Ruling

Cells4Life Group LLP
Units 2-3, Oak House, Woodlands Office Park, Albert Drive, Burgess Hill, RH15 9TN

Media:	Internet (on own site)
Agency:	None
Complaint Ref:	G19-1018431
Complaints:	2

BACKGROUND

Summary of Council decision:
Three issues were investigated. Two were upheld and one was upheld in part.

AD DESCRIPTION

A page on a website for Cells4Life, a cord blood stem cell bank, www.cells4life.com, seen in April 2019, was entitled "TotiCyte - a revolution in cord blood processing". Text stated "The highest performing cord blood processing system in the UK, TotiCyte delivers 3 times more stem cells than any other method that we have tested". Further text stated "Highest cell recovery...TotiCyte delivers up to 3X more viable cells". Beneath this was text describing the potential future benefits of storing a baby's cord blood stem cells. Further text stated "This is why it is crucial that processing retains as many of your baby's precious stem cells as possible".

Further down the page was a chart comparing viable cell recovery both pre-freeze and post-thaw for the TotiCyte system, "Industry leader 1", "Industry leader 2" and "Low-cost system". TotiCyte was shown to have the highest proportion of viable cells for both pre-freeze and post-thaw recovery. Text stated "Further information on how TotiCyte compares to other processing systems can be found on the technical data sheet", followed by a link to further information.

Further down the page text stated "Delayed cord clamping - don't compromise...TotiCyte means that for the first time, cord blood banking is compatible with delayed and optimal cord clamping".

Claims on the homepage stated "More stem cells...more samples...more treatments...and delayed cord clamping for your baby...Only [bold] with Cells4Life". Text further down the page stated “The Cells4Life Advantage. Everything about our service has been designed with one purpose in mind – to provide your baby with the best possible protection for their long-term health. Here are just a few of the benefits of choosing Cells4Life as your baby’s cord blood bank: 3 X more stem cells…”.

ISSUE

1. Future Health Biobank and Smart Cells challenged whether the comparative claims such as "highest cell recovery" and "TotiCyte delivers 3 times more stem cells than any other method that we have tested" were misleading and could be substantiated.

2. Future Health Biobank and Smart Cells also challenged whether the same claims were verifiable.

3. Future Health Biobank challenged whether the claim "TotiCyte means that for the first time, cord blood banking is compatible with delayed and optimal cord clamping" was misleading and could be substantiated.

RESPONSE

1. Cells4Life Group LLP said that in order to be in a position to make comparative claims regarding the superiority of their TotiCyte system over other processing methods, they had conducted extensive, like-for-like testing of the processing systems currently used by UK-based private cord blood banks. Those systems were the Sepax 2 from Biosafe (“industry leader”), the Macopress Smart from Macopharma (“low-cost system”), AXP from Cesca Therapeutics and TotiCyte from CyteTech. Sepax 2 was the system used by Smart Cells and the Macopress Smart was used by Future Health Biobank.

They said their data demonstrated that TotiCyte recovered 2.5-3.3 times more viable CD34+ stem cells (a type of stem cell that could be used for transplantation) at the point when cells were transplanted into a patient than any other system tested. The claim was based on Colony Forming Unit (CFU) testing, which measured the growth potential of the cells prior to transplantation. All of the data presented were a function of the starting number of viable cells in fresh whole cord blood, meaning that they took into account cell loss at every step of the process. Post-thaw viable cell recovery and post-thaw CFU growth were calculated as a percentage of the starting number of cells in the unprocessed unit. This was often not the case in publications, where the data presented were usually a function of post-processing recovery, and of total cell recovery rather than viable cell recovery. They provided further details of the experiment design and the resulting dataset.

Cells4Life said that, despite numerous requests, their competitors had not published their in-house data. To date there were no peer reviewed data available on the post-thaw viable CD34+ recoveries of specific cord blood processing systems. They believed that was likely because post-thaw recoveries were significantly lower than expected, meaning that systems manufacturers were not prepared to publish their data. They said that they had, however, been able to gain access to a confidential data set that reviewed various processing systems and was broadly consistent with their own post-thaw CD34+ recovery dataset.

In addition, they said that their CFU data was consistent with published CFUs successfully used in therapy.

Cells4Life stated that while they did claim to have tested the processing systems that their competitors used, they did not claim to know or to have followed their specific procedures. They said they clearly stated that “all experiments were conducted according to the manufacturers’ recommended protocols”. That notwithstanding, given the expertise, time and substantial cost that specialist manufacturers of cord blood processing systems had invested into optimising the cell recoveries of their machines, they found it highly unlikely that Future Health Biobank and/or Smart Cells would be able to modify the process in such a way as to achieve significantly better results.

They said that they clearly advertised that TotiCyte was a proprietary technology that was developed by Cells4Life, and that the data on which they based their claims was generated in-house.

They did not claim that cord blood processed using TotiCyte had been applied clinically. They said TotiCyte was a CE marked medical device that met all the relevant regulatory standards required. It had been authorised for their use by the Human Tissue Authority. As such, they believed that there could be no doubt over the suitability of stem cell products isolated using TotiCyte for clinical use.

In the absence of any published data or data from their competitors, they considered that a comparison of their technology against the protocols that the manufacturers of their competitors’ systems recommended was reasonable and valid.

2. Cells4Life said that they directed consumers who wanted to know more about cell recoveries using TotiCyte to the technical data sheet on their website. They said the sheet clearly explained the methodology that had been used to arrive at the claim and provided all the information needed to enable a consumer to make an informed decision as to the validity and reliability of their claims.

3. Cells4Life said that delayed cord clamping and particularly optimal cord clamping both resulted in a reduction in the amount of blood available for cord blood collection, meaning that there was often not enough for standard processing methods or it may have too few cells for therapeutic use. They said that only their system could process very small volumes of blood, meaning that it was equivalent to a much larger sample processed using any other system.

They said research showed that after optimal cord clamping, on average only 22ml of cord blood remained, which was lower than the minimum volume required by machines used by their competitors. They said that some competitors using other processing methods would reject samples as unsuitable for processing if there was an insufficient amount of blood available.

They said that, applying their comparative data from in-house testing of other processing systems to a 22ml sample, TotiCyte was the only system that produced a cord blood unit

with therapeutic potential.

ASSESSMENT

1. Upheld

Claims on the website stated "The highest performing cord blood processing system in the UK, TotiCyte delivers 3 times more stem cells than any other method that we have tested", "Highest cell recovery...TotiCyte delivers up to 3X more viable cells" and "More stem cells...more samples...more treatments...Only [bold] with Cells4Life". There was a particular emphasis on the message that having a greater number of cells available could have a major impact on a child's health in the future – for example, in claims such as "More stem cells could mean the difference between only being able to treat a child or having enough cells to treat an adult, one treatment or multiple treatments, failure of success" and "No one knows if and when your baby's cord blood stem cells will be needed. Whether it is for a lifesaving therapy or simply to ease the ageing process, over the course of a lifetime there may be numerous occasions when they are called upon". In that context, we considered that consumers would understand that choosing to bank their child's umbilical cord blood with Cells4Life would result in three times more viable cells being available for treatments in the future, by comparison with the services offered by all other cord blood banks in the UK.

The complainants, Future Health Biobank and Smart Cells, stated that their own in-house data showed average viable CD34+ cell recovery at higher rates than those reported by Cells4Life using the same systems. Future Health Biobank said that the processing procedure they used differed from the standard procedures provided by the manufacturers. Cells4Life had not based their comparative claims on data obtained using the same methodology used by their competitors. While we acknowledged that information had not been made available to them by their competitors, it was Cells4Life's responsibility under the Code to ensure that they held adequate substantiation for claims made in their advertising prior to publication.

In addition, we noted that the tests had been carried out in house, rather than by an independent third party. Given the comparative, breakthrough nature of the claims, we did not consider that in-house testing alone was likely to be sufficient to substantiate them.

Cells4Life referred to a confidential dataset which they said was consistent with the results they had achieved. However, they did not provide that data in full, and in any case we understood it had not been published or peer-reviewed. Furthermore, it was not clear whether the data included all processing systems that were used by UK cord blood banks.

We concluded that the comparative claims made in the ad had not been substantiated and were therefore misleading.

On that point, the ad breached CAP Code (Edition 12) rules 3.1 (Misleading advertising), 3.7 (Substantiation), 3.33 (Comparisons with identifiable competitors) and 12.1

(Medicines, medical devices, health-related products and beauty products).

2. Upheld in part
The CAP Code required comparisons with identifiable competitors to be verifiable. That meant that an ad which featured a comparison with an identifiable competitor or competitors needed to include, or direct a consumer to, sufficient information to allow them to understand the comparison, and be able to check the claims were accurate, or ask someone suitably qualified to do so.

Approximately halfway down the “TotiCyte technology” page was a graph labelled “Viable cell recovery”, displaying pre-freeze and post-thaw viable cells for TotiCyte and three competitor systems. Accompanying the chart was an explanation of the difference between pre-freeze and post-thaw recovery and analysis of the graph. Below that, further text stated “Further information on how TotiCyte compares to other processing systems can be found on the technical data sheet”, with a link to a PDF. The sheet stated “We have conducted in-house testing or our own system and the two systems used by other private umbilical cord blood banks in the UK…All experiments were conducted according to the manufacturers’ recommended protocols by technicians who had received training by the manufacturers of each system”. It also included additional definitions and details of Cells4Life’s data and methodology.

Notwithstanding that we did not consider that the claims had not been substantiated, as per point 1, we concluded that the claims on the “TotiCyte technology” page were presented in prominent conjunction with sufficient information to allow competitors to verify the claims and to allow consumers to ask someone suitably qualified to do so.

We concluded that the claims on the “TotiCyte technology” webpage did not breach the Code.

The homepage also featured the claims “more cells” and “3 X more stem cells”. A button labelled “Find out more” linked to another page entitled “Cells4Life difference”. That page did not include a link to the technical data sheet.

Given that the homepage did not feature further information about the basis of the comparative claim, or direct consumers to where it could be found, we concluded that the claims “more cells” and “3 X more stem cells”, in that context, were not verifiable and therefore breached the Code.

On that point, the ad breached CAP Code (Edition 12) rule 3.35 (Verifiability).

3. Upheld
Claims on the “TotiCyte technology” page stated "Delayed cord clamping - don't compromise...TotiCyte means that for the first time, cord blood banking is compatible with delayed and optimal cord clamping”. Further text stated “If you choose delayed cord clamping or especially optimal cord clamping, it is likely that there will be less blood available for cord blood collection. For most processing methods, the sample may simply not be large enough to be processed, and even if it is big enough, the cell count may be

too low to be therapeutically useful. TotiCyte can process even the 10-20ml of blood left in the placenta after a long period of delayed cord clamping".

The homepage stated "delayed cord clamping for your baby…Only [bold] with Cells4Life".

We considered that consumers were likely to understand from those claims that Cells4Life was the only cord blood banking company in the UK that was able to process samples resulting from delayed and optimal cord clamping. However, we understood that Future Health Biobank also processed all samples it received, regardless of the volume. While Cells4Life referred to anecdotal examples of other companies rejecting samples below a certain volume, they had not provided evidence to show that they were the only company in the UK that processed samples resulting from delayed and optimal cord clamping.

We concluded that the claims "TotiCyte means that for the first time, cord blood banking is compatible with delayed and optimal cord clamping" and "delayed cord clamping for your baby…Only [bold] with Cells4Life" had not been substantiated and were therefore misleading.

On that point, the ad breached CAP Code (Edition 12) rules 3.1 (Misleading advertising), 3.7 (Substantiation), 3.33 (Comparisons with identifiable competitors) and 12.1 (Medicines, medical devices, health-related products and beauty products).

ACTION

The ad must not appear again in the form complained about. We told Cells4Life Group LLP not to make comparisons with identifiable competitors unless they held adequate substantiation to support them. That included claims that stated or implied that their service resulted in "more cells" or "3 X more cells" than those of their competitors, and claims that stated or implied that Cells4Life was the only cord blood banking service able to process samples from delayed and optimal cord clamping. We also told them to ensure that comparative claims were verifiable.