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HOME-USE BEAUTY DEVICES: A FAST-EMERGING MARKET

With the home-use laser device market becoming one of the fastest emerging markets for device manufacturers, Godfrey Town, Ron Petersen and Dominique du Crest analyse the market's development and regulatory standpoints on behalf of the Home Use Device working group

FROM THE SAFETY RAZOR TO HOME WAXING AND electrolysis kits, the advent of light-based HUDs marks the latest development in the consumer hair-removal market. But this is just one example of many technology-led developments occurring in the overall HUD market, which is set to boom in the coming years.

Other than hair removal, which is currently the largest HUD category, consumers can already choose from anti-ageing, body shaping, cleansing and anti-acne devices. In the future, multi-functional devices may well become the norm, and moves are afoot to develop HUDs to treat medical skin conditions such as eczema and actinic keratosis. Even the potential for diagnostic and 'quantified self' capabilities is on the radar.

What does all this mean for professional service providers, such as specialist physicians and aestheticians? Too much competition or an opportunity to lead the way in a burgeoning market? Perhaps neither, but now is the time to position yourself strongly in the market and shape your destiny.

Current market overview

The announcement late last year of Unilever Venture's $25 million investment into a joint venture with Syneron Beauty ('Iluminage Beauty') marks a turning point in the home-use device (HUD) industry. However, it is worth reflecting where we were a couple of years ago:

- Palomar was a powerful force, exploiting its laser hair removal patent portfolio, while forging a development agreement with Gillette to build a home-use hair removal device and developing a home-use skin rejuvenation device
- Syneron was expanding its professional range while developing a home use hair removal device – launched under the 'MeMyElos' brand. In 2007, Syneron signed an 'exclusive' agreement with P&G, aimed at developing home-use skin rejuvenation devices
- In 2009, Unilever signed a long-term deal with Cynosure to develop a home-use wrinkle reduction device
- Philips embarked on a long-term research project to explore the potential for light-based, home-use skincare devices, resulting in the

2008 launch of their Lumea hair removal device and the RéAura skin rejuvenation device in 2010/11

- Tria Beauty was formed in 2003. It launched its home-use hair removal device in Japan in 2005 and gained US Food and Drug Administration (FDA) clearance in 2008
- Home Skinovations was founded in 2006, launching its Silk'n hair removal system in 2008 following the first FDA marketing clearance, predicating the HUD on several professional devices
- Remington launched its home hair removal system in 2009

Groupe SEB (France) entered the market in 2012 with an intense pulsed light (IPL) device

- CyDen launched the co-branded Boots SmoothSkin in early 2009, capturing the attention of P&G and leading to a worldwide exclusive distribution agreement
- Dezac Group launched its first home-use laser hair removal device in Europe in 2006
- Radiancy launched the no!no! 'hot wire' device in 2008. It rapidly became the direct response TV shopping sensation, with sales to date of over 5 million units worldwide.

What's happened since?

- Palomar has been acquired by Cynosure
- Unilever Ventures have announced the formation of their joint venture with Syneron. All of Syneron's home use products will be sold through this venture
- Philips have formed a new, dedicated unit (Philips Light & Health) to develop new light-based technology
- Radiancy has become a global player. A few years ago, they effected a reverse takeover of Photomedex, a NASDAQ-listed US company.

A recent Kline & Company report showed 'steady growth' (+20%) in the global HUD market in 2012, taking the total annual value up to $1.3 billion (USD)[1]. To put this figure into context, the global skincare market (excluding hygiene) is estimated at $130 billion, so at a mere 1% the potential for HUD growth looks substantial.

The US currently tops global HUD sales with a 40% share, followed by Asia (35%) and Europe (15%). A mix of global, regional and local brands are currently battling ▷

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▷ for dominance across existing categories, but you can't help feeling that, with the odd exception, the global companies will prevail in the majority of geographies and categories over time. In Asia, for example, Japan currently commands more than two thirds of market value with the top two brands provided by local companies MTG and Ya-man. China, however, is experiencing exceptional market growth (+100% in 2012), being led by the established global player Nu Skin.

> "Up-and-coming trends to follow include developments for treating specific medical conditions, the emergence of multi-benefit devices, and the opportunity for growth in the male market category."

Market development

While the overall skincare market continues to achieve solid growth, higher-priced luxury brands are making the largest gains. It therefore seems appropriate for HUD manufacturers to focus on innovation and quality to develop the market, while simultaneously establishing efficacy and safety credentials – the latter being the route to long-term success when borne out in practice.

New product offerings can be expected to be the key market driver for some time, with an almost endless array of aesthetic indications to satisfy. Up-and-coming trends to follow include developments for treating specific medical conditions, the emergence of multi-benefit devices, and the opportunity for growth in the male market category. Longer term, quantified self and the fashion aspect of devices are likely to help sustain growth as brands mature.

An effective digital strategy to maintain a direct link with consumers, a large distribution network with a mix of trade presence and web availability, and ultimately professional endorsement, will contribute to retail success.

What do the professionals say?

Many leading dermatologists with an interest in aesthetics see the rising popularity of HUDs as a valuable door opener to their aesthetic business. Rather than being seen as competing with office-based procedures, the use of HUDs may prove to be a stepping-stone for many consumers to seek medical help when otherwise it would have been a leap too far. Furthermore, the possibility of HUDs acting as a companion to procedures between visits may help physicians to maintain long-term relationships with patients.

However, reasonable concern is being voiced about the lack of specific safety standards and appropriate regulations for HUDs, primarily motivated by the potential risk of eye and skin damage with device misuse. In lieu of this, the European Society for Laser Dermatology recently published guidelines on the safety of light-based hair removal HUDs, in part to encourage manufacturers to adopt best practices[2]. This interim measure highlights an urgent need for regulators to catch up with market developments and pin down suitable safety standards that apply to the breadth of devices both available and in development.

Once these are in place, the need for sufficient clinical evidence of safety and efficacy will come to the fore before professional endorsement can become a reality. A recent systematic review of published trials of light-based HUDs for hair removal found only seven prospective studies, only one of which was controlled and none were randomised[3]. The data so far indicate that the devices tested provided short-term efficacy, but further studies will be required to confirm and extend the results, and to establish the incidence of adverse events in selected cohorts of patients. Longer-term surveillance studies will then be required to demonstrate the safety profile of HUDs in real-world use.

The regulatory environment

Since their introduction, manufacturers of home-use lasers and IPL devices have relied on existing international standards and national regulations covering household electrical appliances to achieve safety compliance. In the absence of specific national regulations, in the European Union this would typically include compliance with the General Product Safety Directive (GPSD), Electromagnetic Compatibility (EMC) legislation, and international standards covering household and similar electrical appliances, such as the International Electrotechnical Commission (IEC) 60335 family of standards.

In order to obtain FDA marketing clearance for HUDs for over-the-counter sale in the USA, some consumer device manufacturers have sought to comply with existing laser and lamp standards, as far as they could be reasonably applied. These have included the current IEC 'parent' standard for lasers, 60825-1 and the IEC 60601 family of standards, which were largely formulated for professional medical, dental, diagnostic and cosmetic electrical equipment.

Embedded lasers: Class 1C

Home-use laser products have 'Accessible Emission Limits' from 'embedded' lasers that would result ordinarily in them having laser hazard classifications of Class 3R, 3B or 4, but because of interlocks and design features cannot emit hazardous radiation when the product is not in contact with the skin. With no 'free' emission control measures, current standards do not make much sense. The IEC has therefore defined a new laser category, Class 1C, in its draft revisions to IEC standard 60825-1 (Ed.3 Safety of laser products - Part 1: Equipment classification and requirements), which may be applied to the laser products that are being marketed for skin treatments in the home.

The latest IEC 60825 Committee Draft 'parent' standard, while specifying the requirements for a Class 1C laser, clearly states that if an applicable IEC ('daughter') standard specifying engineering controls to prevent emission into the surrounding space or to the eye does not exist, then classification to laser Class 1C is not permitted. Typical Class 1C laser products would embrace those intended for home-use hair removal, skin wrinkle reduction, and acne reduction. ▷

▷ The IEC has also started to draft a vertical standard IEC 60335-2-xx (Household and Similar Electrical Appliances – Safety – Part 2-xx Particular requirements for cosmetic and beauty therapy appliances incorporating lasers and intense light sources), which anticipates the new laser classification wording contained in the future IEC 60825-1 Ed.3, and provides the necessary design features, engineering controls, interlocks, skin pigment detection, and suitable user instructions to ensure safe use by a consumer.

> "Lasers and intense light sources discharging in the visible and infrared spectrum present no risk of cancer as compared with malignancy-provoking UV sources."

The invention of the laser Class 1C opens the market for new products being offered by manufacturers of cosmetic light-based appliances, thus 'enabling' them. This seems to make sense, since the laser appliances otherwise classified laser Class 3B or 4 would be regarded as being very hazardous to the eyes (which they are not when interlocked) and hence suffer from strong regulation of their use.

In similar cases, such as UV-emitting devices, in some countries national regulation comes into play. However, lasers and intense light sources discharging in the visible and infrared spectrum present no risk of cancer as compared with malignancy-provoking UV sources. The worst effect of visible and infrared light is skin burns, which might include blistering. Although some adverse event cases may require medical care, most of them will heal over time. Permanent effects may comprise scarring and hyper/hypopigmentation. Although this risk seems tolerable, eye injury as a result of non-functioning safeguards or misuse of the equipment is a serious concern. Apparently, there are only a few reports available about incidents of any type in the home-use area, although many hundreds of thousands of units have already been sold. This should not prevent those who are concerned from collecting data and evaluating the true risks.

Regulation outside the EU and USA

International efforts continue to develop consistency in regulatory frameworks, and as in the EU and the US, regulatory controls usually include a three-tiered approach:

- Pre-market assessment, assuring quality and safety for sale
- In-market monitoring of advertising, claims and labelling
- Post-market surveillance, to check adverse events and ensure continuing safety in use.

While Australia and New Zealand treat home-use light-based devices in a similar way to other household electrical appliances, as in the EU, no clear pattern is seen in most other world markets.

Japanese manufacturers produce significant numbers of home-use laser and intense light devices, which are both exported and actively sold in the domestic market. However, the regulatory position of such devices in Japan is at best ambiguous, with strong opinions expressed by professional interest groups about whom should use light-based devices such as lasers, but are not backed by any visible statutory framework or guidelines from government ministries. Despite many anecdotal reports of adverse events in the media and at national medical conferences, between 1999 and 2003 there were only seven complaints to the Consumers' Center of the Tokyo Metropolitan Government about home-use laser hair removal devices.

Conclusions

We are dealing with a new and fast emerging market, worth multi-millions of dollars every year. This HUD category reflects the needs of an ageing, wealthy and wellness-oriented population. The new miniaturised products and appliances entering the market, and using powerful and complex technology do, however, raise some health concerns. Safety standardisation and national regulation seems to be somewhat behind market development.

▶ ***For further information*** *on home-use devices visit www.home-use-device.com*

The Purpose of the HUD Working Group

- To assist in the development of international standards and regulations relating to safe and effective home use, light- and energy-based aesthetic devices
- In advance of the publications of standards, to develop best practice recommendations, starting with safety
- To encourage and disseminate communication about the efficacy and safety of home-use, light- and energy-based aesthetic devices

In conjunction with the following shows, we will provide a scientific programme:

AMWC Monaco (3–5 April 2014) ● **5CC** Berlin (31 May 2014) — Web broadcast
DASIL Sun City, South Africa (7–10 September 2014)
EADV Amsterdam (8–12 October 2014) ● **5CC** Hong Kong (10–13 December 2014)

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