EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

on the group of products whose principal intended action, depending on proanthocyanidins (PAC) present in cranberry (Vaccinium Macrocarpon), is to prevent or treat cystitis

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[1], and in particular Article 13 (1) thereof,

Having regard to the request submitted by France in accordance with Article 13 (1) (d) of this Directive,

Whereas:

(1) France has requested the Commission in accordance with Article 13 (1) (d) of Council Directive 93/42/EECC to take a decision that the group of products whose principal intended action, depending on proanthocyanidins (PAC) present in cranberry (Vaccinium Macrocarpon) extract, is to prevent or treat cystitis, does not fall within the definition of medical devices set out in point (a) of Article 1(2) of Council Directive 93/42/EEC.

(2) The definition of a medical device set out in Article 1(2)(a) of Council Directive 93/42/EEC provides among others that a device falls within that definition if it does not achieve its principal intended action by pharmacological, immunological or metabolic means.

(3) The European Medicines Agency (EMA) in its opinion of 22 July 2016[2] concluded that the principal intended action of the group of products mentioned in recital (1) is achieved probably by pharmacological means as metabolites of PAC and other constituents of cranberry exhibit most probably a pharmacological activity and that a mechanical mode of action of PAC is highly unlikely.

(4) The mechanical mode of action would indicate that the group of products in question fall within the definition of medical devices. As such a mode is highly unlikely and a pharmacological mode of action is most probable, this indicates that the group of products in question should not fall within the definition of medical devices.

(5) Results of a questionnaire circulated at the Medical Devices Expert Group in November 2014 showed that the majority of Member States, based on their scientific expertise, is of the view that this group of products should not fall within the definition of medical devices.

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1 OJ L 169, 12.7.1993, p. 1.

2 CHMP (Committee for Medicinal Products for Human Use) scientific opinion to DG Internal Market, Industry, Entrepreneurship and SMEs, Unit GROW D.4. "Health Technology & Cosmetics" on the principal mode of action of proanthocyanidins intended to be used for prevention and treatment of urinary tract infections, EMA/427414/2016, http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8684&lang=en.

(6) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 7 (1) of Council Directive 93/42/EEC.

HAS ADOPTED THIS DECISION:

Article 1

The group of products whose principal intended action, depending on proanthocyanidins present in cranberry (Vaccinium Macrocarpon) extract, is to prevent or treat cystitis, does not fall within the definition of medical devices set out in point (a) of Article 1 (2) of Council Directive 93/42/EEC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude Juncker