Introduction of fees to be charged by the EMA for Pharmacovigilance EIGA Comments	
	General comments
	EIGA is a European based Association representing the manufacturers and distributors of industrial, medicinal and food grade gases and related equipment and services in Europe. 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 Europe, working through a dedicated Medicinal Gas Working Group. 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 National and European Health Agencies.* *The EIGA Medicinal Gas Medicinal Gas Working Group have reviewed the Concept Paper submitted for Public Consultation (Ref. Ares (2012)723154 - 18/06/2012) on the proposals for introduction of fees to be charged by the EMA for pharmacovigilance. 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 for the EMA to levy fees for pharmacovigilance, we believe that medicinal gases should be exempt from these proposals (as they are medicinal products that are all based on well established medicinal use).* *The comments made against each of the consultation points endorse this opinion and provide the suggestions as to how the proposals could be modified to make them more 'fair' with respect to the use and value of the medicinal gases.*
1	***Consultation Item N°1:*** ***Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.***
	We do not agree with the single approach to the fee structure proposed in the Consultation document for arriving at how much will be charged for each product put on the market in more than one member state. *There should be a structure for fees dependant on the complexity of the product, the length of time it has been available for use (and whether it is well established), the unit cost of the product.* *Within the medical gas industry, the products that are available for administration to patients (covered by MAs in most Member States) have been used for many decades, even before the establishment of the original EU legislation in 1965. For example, medical oxygen, medical nitrous oxide and medical air have been used safely for more than a century.* *The definition of 'well established use' needs to be better defined so as to ensure that*

	simple products such as those described above are exempt from these fees. *For other products the fee structure needs to take account the simplicity of the product and the fee adjusted to suit.* *We would propose that there should be three categories of fees:* • *For products with the highest level of complexity, it is appropriate to charge the fee as proposed, for these products that are normally marketed at a high price.* • *For products with a lower level of complexity the fee could be reduced by half.* • *For those products that are classified as simple (where the licence is granted based on well established use) there should be no requirement for a PSUR and hence no fee.* *The proposals allows for a reduced fee for newly approved products.*
2	***Consultation item N°2:*** ***Do you consider relevant the concept of grouping as proposed?*** ***If not, please explain and/or suggest alternative.***
	As the licenced products supplied by the medical gas industry are normally considered as being of a well established use, the requirement for grouping would not be required. *However, we see that the proposal to allow grouping as an acceptable way to approach the assessment of products with the same APIs covered by different MAs, issued in different member States.*
3	***Consultation Item N°3:*** ***Do you agree with the proposed fee for the assessment of PASSes?*** ***If not, please explain and/or suggest alternative.***
	As with our response to Item No 1, we do not agree with the single fee structure for the assessment of PASSes but believe that the fee should be commensurate with the complexity of the drug. *Clearly, the activities associated with products classified as having well established use would attract no fee.*
4	***Consultation Item N°4:*** ***Do you consider relevant the concept of grouping as proposed?*** ***If not, please explain and/or suggest alternative.***
	As with our response to Consultation Item No 2, we believe that the concept of Grouping is appropriate.
5	***Consultation Item N°5:*** ***Do you agree with the proposed fee for the assessment of pharmacovigilance referrals?*** ***If not, please explain and/or suggest alternative.***
	As with our response to Item No 1, we do not agree with the single fee structure for the assessment of pharmacovigilance referrals but believe that the fee should be

	commensurate with the complexity of the drug. *The activities associated with products classified as having well established use would attract no fee.*
6	***Consultation Item N°6:*** ***Do you agree with the concept of grouping as proposed? If not, please explain and/or suggest alternative.***
	As with our response to Consultation Item No 2, we believe that the concept of Grouping is appropriate.
7	***Consultation Item N°7:*** ***Do you agree with the proposed pharmacovigilance service fee?*** ***If not, please explain and/or suggest alternative.***
	We do not agree with the single approach to the service fee structure proposed in the Consultation document. Our view is that the service fee structure should be based on the same philosophy as the PSUR Assessment Fee, with three levels of fee for complex, simple and well established products. *As there is no requirement for the well established product to undergo a PSUR, it is proposed that the service fee for this type of product should be zero.*
8	***Consultation Item N°8:*** ***Do you agree with the proposed approach for fee reductions for SMEs as regards the pharmacovigilance procedures at EU level (point 3.5.1)?*** ***If not, please explain why and provide suggestions how this could be improved.***
	We believe that the principle of a reduced fee for an SME is an appropriate approach to the fee structure. *However we would want to see clarification of the requirements for the assessment of the MAH. Within the medical gas business, the part of the company that is responsible for the management of the Marketing Authorisation is often only a small part/division within an industrial company.* *Hence our view is that when reviewing whether a company can be considered as a SME, only the number of employees and annual revenue involved in the manufacture and marketing of the medicinal products should be considered and not the industrial activities of the encompassing industrial company.*
9	***Consultation Item N°9:*** ***Do you agree with the proposed approach with regard to the pharmacovigilance service fee for SMEs (point 3.5.2)?***
	In line with our comments above, we agree with the proposals concerning the pharmacovigilance service fee for SMEs.

10	***Consultation Item N°10:*** ***What other aspects would you like to raise? Do you have additional comments?***
	Other than the confirmation that our medicinal gases products will be classified as products defined under the well established use, we have no further comments.