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Title Assessment of the risks associated with aesthetic mesotherapy practices

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Aim

The aim of this work is to map out the risks associated with the use of aesthetic mesotherapy (AM) in France. The work has thus attempted to document the following types of risks:

- infectious risks;
- pharmacological risks;
- those associated with certain psychopathological settings.

The analysis took account of additional aims that put the risk mapping and mesotherapy itself into context.

Conclusions and results

AM includes a number of practices which in technical terms have the following characteristics:

- multiple injections;
- intradermal injections;
- injections of medicinal products or mixtures of medicinal products used off-label;
- injections of medical devices of the hyaluronic acid (HA) type, either alone or combined with vitamins;
- generally involving several sessions of injections.

This assessment, which is based on published data and a broad consultation of all the stakeholders concerned, shows that the practice of mesotherapy is based on poorly understood or unconfirmed facts:

- there is no consensus definition of AM;
- the practices are diverse and the protocols have not been standardised;
- the medicinal products are used off-label, alone or in mixtures (medicinal products together, medicinal products and medical devices, medicinal products and vitamins);
- the actual conditions under which procedures are carried out are not known in detail;
- there is no legal framework for the practice of mesotherapy;
- according to the standards of evidence-based knowledge, mesotherapy is at present not soundly based on scientific data. This also raises the question of the rationale for and types of scientific evidence in the training materials;
- the qualifications of healthcare professionals in mesotherapy are based on affirmations from those universities which provide training in it; however, such university training is not a prerequisite for practising AM.

An analysis of all the available data identified a number of different risks:

- there are known risks of infection, either from typical bacteria or atypical mycobacteria;
- "pharmacological" risks such as granulomatous reactions or systemic and allergic reactions have also been reported; the published studies with low levels of evidence do not allow any conclusions to be drawn about the physicochemical compatibility of the mixtures used in AM;
- finally, the occurrence of adverse events linked to certain psychopathological settings has not been observed but seems possible.

As regards severity, the analysis revealed one major event involving fatal anaphylactic shock. Other serious adverse events linked to mycobacterial infections or to granulomatous reactions, or systemic effects (thyrotoxicosis, Behçet syndrome) have been described, as have events rated as minor or mild. In the absence of any numerical data, it was not possible to assess the frequency of complications in relation to the number of AM procedures carried out in France.

The existing systems for follow-up monitoring are not working.

Medicinal products injected alone or in combination are used off-label in terms of their route of administration and their indications. While the off-label use of products is not prohibited, it must be done on the basis of the risk-benefit ratio (referring in particular to the scientific data and the lack of any alternative treatment).

From an ethical point of view, the risk-benefit ratio for an AM procedure should be analysed to allow those requesting it to reach an informed decision about its use.

HAS believes that the published literature does not provide any positive clinical evidence. HAS thinks that the practice of AM primarily carries a risk of infection linked to the use of injections, and secondly that the injection of medicinal products or medical devices necessarily involves a risk, irrespective of the doses or volumes used. In addition, pharmacologically, the fact that the contents of the products and the methods for mixing them have not been standardised makes it difficult or even impossible to assess all the potential risks, even though some have occasionally

been reported. The very large number of unknowns that still surround AM makes it impossible to provide the public with enough information to make informed choices, especially since large-scale advertising campaigns contain only positive claims.

Finally, HAS points out that:

- the extemporaneous preparation of mixtures of medicinal products can be done only in pharmacies and is not permitted in doctors' surgeries;
- the off-label use of medicinal products is not prohibited, but is strictly regulated and requires an in-depth assessment of the risk-benefit ratio. The patient must be informed of the off-label nature of the product's use, and the doctor is responsible for that use.

HAS emphasizes that the issuing of guidelines or recommendations on providing more information for patients and compliance with the rules of good practice does not in any way constitute recognition or legitimation of the practice of aesthetic mesotherapy which in any case is completely without scientific foundation.Text (ne pas oublier de décrire les principaux résultats chiffrés en plus des conclusions).

Methods

The assessment method used for this document is based on:

- a critical analysis of data from the scientific literature;
- a request from the Institut national de veille sanitaire (InVS [Health Monitoring Institute]) for feasibility models to be prepared that were used to assess the quantifiable risk of non-tuberculous mycobacterial (NMT) infections associated with AM care;
  a request from the Agence nationale de sécurité du médicament et des produits de santé (ANSM [French National Agency for Medicines and Health Products Safety]) for the type of products and mixtures injected to be documented and data to be collected on any adverse events reported with the products used;
- a survey of regional health agencies (RHA) to collect any information likely to describe the application of AM practices in the field;
- the collected opinion of experts from different specialties meeting in two multidisciplinary working groups to give their reasoned views on aspects of the pharmacological risks associated with using mesotherapy products and mixtures and the risks of infection associated with AM care;
- thematic consultations of various stakeholders, organised in the form of hearings.

Conclusions have been reviewed by the Commission Evaluation Economique et de Santé Publique (CEESP [Commission for Economic and Public Health Evaluation]), the HAS specialised appraisal committee.

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