DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION
CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

D. CONSULTATION TOPIC N°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

Consultation item n°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?

EIGA supports the opinion that medicinal gases should be excluded from the requirement to introduce a unique identifier on the basis of the following considerations:

1) Medicinal Gases have a different means of distribution compared to the standard medicines. They are delivered directly to the users (hospital pharmacy, homecare patients and providers) and are not sold or repacked by pharmacies or wholesalers. Therefore the verification step is missing and the concept of a unique identifier would not work.
2) Medicinal gases require a large investment in the procurement of the packages used to supply the product which is extremely high in comparison to the price of the medicinal gas.
3) Medicinal gases are supplied in a very limited number of units in comparison to other medicinal products.
4) Medicinal Gases packages are not single use and consist of specific high value containers such as cryogenic tanks fixed to the ground, high pressure cylinders and bundles and mobile cryogenic homecare vessels.
5) Medicinal gases packages are traceable at any time with different audit trail systems (as required by GMP annex 6 point 29 and EMA website Q&A section). The traceability system involves all steps from filling, analysing and certification of the QP up to the delivery to the customer. The packages are already provided with a different barcode or similar electronic system.
6) The package (tank, cylinder, cryogenic vessel) is of high value and are not readily available to purchase and to falsify, so consequently the risk of falsification is reduced.
7) Medicinal gases are not straightforward to handle because they exist as cryogenic liquids or high pressure gases (more than 150 bar) and in the case of oxygen an oxidising gases
8) Medicinal gases are considered safe products, with only a small number of adverse events or reactions reported each year. Moreover, these gases and their packages are also managed under the requirements of the Transportable Pressure Equipment Directive and associated regulations.
9) To date, there have been no reports that medicinal gases have been falsified. Considering the manufacturing steps and the type of the package the risk of a falsification is very low. Moreover, they cannot be transported economically over large distances, which reduces or prevents purchasing via the internet.

For the reasons above mentioned, EIGA believes that medicinal Gases should be included in the "white list" across the EU, which supports the exclusion of the application of the unique identifier for medicinal products due to the very low risk of falsification that could occur with Medicinal Gases.