

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

TITLE III

**PLACING ON THE MARKET**

CHAPTER 1

**Marketing authorization**

*Article 9*

In addition to the requirements set out in Articles 8 and 10(1), an application for authorization to market a radionuclide generator shall also contain the following information and particulars:

- a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter nucleid preparation,
- qualitative and quantitative particulars of the eluate or the sublimate.