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INFORMATION NOTE

from:	General Secretariat
to:	Permanent Representatives Committee/Council
Subject:	Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 - Outcome of the European Parliament's first reading (Brussels, 2 to 3 April 2014)

I. INTRODUCTION

On 22 October 2013, the Parliament voted in plenary to adopt 260 amendments to the Commission's proposal, but then postponed the vote on the legislative resolution to a later session - thereby not bringing the Parliament's first reading to a close. The proposal was instead referred back to the Committee on the Environment, Public Health and Food Safety, pursuant to Rule 57(2) of the European Parliament's Rules of Procedure ¹.

¹ Please see doc. 14937/13.

II. VOTE

On 2 April 2014, the Parliament in plenary voted to adopt its legislative resolution (thus bringing its first reading to a close), adopting as its first-reading position the 260 amendments it had adopted on 22 October 2013.

Medical devices *I**

European Parliament legislative resolution of 2 April 2014 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0542),
 - having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0318/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 14 February 2013¹,
 - after consulting the Committee of the Regions,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Employment and Social Affairs and the Committee on the Internal Market and Consumer Protection (A7-0324/2013),
1. Adopts as its position at first reading the text adopted on 22 October 2013²;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 133, 9.5.2013, p. 52.

² P7_TA(2013)0428.