COUNCIL OF THE EUROPEAN UNION

Brussels, 26 February 2014 (OR. en)

17583/13
ADD 1 REV 2 COR 1

PV/CONS 63
SOC 1028
SAN 516
CONSOM 221

DRAFT MINUTES

Subject:	**3280th** meeting of the Council of the European Union (**EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS**) held in Brussels on 9 and 10 December 2013

In document 17583/13 ADD 1 REV 2:

= *page 6, item 12, text should read as follows:*

The Council took note of the progress report as set out in doc. 16609/13.

The Council held an exchange of views on the legislative files mentioned above on the basis of the questions set out in doc. 16610/13.

Delegations intervened to reaffirm the need to reinforce **control** measures in order to avoid incidents and restore **patient**, consumer **and healthcare professional** confidence.

The means referred to by some delegations to achieve that aim include stricter requirements on notified bodies, subjecting high risk medical devices to a scrutiny mechanism and ensuring traceability of devices.

Several delegations supported the approach of the Commission regarding the provisions proposed on the reprocessing of **single-use** medical devices: the processor should assume the obligations of the manufacturer. Nevertheless, Member States would like to keep the possibility to forbid the **reprocessing and** use of reprocessed medical devices within their territory.
