Question for written answer E-010124/2014
to the Commission
Rule 130
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Subject: Inclusion of advanced eye scanners within the definition of a medical device as referred to in Directive 2007/47/EC

In the world each year between 0.5 and 2 cases of amyotrophic lateral sclerosis (ALS) are diagnosed per 100 000 people, a progressive neuromuscular disease which affects the motor neurons.

The disease is not currently curable, but it is possible to improve patients' quality of life and autonomy through the use of new applied therapies and technology such as eye scanners. This system, which enables the computer to be controlled accurately and intuitively with the eyes and which is already being sold, facilitates autonomous communication and helps patients suffering from diseases with degenerative neuromuscular disorders (ALS, cerebral palsy, paraplegia...) to look after themselves.

The European Union's intervention in the field of medical devices is intended to ensure greater levels of patient safety and to promote innovation and competition in the sector.

1. Can the Commission confirm that advanced eye scanners fall within the definition of a 'medical device' as referred to in Directive 2007/47/EC?

2. Does it therefore believe that they are likely to be considered within Member States as part of the methods, activities and resources based on scientific knowledge and experimentation through which health services are provided?