Modular cosmetics

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Modular cosmetic products help beauty institutes earn points with their customers. Certain basic conditions should be observed when using modular cosmetics. Dr. Hans Lautenschläger explains the parameters.

Well-conducted cosmetic institutes aim at offering their customers the most suitable preparation for the individual skin. However, not all institutes can afford to store a broad range of preparations in small quantities and risk losses if the shelf life of the products expires. Moreover, the best finished product can only be seen as a compromise as its composition is invariable and product selection inevitably is limited to the articles available on the market.
The formulation of modular preparations is based on a previous diagnosis of the skin. The preparations are adapted to the individual needs of the skin and provide ample opportunities for beauty institutes to apply their professional competence and creativity - actually a key advantage in competition:

- The results of the skin diagnosis can be applied in minute detail to formulate adequate skin care products. Individually adapted treatments can be realized – a particularly interesting business model for dermatological practices with associated skin care institutes.
- Treatment routines can easily be modified, e.g. adapted to seasonal needs.
- Customers can be assured of excellent service and professional advice.

Bases

Basic ingredients for modular cosmetic preparations are the so called base creams which can be used for both dermatological magistral preparations but also cosmetic creams. Especially interesting is the option to combine the dermatological therapy with cosmetic preventive care. Dermatological patients and customers of cosmetic institutes with problem skin are privileged in this case as they don't have to change their base cream. Depending on the client's needs, it is either mixed with pharmaceutical or cosmetic active agents.

All substances should be compatible

Modular systems are not limited to fatty base creams. Non-fat base gels are a further base substance which can be combined with base creams in order to obtain the accurate fat content needed for the treatment; alternatively/ or additionally they can be combined with sera. A third option is to mix different sera and use them in the form of lotions.
What seems logical and simple at a first glance actually implies that the resulting compounds remain physically, chemically and microbiologically stable for the period of application. Reactions among the different components have to be excluded and the resulting individual product should be well-tolerated by the skin. The parameters mentioned are quite a challenge for the development of modular systems. Also certain legal requirements have to be observed.
When pharmacists compound and sell dermal magistral prescriptions (pharmaceuticals) with base creams, they are subject to the German Medicinal Products Act (Arzneimittelgesetz, AMG) and the Pharmacy Operations Ordinance (Apothekenbetriebsordnung, ApBetrO). Both the legal texts stipulate the quality testing of modular components and the conditions applying for preparation, bottling and dispensing of the drugs (GMP). While base creams frequently are used in the form of finished products, other components often are pure active agents and pharmaceutical additives.

The European Cosmetic Directive No. 1223/2009, in Germany implemented by the German Cosmetic Directive (Kosmetikverordnung, KVO), applies to the preparation of skin care products in pharmacies. Pharmacists frequently only become aware of this regulation after the food chemist of the Investigative Office for Food Control and Animal Health (Chemisches und Veterinäruntersuchungsamt, CVUA) is knocking at the door instead of the health authority pharmacist who supervises the compliance with the Pharmacy Operations Ordinance. Cosmetic products are subject to the German Food and Feed Code (LFGB).

Own pharmaceutical production is complex

When pharmacies maintain a small-scale production of skin care preparations, they are obliged to register the preparations and their composition (INCI) with the European Cosmetic Products Notification Portal (CPNP) just as any other cosmetic manufacturer. The preparations have to comply with the guidelines of the cosmetic Good Manufacturing Practice (GMP) and be documented in the product information file (PIF). In addition, a safety assessment (safety report) is required for every preparation in which all the risks and toxicity data of the different components are documented or in other words, which finally proves that the product is harmless for the human health. This is a complex effort and most of the pharmacies just cannot afford it.
Needless to say, the restrictions of the German Cosmetic Directive (KVO) also apply for dermatologists and cosmetic institutes. In a legal sense, they become manufacturers and hence have to comply with all the conditions stipulated in the German Cosmetic Directive when they use modular systems for serial production and display the preparations in the shop windows or sell them via web shop – including all the respective consequences with regard to liability, documentation and supervision by public authorities.

Not permitted

As a matter of fact, pharmacies or institutes basically are not interested in manufacturing a number of identical preparations (serial production) but rather focus on individual preparations formulated on the results of previous skin analyses. Nevertheless, the restrictions of the German Cosmetic Directive even apply for in-house treatments.
Example: The cosmetician would like to mix urea into a cosmetic mask in order to improve the skin hydration and inhibit itching: This, however, is not allowed according to the German Cosmetic Directive since urea is a pure chemical substance and not registered as a ready-to-use cosmetic product. This provision is quite reasonable as an overdose of urea would lead to an uncontrolled and hence unwanted keratolysis instead of improved skin hydration. The only substance she is allowed to use is water for the preparation of a cosmetic mask or for improving the consistency of a mask.
The restrictions of the German Cosmetic Directive are inapplicable if modular components are used during the treatment which themselves have been registered with the CPNP as finished products with the respective documentation. As a matter of fact, the institutes have always been observing the above-mentioned provisions.

Modular techniques

Example cleansing: Cleansing gel (free of lipids) and a cleansing cream (containing lipids) are mixed – both finished products – to use the compound for an initial cleansing of the skin. Actually, it is a convenient, effective approach and in sensorial aspects a rather pleasant feeling for the skin. Similar applies to prefabricated sera (active agent concentrates) which frequently are not applied as single substances one after the other but rather used as a mixture. Example skin hydration: A mixture of amino acids (serum A) and hyaluronic acid (serum B) to improve the skin hydration. Both sera complement each other: serum A is effective in the deeper skin layers whereas serum B takes effect on the skin surface.
In this manner, well-matched modular preparations in the form of CPNP registered gels, creams and active agent concentrates can be integrated into the individual treatments of beauty institutes, pharmacies and dermatological practices. If the protagonists use their specific know-how and can successfully treat difficult skin problems in the process, customers will sooner or later ask to buy the specific cream compound in order to continue the cosmetic treatment at home. In other words: the question now rises whether the different, specifically mixed modular preparations may leave the treatment room to be publicly marketed over the desk?
In the legal sense, the institutes, pharmacies and dermatological practices would be classified as distributors although the modular preparations neither are displayed in shop windows nor offered in web shops or mail order trade. A way out of the dilemma is to sell the different components which actually are licensed cosmetic products separately and also hand out the formulas. The suggested proceeding is within the law and equivalent to the sale of modular components à la „Hobbythek“ which used to be a German TV broadcast on, among other things, homemade cosmetics.
Mixing the components at home is not really convenient, though. Not everybody is used to handle a balance or graduated pipette and is familiar with the required hygienic precautions. It would be more reasonable if the cosmetic professionals handled the operation. As a matter of fact, professionals can take over the task on condition that the modular single-unit production (mixing) is offered as an individual service.

Important general conditions

Several conditions have to be observed with regard to the above mentioned service:

- The modular components should be compatible in physical, chemical and microbiological aspect. As a general rule, they only can be compatible if they originate from the same manufacturer.
- The remaining shelf life of the components needs to be sufficient in order to fix an adequate shelf life for the resulting modular preparations.
- On the part of the manufacturer, the base (cream, gel) should already be contained in an adequate receptacle preferably an airless dispenser with double bottom in order to facilitate both the adding of modular components but also the mixing process without an additional filling cycle. Modern systems consist of a sealed container with a separate dispenser head which is attached and locked in place after mixing. Any potential manipulation afterwards can thus be avoided.
- It is strongly advised to refrain from filling mixtures into non-original containers. There are many imported containers made of recycled plastics on the market. Recyclates frequently emit unwanted substances such as plasticizers and not declared pesticides into the filled material.
- Modular preparations have to be labeled. The label should carry the address of the service provider, the manufacturing date, identification number of the formulation and the symbol of an opened book. Desirable would also be the INCI of the used base component (cream, gel etc.) and the expiration date. The latter one is defined by the manufacturer of the modular system who also meticulously examined the compatibility of the different components. The manufacturer frequently also assumes the liability for modular preparations mixed to his specifications.
- The above-mentioned opened book symbol has been borrowed from the German Cosmetic Directive and refers to a documentation deposited at the service provider (formula) in which all the modular components are listed together with their compositions and ratios. In addition to it, the documentation contains the identification number listed on the label and the manufacturing date; in this way the traceability is ensured. The documentation is handed out to the customer on request.

The modular products prepared as an additional service, in other words on behalf of the customer, are safe products and, together with professional competence and adequate customer advice, they are an excellent option for institutes and pharmacies to improve their market position. A further advantage is that objective and also from the point of view of customers critical ingredients and additives can be avoided. Moreover, modular cosmetic preparations allow for an individually tailored treatment with high doses of appropriate active agents. And last but not least, sale and application of modular preparations also promote customer loyalty.

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