

*Agenzia Italiana del Farmaco***AIFA**

Administrative Department

Estimable Companies

Rome, 10 July 2017

Re: Terms of communication(a) Public body/self-certification(b) pursuant to articles. 46 and 47 of the Presidential Decree no. 445/2000 - SME requirements.

We hereby represent that, in order to be eligible for the reductions provided by art. 4, par. 6, of the Decree of the Ministry of Health of March 29, 2012 no. 53 and by point n. 3 of the resolution no. 21 of May 30, 2012 as well as by art. 6, paragraphs 1 and 2 of the Decree of the Ministry of Health of December 6, 2016 offered to public bodies and to micro, small and medium-sized enterprises, as of Recommendation 2003/361/CE, the company shall attest to possess the requirements provided by the law submitting appropriate communication or the relevant self-certification pursuant to articles. 46 and 47 of the Presidential Decree no. 445/2000, using the attached forms.

In order to benefit of advantages foreseen for the current year, the above mentioned communication/self-certification shall be based on information/data referring to December 31 of the previous year (eg.: in order to benefit of advantages for the year 2017, the declaration must be based on information/data referring to December 31, 2016).

Before or no later than along with the request to benefit of reductions, the communication or self-certification must be transmitted to the certified e-mail address protocollo@aifa.mailcert.it, specifying in the subject of the e-mail if it is a communication (a) or a self-certification (b).

In case the criteria are still met, the communication or self-certification should be submitted again the following year by 30th June, under penalty of expiration of the benefit.

The Italian Medicines Agency (AIFA) reserves the right to carry out any verification aimed at verifying the applicant enterprise actually possesses the self-certified requirements.

Head of the Administration Department

(Giovanni Torre)

Small Medium Enterprises data form

Estimable

Italian Medicines Agency – Aifa

to send to:
protocollo@aifa.mailcert.it

SELF – CERTIFICATION ACCORDING TO ART. 46 of the Decree of President of Republic of 28 December 2000, No. 445

I, the undersigned _____ born in _____
on _____ (identity card _____ issued on _____
by _____), as _____ of (hereinafter referred to as " company
/institution), sis code _____, with office in _____, address
_____, tax code number _____, valued added tax identification number
_____, pursuant to and in accordance with Articles 46 and 47 of the Decree of
President of the Republic of 28 December 2000, No. 445, duly warned about the liability and the
criminal and civil consequences provided by art. 76 of Decree of President of the Italian Republic
of December 28, 2000 No. 445, in case of false statements

DECLARE

- that that the Company / Institution, on 31/12/xxxx¹ belonged:

- ☐ to "medium sized enterprises" company with fewer than 250 employees, and either an annual turnover not exceeding € 50 million or an annual balance-sheet total not exceeding € 43 million;
- ☐ to "small sized enterprises", company with fewer than 50 employees, and an annual turnover and/or an annual balance-sheet total not exceeding € 10 million;
- ☐ to "micro sized enterprises", company with fewer than 10 people, and an annual turnover and/or annual balance-sheet total not exceeding € 2 million; these criteria, set out in Commission Recommendation 2003/361/EC should be calculated keeping also into the ownership structure, including any partnership or linkage².

- that this self - certification contains information/data registered at the Companies Registration Office to date.

Signatory's simple copy of ID is attached to this document.

Date

Signatory

¹In order to benefit of advantages foreseen for the current year, this self-certification should be based on information/data referring to 31st December of the previous year (e.g. in order to benefit of advantages for the year 2017, the declaration should be based on information/data referring to 31/12/2016) and, in case the criteria are still met, it should be submitted again the following year under penalty of expiration of the benefit.

²Commission Recommendation 2003/361/EC "ANNEX - TITLE I DEFINITION OF MICRO, SMALL AND MEDIUM-SIZED ENTERPRISES ADOPTED BY THE COMMISSION Article 6".