Comments on: “Intralipotherapy, the State of the Art”

Sir:

I read with a lot of interest the article entitled “Intralipotherapy, the State of the Art” written by Amore et al.1 As soon I read it, I noted it is really close to the already published Italian article “Intralipoterapia, lo stato dell’arte.”2

When this article was published in Italy, the editor of the journal asked me to comment on the article and clarify some points.3

Aqualyx (Marllor International, San Giovanni in Mariniano, Italy) is a DC-based solution with a lactose-based delivery system formulated for the purpose of controlling and enhancing the action of external ultrasound waves for the microcavitation of adipose tissue for the medical treatment of localized adiposity’s reduction (Table 1).4 This solution is not recorded as a drug but only as a medical device, although it is a DC-based solution; this anomaly was first underlined by Duncan in a recent multiplex assay published in 2013.5

Duncan compared Aqualyx with a PC/DC solution and with placebo (saline solution alone); the first solution was shown to be more unselective and cytolitic.6

Effectiveness of Aqualyx injections without external ultrasound application has been already described in literature6–8; moreover, skin necrosis secondary to injections has also been described9 although this complication is not described as side effect in the package leaflet.10

As underlined by Amore et al, recently ATX-101, a DC-based solution for the unwanted submental fat (Kybella in the United States and Belkyra in Canada; Kythera Biopharmaceuticals, Inc., Westlake Village, Calif. [an affiliate of Allergan Plc, Dublin, Ireland]), has been sold in the United States and Canada; however, there is a big difference between this solution and Aqualyx, although both contain DC: the first is recorded as a drug, and the second as a medical device; a claim regarding this issue has been raised with the Italian Ministry of the Health.8

Since 2004, Rotunda et al10 isolated DC from PC and identified it as the predominant lytic agent in the PC/DC formulation.

The use of DC alone to reduce localized adiposity can be very damaging, inducing skin necrosis in some cases; however, a recent study, published by Dayan et al,11 stated that ATX-101 injections, in a 4-year follow-up study, were a safe and predictable mini-invasive procedure for nonsurgical reduction of submental fullness. I thank Amore et al for their interesting results; however, as I already commented in the Italian version of this article,3 it would be really interesting to understand why a DC solution is recorded as a medical device and not as a drug. Most of the authors of the commented article are external medical advisors for Aqualyx; at least they should have specified whether in their large-case series Aqualyx has been used with or without the application of external ultrasound after the injections, as recommended by the manufacturer of the solution.

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DISCLOSURE

The author has no financial interest to declare in relation to the content of this communication. Dr. Rauso received grants from Healthxchange and Marllor, the companies that distribute the drug solution in the United Kingdom and Italy, respectively. The Article Processing Charge was paid for by the author.

Table 1. Italy’s Ministry of Health Card Regarding Aqualyx Registration

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<td>Device type</td>
<td>Identification number</td>
<td>Inventory subscription</td>
<td>Manufacturer’s code</td>
<td>Brand name</td>
<td>CND</td>
<td>CE class</td>
<td>Date of the first publication</td>
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<tr>
<td>Device</td>
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<td>N</td>
<td>PFLX0010</td>
<td>Aqualyx</td>
<td>K029280—surgical device with ultrasound generator</td>
<td>III Class</td>
<td>28.01.2010</td>
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<td>290990373</td>
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This DC solution is recorded as an injectable medical device formulated for the purpose of controlling and enhancing the action of external ultrasound waves for the microcavitation of adipose tissue for the medical treatment of localized adiposity’s reduction (translated from www.salute.gov.it/interrogazioneDispositivi/RicercaDispositiviServlet?action=ACTION_RICERCA; updated on April 4, 2016).

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