where do you***

	see the benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible. ***This applies in particular to the:*** • ***number of wholesale distribution plants;*** • ***costs for adapting such plants;*** • ***duration of scanning of the serialisation number;*** • ***number of pharmacies, including hospital pharmacies;*** • ***number of medicinal products dispensed by pharmacies and a hospital pharmacy.***
	For medicinal gases (if they were to be covered by the new requirements), due to the way that product is supplied directly to yhe customer or patient, Option 1 is seen as the only appropriate way of achieving the stated aims of the proposals. *Option 2 is seen as not adding any value to the security of the regulated supply chain compared to the costs of implementing the system. If only random checks were carried out, the set up costs associated with checking at this level would be as high as for Option 3.* *Option 3 would clearly give additional benefits to the controls of the regulated supply chain but would add significantly to the supply chain costs.* *Our view is that the decision as to the method used should be based on a risk assessment to identify where the risk of falsification is high and where there is a high risk to the patient. Where there is seen to be a requirement for adding the proposed randomised unique identifier, Option 1 would be seen as the appropriate method for low risk product and Option 3 for high risk product. The classification method used in Consultation Topic N°4 could be used as the means of assessment.*
8	***Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, wherever possible.*** ***This applies in particular to the estimated one-off costs and running costs for a repositories system. Where possible, please provide information on past experiences with a repositories system at individual company level and at national level (taking into account the experiences of Member States and companies).***
	Of the three options for maintaining the repository, should it be required for the medicinal gas industry, Option 1 would be seen as the preferred option. *As medicinal gases are very unique, it would be easier to define and maintain a gas specific system that would offer a more appropriate level of control.*

	From an industry perspective, it would be acceptable that the repository is controlled by individual manufacturers or a consolidated system managed for the medicinal gas industry. *A benefit of having an industry specific repository would be that the industry would be able to define the format of the unique identifier attached to the product.* *However, our view is that the proposals do not add any significant benefits over the company based systems that are currently in place for managing and controlling the medicinal gas cylinders and containers. These identify the unique packaging components and link to the batch details of the contained product. As the cost of these packages are high relative to the cost of the medicinal product, it is necessary to ensure that their location is identified (both when supplied and when returned) to provide a basis for charging customers for their rental (and to charge them should they be lost).*
9	***Please comment on point 4.1.*** ***Are there other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act.***
	For medicinal gas supply, there are no other issues that concern commercial confidentiality other than those specified in 4.1
10	***Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act***
	It is common for the medicinal gas manufacturer or Marketing Authorisation holder to supply product directly to individual patients and as such this activity should be exempt from the requirements. *In these cases the risks associated with counterfeit medicines is negligible making this concession to the proposed regulations acceptable.* *Repackaging is generally not done within the medicinal gas industry.*
11	***Which approach seems the most plausible from your view*** • ***Can you think of arguments other than those set out above*** • ***Can you think of other identification criteria to be considered***
	As there are only a limited number of gases supplied, the most appropriate approach for the identification criteria would be to use the name of the API (or the combination of the APIs for mixtures) as this is most specific way of identifying the product group. *Considerations could be given to include the means of administration in conjunction with*

	the name of the API(s).
12	***Please comment on the quantified approach set out above***.
	The criteria selection chosen in this proposal are not relevant to the specific conditions for medicinal product supplies. *The main differences for medicinal gases relates to the fact that medicinal gases are supplied in a high pressure cylinder or an insulated cryogenic container which are of a value that is significantly higher than the value of the gas they contain.* *The other main difference is that the packages that we supply are not based on dosage requirements for one patient and a cylinder may be used to administer product to a number of different patients for a number of different periods.* *The concept of price (with €2 as a benchmark for 'high price') is seen to be an inappropriate figure. The requirements for Criteria 1 needs to take account of the cost of supply as well as the average selling price for the product.* *With respect to the volume criteria, as there is no unit dose for medicinal gases, it makes it impossible to determine whether the volume is high or low.* *Hence, for medicinal gases, taking the cost and volume as the only criteria is inappropriate.* *The costs associated with falsifying medicinal gases are very high (due to the high cost of the containers), the nature of the bulk product and the specific equipment needed to fill high pressure cylinders and cryogenic containers, this section also needs to make reference to the cost of manufacture and the cost of supply.* *We would see the other criteria as being suitable for selecting the classification of the product to determine which list it should be assigned to.*
13	***Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.***
	Our main concerns about the proposals to control the use of counterfeit product is that labelling of cloned product would not necessarily prevent the counterfeit product being supplied provided the counterfeiter is clever enough to control the amount of product distributed. *The costs associated with introducing a European wide IT system that will robustly control the distribution and supply of counterfeit product are likely to be so high that it will become prohibitive.* *The better way of controlling the supply of counterfeit product would be to set up local systems that would be auditable by the national Regulatory Authority and place the onus on the supplier to ensure (and document) their processes to ensure that only genuine products are supplied.*