POSITION PAPER

Prepared by WG-7 Position Paper PP-26/18 – December 2018

FILLING OF CUSTOMER OWNED MEDICAL GAS CYLINDERS

1 Introduction

Throughout Europe there are a number of customers that own medical gas cylinders and request that they are filled by a third party. These can include healthcare institutions, fire services, military services, homecare service providers and homecare patients.

Regulatory authorities in each Member State, require these cylinders to be filled under a Manufacturer's Licence (ML).

Irrespective of the regulatory requirements, extreme care is needed to ensure that the specification and condition of the cylinder package does not jeopardise either patient safety or the safety of the person filling the cylinder. This covers both the specification of the valve and cylinder shell and the internal and external condition of the package.

There should be a formal approach to the filling of these customer owned cylinders to ensure that the package is safe for the service for which it is intended.

2 Scope

This Position Paper covers the filling of medical cylinders which are not owned by the cylinder filler but are owned by the customer, where the owner is the end user. It does not cover the filling of medical cylinders not owned by the cylinder filler, where the owner is supplying them to their own customers (under a separate Marketing Authorisation, where required).

This Position Paper provides guidance on how to determine whether it is permissible to fill customer owned cylinders where the customer is the end user from a legislative perspective.

It outlines the appropriate precautions and regulatory steps that need to be taken where it is allowed.

The position paper only covers the pharmaceutical regulatory requirements for filling medical gas cylinders owned by the customer, assuming that all other regulatory and statutory requirements have been met.

3 Best practice for filling medical gas cylinders

3.1 Manufacturer's Licence

Where a Manufacturer's Licence is issued by the national regulatory authority, this requires the Manufacturer Licence holder to operate to the principles of Good Manufacturing Practice (GMP) as detailed in the EU GMP Guide, as specified in EIGA Doc 99 Part 1 *Good Manufacturing Practice Guide Part 1 for Medical Gases*.

3.2 Marketing Authorisation

Where a Marketing Authorisation (MA)is required by the regulatory authority, this requires the MA holder to specify the cylinder and valve details in the MA.

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Where an MA is not required by the regulatory authorities, the cylinder filler should ensure that the cylinder and valve complies with the Transportable Pressure Equipment Directive (TPED) and relevant sections of the Directive 2001/83/EC *Community code relating to medicinal products for human use*.

3.3 Contractual technical agreement

Where the cylinders filled are not owned by the cylinder filler, pharmaceutical best practice is that there should be a contractual technical agreement between the cylinder filler and the cylinder owner.

The contractual technical agreement should:

- define the specific responsibilities for the cylinder filler and the cylinder owner;
- detail the specifications of the cylinders to be filled including:
  - details the materials used that are in contact on the wetted surface areas of the cylinder shell and the valve, which could affect the stability of the gas in the cylinder;
  - specify the polymers and lubricants used in the valve seals / seats and the cleanliness of components are in accordance with the requirements of ISO 15001 Anaesthetic and respiratory equipment. Compatibility with oxygen and EIGA Doc 73 *Use of Non-Metallic Materials in High Pressure Oxygen Breathing Gas Applications*.
- specify how the cylinder should be labelled, including:
  - requirement for identifying the owner and MA number (if required);
  - any specific details for product use;
  - appropriate literature and leaflets that need to be used in conjunction with the cylinder package.
- define who is responsible for ensuring cylinders have undergone the necessary statutory test requirements before filling;
- specify the name and contact numbers for recall issues.

4 Conclusion

The pharmaceutical best practice is that medical gases should be supplied in cylinders owned by the ML holder, and covered under an MA.

Where medical gas cylinders are owned by the end user, these cylinders should be covered by the cylinder specifications detailed in the relevant MA (where required).

When there are no regulatory requirements for an ML or MA, the processes used for the filling of customer owned cylinders shall follow the basic principles detailed in the EC GMP Guide, as specified in EIGA Doc 99 Part 1 *Good Manufacturing Practice Guide Part 1 for Medicinal Medical Gases*, covered by a Technical Agreement.

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