COSMETICS, HEALTH AND THE QUALITY OF LIFE

The Italian and international documents mentioned so far are the most authoritative among those that concern the topics under examination. Yet no reference is made to the possible role of cosmetics as one of the determinants or indicators of health or well-being. It is also surprising to note that personal hygiene is not considered as being part of a healthy lifestyle, whereas other indicators recognise its important role in the primary prevention of certain diseases. Hygiene and public health were revered by the ancient Romans, as can be seen from the remains of their aqueducts, sewers and numerous Salus per aquam (SPAs).

In 1998 the National Institute of Health hosted a meeting on the topic of “Cosmetics, health and the quality of life” (9).

The cue for this initiative was the reaffirmation at international level of health as a fundamental good for individuals and for society as a whole. It thus seemed appropriate to include the ultimate purposes of cosmetics among the needs, behaviour and lifestyles of modern society, in which hygiene, personal care and disease prevention are considered among the prerequisites for a civilised way of living. How can we fail to recognise that there is, in today’s world, a role for cosmetics in improving the quality of life?

The same rationale is present in this meeting, which restates the principle that cosmetics are not a luxury good – as certain members of the scientific community and general government continue to maintain – but an important determinant of health and an instrument of well-being.

When more money is spent on cosmetics than is spent on medicinal products, and there is a tendency for expenditure on the latter to diminish over time, it is a sure index of a healthy population. Personal care and hygiene are generally neglected by those in ill-health and little attention is paid to them when times are hard; one of the first signs that an individual is recovering from illness is when he or she begins again to pay attention to hygiene and personal appearance. One of the psychological aspects of cosmetics to which little consideration is given is the pure pleasure of using them: for women, especially, they offer an interlude in which to forget the world and to indulge oneself.

According to Giuseppe Salvatore:

* A lifestyle is a way of living based on identifiable models of behaviour that are not fixed but subject to change and which are the result of interaction among an individual’s characteristics and of social interactions with socio-economic and environmental living conditions. Individual lifestyles may have far-reaching effects both on an individual’s health and on that of other people. Lifestyles comprise: cultural background, income, family structure, age, physical abilities, and domestic and working environments.
Even animals spend much of their time taking care of their bodies: by licking themselves, killing parasites or wallowing in the mud, according to their species. When they neglect these pastimes it is a sign of poor health and incipient disease.

Cosmetics today have carved a role for themselves in the daily habits and customs of people of all ages. The newborn child's first bath is his first encounter with a cosmetic product and with the practice of hygiene to make him ready to be presented to his mother and the world; but it is also his first contact with a chemical substance other than those encountered in his mother's womb. As he grows his use of cosmetic products for varying purposes will expand in parallel with his needs. Inevitably, at his passing, cosmetics will fulfil their final function.

Data on the consumption of cosmetics, broken down according to type of product, are available elsewhere: they reveal considerable popularity with consumers of all age groups. It is interesting to examine the age group of 60-65-year-olds, mainly on account of the motivations of these individuals, who may tend to make greater and more varied use of cosmetics than in the past. Members of this age group usually have a high income; they are often keen to re-invent themselves and to make up for past sacrifices, to stay youthful and on form both psychologically and physically, as well as aesthetically; they frequent SPAs, beauty farms and similar establishments; they are prepared to spend money, for example on holidays and travelling, clothes and cosmetics - particularly products for hygiene, hair dyes, perfume and anti-age products. Lastly and certainly not least, albeit maybe less well known, this age bracket comprises a larger proportion of women than men, as can be seen in Table III which refers to 2003 distribution of the Italian population by age, sex and percentage age group.

On an ironic note: those members of the gentle sex who are over 80 may like to be reminded that in 2002, life expectancy at birth was 82.5 for the ladies and 76.8 for the men (Table I - Health indicators for the population of Italy) (4). However, women between 65 and 84 years of age are more likely to suffer from depression (Table II, indicator no. 16) (5).

This fact has not escaped the notice of the producers of cosmetics, who are highly skilled at producing functional cosmetics and at aiming their products towards more lucrative markets, titillating the imagination of the "less youthful". But, as we all know, fashion and advertising are the keys to consumer preference: the shift in attention in women's cosmetics away from the lips and towards the eyes has led to an increase in the production of articles for the eye area over lipstick.

It may be useful here to recall the definitions mentioned above, particularly the definition of health as a sound social investment that can bring economic benefits in the long term. In this regard it is interesting to note that since 1996 Italy's balance of trade for the cosmetics sector has been positive, indicating that Italy's exports in this field can compete with foreign markets, including those of the developing countries. In terms of turnover, Italy, with a turnover of € 6.87 billion, occupies fourth position among the countries of Europe, after Germany, France and Great Britain (10). In the global cosmetics market (which totals € 175 billion) Europe accounts for the largest share (€ 57.6 billion, or 32.3%), followed by North America (€ 46.2 billion), S.E. Asia (€ 44.3 billion, or 25.3%) and Japan.

The general trend in consumer preference is moving away from traditional cosmetics towards products perceived as promising more in terms of efficacy: new categories of products, such as cosmeceuticals and nutriceuticals, are being added to natural and plant-based products.
The most dynamic market is still in personal hygiene products, followed by articles for the care of the face, body and hair, perfume and make-up, with the latter comprising both mass-produced and more exclusive lines. The introduction of ever more sophisticated and effective raw materials and active ingredients is providing a boost particularly for face-care lines such as moisturisers and anti-age products. The markets in articles for oral hygiene and cosmetics for men are also expanding strongly.

Beauty salons are proliferating and the demand for cosmetic and aesthetic treatments in SPAs is also growing.

Because the level of education and general awareness of the population is growing — thanks partly to new and simpler means of communication — consumers are more critical and more demanding in their expectations regarding what they purchase and consume. So far as cosmetics are concerned, efficacy and gratification are the requisites most sought-after by consumers. Presentation and labelling supply information regarding the nature of the product and its chemical composition (although this may not be understood by everyone), its properties, how to use it and precautionary measures where applicable. This provides the end-user with the necessary guarantees of efficacy and quality and, at least for the consumer, safety would appear to be taken for granted. But the process of assessment rests on more objective foundations, which are highly complex and involve various levels of responsibility: the producers and distributors of the raw materials, the producers and importers of cosmetic products, the technical manager, the expert in imported articles, the safety assessor and public authorities at national and local level. All these details are beyond the comprehension of consumers, and often difficult to understand even for the experts, especially when some of the regulations are ignored, incomplete or not yet ready to come into force.

**COMPLIANCE WITH REGULATIONS AND LEGISLATIVE DEVELOPMENTS**

From the legislative point of view the only requirement of a cosmetic product is that it comply with the regulations applicable to products for that particular use. In matters of safety, which concern us here, reference will be made to only a few of the various European Union and Italian regulations, which it is presumed are known to those present. Recent events include:

- Directive 2003/15/EC of 27 February 2003 (11);
- Directive 2004/94/EC of 15 September 2004 (12);
- Directive 2004/93/EC of 21 September 2004 (13);
- The opinion concerning the “Report for establishing the timetable for phasing out animal testing for the purpose of the Cosmetic Directive” issued by ECVAM on 30 April 2004 and adopted by the Scientific Committee for Cosmetics and Non-Food Products (SCCNFP) (14);
- Fifth revision of the guidelines for the safety assessment of cosmetic ingredients adopted in the European Union on 20 October 2003 by the SCCNFP (15).

EU Directive 2003/15/EC is the seventh amendment of Directive 76/768/EEC, which first introduced regulations relating to cosmetics. If we look at the earlier amendment of almost a decade earlier Directive 93/35/EEC (16), incorporated into Italian law in Legislative Decree no.126 of 24 April 1997 (17), which laid down the new safety principles, we can see that these principles have either still not been entirely implemented or have not achieved the desired effect, as in the case of the ban on using ingredients or combinations of ingredients that have been tested on animals from 1st January 1998. The ban was con-
ditional on the development of alternative methods that would satisfactorily replace animal testing while offering consumers scientifically validated equivalent levels of protection. The lack of alternative methods has led to 6 prorogations of the date for the ban and the seventh Directive, 2003/15/EC (11) provided for further postponements. This Directive laid down a timetable for the adoption of alternative methods, to be established by 11 September 2004. It had already been established that the entire process was to be completed between 2009 (for tests listed in the timetable) and 2013 (for repeated dose toxicity, reproductive toxicity, toxicokinetics), except where special waivers were provided.

The timetable proposed by the European Centre for the Validation of Alternative Methods (ECVAM) was the subject of an opinion expressed by SCCNFP (14). This opinion gave a scientific summary of the meaning of and state of knowledge regarding the following toxicological tests and comments on their possible replacement with alternative methods: acute toxicity, skin irritation/corrosion, eye irritation, skin sensitisation, skin absorption/penetration, subacute and subchronic toxicity, genotoxicity/mutagenicity, UV-induced effects (acute phototoxicity, photochemical genotoxicity, photo-sensitisation), toxicokinetics and biotransformation, carcinogenicity, reproductive toxicity. The most significant criticisms directed by the SCCNFP against the ECVAM document were the following:

“The SCCNFP wants to clearly give the message to the Commission that total abolishment of animal tests within 10 years is not feasible from an objective scientific point of view (14; p. 2).”

“The timetable summarising all tests in the executive summary is unacceptable and unrealistic ... It must not be forgotten that this document must enable the European Commission to establish realistic timetables for the abolition of animal testing for cosmetic ingredients ... Scientifically, some problems have to be recognised and solved. Top scientists are not always involved in alternative research and the field seems to lack new ideas and developments. Young people should be stimulated more effectively (14; p. 16).”

Following consultation with the SCCNFP, Directive 2004/94/EC (12) concluded that “as animal testing may not be replaced completely by an alternative method ... There are at present, no alternative methods validated by ECVAM, other than those listed in Annex V to Council Directive 67/548/EEC” (18).

The result of all this is that the whole issue of abolishing animal testing and developing alternative methods is in the critical state of receding further into the future - despite the fact that much of the discussion concerning directives to regulate cosmetics products has been dedicated to these problems since 1993, albeit with scant results. In effect, the measures to regulate the matter have been founded exclusively on ethical considerations regarding laboratory animals, but the scientific world is still unable to manage without them. The principles, methods and protocols applied today, including good laboratory practice10, are internationally recognised for the safety assessment of substances with which humans come into contact for various reasons, including cosmetics.

It is useful to recall that each cosmetic product is certified as being safe for human health by a safety assessor in a special dossier which must be available to the Ministry of Health. In providing this, the producer takes into consideration:

• the general toxicological profile of the ingredients;
• their chemical structure; and

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10 This practice guarantees the quality of data, their reciprocal recognition at international level and conditions of treatment for laboratory animals that ensure maximum possible protection of their well-being.
• their level of exposure;
• the specific exposure characteristics of the areas on which the product will be applied or of the populations for which it is intended;
• a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

The requisite information regarding ingredients must be provided to purchasers by the producers and distributors of raw materials, including data on the irritant and allergenic properties of substances, although the procedures for this process have not yet been laid down.

The SCCNFP guidelines mentioned earlier (15) envisage the safety assessment of a given cosmetic ingredient as being expressed as an estimate of the related toxicological risk, reached by following a four-stage procedure:

1) identification of the danger of a cosmetic ingredient on the basis of the results of various toxicological studies and the physical, chemical and toxicological properties of the substance concerned;
2) assessment of the dose-response, based on the NO(A)EL (no observed (adverse) effect level) in mg/kg body weight/day. This is the highest dose at which no (adverse) effects are observed and is obtained from long-term studies of toxicity (for example, over 28 or 90 days, with rats, mice, rabbits and dogs; studies of chronic toxicity, carcinogenesis, teratogenesis, reproductive toxicity);
3) evaluation of human exposure to the ingredient (quantity, frequency, groups at risk);
4) characterisation of the risk (i.e. the probability that the molecule being studied can cause damage to human health). Different methods are used to calculate the risk, according to whether or not the effect has a threshold: they may be based on the margin of safety (MoS)\(^{11}\), which takes into account the NO(A)EL and the SED (Systemic Exposure Dose) (i.e. the quantity, in mg/kg body weight/day, of substance that will reach the circulatory system as a result of percutaneous absorption), or on a procedure that defines the calculated quantity of a carcinogenic substance that noticeably increases by a certain percentage the frequency of tumours in a certain site\(^{12}\).

The toxicological tests that the SCCNFP recommends should be performed in vivo and in vitro are (15):

- normally recommended basic tests
  1. acute toxicity
  2. irritation and corrosion
  3. skin sensitisation
  4. dermal absorption/percutaneous penetration
  5. in vivo repeated dose toxicity studies: at 28 days (oral, dermal, inhalation); sub-chronic toxicity at 90 days (oral in rats and non-rats; dermal in rats; inhalation in rats); chronic toxicity tests
  6. mutagenicity/genotoxicity.

- Tests required where there is considerable oral intake or skin penetration of ingredients
  7. carcinogenicity
  8. reproductive toxicity
  9. toxicokinetic studies
- tests required in cases of exposure to sunlight
  10. photo-induced toxicity; phototoxicity (photo-irritation) and photosensitisation; photomutagenicity/photo-clastogenicity
- observations in humans
  11. available data

On the subject of the latter, it may be helpful to recall the assertion by the SCCNFP (15; p. 29) that “... it is known that tests in animals and

\(^{11}\) The margin of safety, or MoS = NO(A)EL/SED. A substance may be considered safe if the MoS is equal to at least 100.

\(^{12}\) No exposure level exists that does not carry a small but finite probability of causing cancer.
alternative methods are of limited predictive value with respect to human exposure. Therefore, a skin compatibility test with human volunteers ... may be needed scientifically and ethically ... It is self-evident that such a test can only be envisaged provided that the toxicological profiles of the ingredients, based on animal testing and/or the use of alternative methods, are available and pose no problem."

Opinion concerning guidelines on the use of human volunteers both in testing of potentially cutaneous irritant cosmetic ingredients or mixtures of ingredients and in compatibility testing of finished cosmetic products also were adopted by SCCNFP (19, 20).

Nonetheless, so far as human ethical considerations are concerned, we cannot fail to note that no real regulations have yet been implemented to govern the performance of clinical tests to establish the tolerability or efficacy of cosmetics, nor the type and requisites of the centres for carrying out such tests. One might wonder whether the informed consent of volunteers, the binding opinion of appropriately-formed ethical committees and the implementation of special good practice regulations are to be included in such criteria.

The matter of safety poses various other specific questions such as: hair dyes, products and preparations of vegetable or animal origin, the sensitising effects of fragrances, endocrine disruptors, substances classified as Category 3 carcinogens, mutagens or toxic for reproduction (CMR, the subject of Directive 2004/93/EC (13), which includes them in Annex II as prohibited substances unless they have been evaluated and approved by the SCCNFP for use in cosmetic products), substances that are prohibited but allowed in certain cases, a review of the European inventory of cosmetic ingredients. But most of all there is an urgent need to put in place, throughout Italy, the system of cosmetic market surveillance announced in Legislative Decree no. 126 of 24 April 1997 (17). This should not be restricted to the monitoring of undesired effects caused by cosmetics, but should envisage more comprehensive measures of primary disease prevention aimed at verifying global compliance with current provisions.

Each of the topics indicated requires more space and time than is available today and must therefore be postponed to some future date. However, one topic is worth mentioning, since it affects the "new youths" of both sexes who are presumed to make habitual use of hair dyes, and hairdressers. The problem is that of a possible association between hair dyes and bladder cancer, a hypothesis reproposed in recent publications (21-26).

CONCLUDING REMARKS

From the observations presented at the outset it can be clearly seen that the modern condition of well-being falls between two opposing concepts: on the one hand are the problems associated with poverty, hunger and malnutrition, the ills that negatively affect the health of millions of people; on the other hand lies the rampant consumerism that characterises the industrialised countries, often taking root in the aspirations and vanity of individuals and in the urge to do more and better, to improve physical and psychological performance, to outshine. Thus the conviction has gained hold that all this can be achieved by using the products offered in the market, which are usually expensive, skilfully studied and presented and exalted by means of advertising that is subtly convincing, promises much and often verges on the misleading.

In pursuing the goal of well-being, today's westernised society uses varying means: from different types of consumer products to physical devices and venues that range from SPAs to a multitude of well-being centres, all promising health, youth and beauty.
This consumer-fuelled westernised state of affairs does not exhaust the possibilities of pursuing well-being. The exotic appeal of the East opens up new horizons, filled with products associated with different practices in addition to those with therapeutic aims. Although products aimed at promoting well-being are intended for healthy individuals, they must nonetheless contain active ingredients if they are to be as effective as they claim.

With regard to functional cosmetics, some types of action can be justified if they are directed towards the deepest layers of the skin. The concept of cosmetic products that cover but do not penetrate is in contrast to the very definition of cosmetics, even though the action must never stray from the physiological. Research in skin enzymology has been developed less within the field of cosmetology than in that of dermatology. The results of such research could probably provide useful indications regarding the functioning of cosmetics. Studies of skin enzymology in terms of the induction or inhibition of enzyme expression by topically applied cosmetic substances could help shed light on the suitability of ingredients to be included in a particular formula. For example, a substance that can inhibit tyrosinase should not be contained in any cosmetic product implying exposure to sunlight.

On the subject of alternatives to animal testing, such studies could provide preliminary indications as to whether or not an ingredient is acceptable even before testing or toxicological assessment is initiated.

In conclusion it is hoped that this paper may provide a useful reference for understanding health and well-being in the true meaning of the terms and, within the resulting holistic framework, substantiate the claim of the science of cosmetics to its proper role: that of a determinant of health intended to improve the quality of life and, thereby, the psychological and physical well-being of individuals. Numerous matters relating to safety remain unsolved; these are exacerbated by the failure to implement regulations (such as, for example, those on consumer market surveillance, the identification of harmful effects, an updated inventory of cosmetic ingredients), delays in developing rules to regulate proper manufacturing processes and methods of testing, the lack of toxicological data (which makes it impossible to assess the safety of numerous ingredients) and, finally, the ban on animal testing and the failure to develop alternative methods. This latter problem is destined to remain unsolved for another ten years.

The aim of cosmetics is not to provide a cure — except in limited circumstances — but to enable individuals to stay healthy through prevention and the adoption of correct behaviour and lifestyles. Products to promote well-being, including cosmetics, may help but should not be used without proper knowledge of their effects and without proper guarantees as to their quality and safety for consumer health. These guarantees should be the result of scientific research and of unequivocal regulations that are adequate, obeyed and, where necessary, enforced.
References


14) The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers. Opinions concerning “Report for establishing the timetable for phasing out animal testing for the purpose of the cosmetics directive” issued by ECVAM (30/04/2004) adopted by the SCCNFP on 1 July 2004. SCCNFP/0834/04.

15) The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers. The SCCNFP’S Notes of Guidance for the testing of Cosmetic Ingredients and their Safety Evaluation. 5th Revision. Adopted by the SCCNFP during the 25th plenary meeting of 20 October 2003. SCCNFP/0690/03 Final.


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