

“Use of monitoring tools (cosmetovigilance, epidemiology data, etc.) and data centers / expert networks (ESSCA, IVDK, etc.) to characterize fragrance allergens”

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Background

Cosmetovigilance

General patch test data

Future

Why do we need surveillance?

- ▶ Pre-marketing methods to identify hazards, including contact allergy (CA), are not perfect
- ▶ Pre-marketing risk management may fail due to inappropriate assumptions regarding exposure / dose
- ▶ Hence, CA cases may arise that should not have arisen
- ▶ These can *only* be identified by “post-marketing” surveillance

Focus on the 'unwanted event' (UE)

- ▶ We are at the end of the chain
from chemical synthesis / extraction
→ formulation of products
→ marketing and use of products
→ adverse effect (contact sensitisation)
- ▶ Thus, '*post hoc* evidence' instead of *prediction*
- ▶ Consumers experiencing adverse effects are the indicator of a problem
- ▶ Patients are the tip of the iceberg of affected consumers, surfacing into the medical system (proportion unclear ...)

Possible surveillance methods of UEs

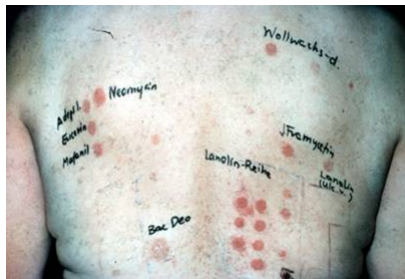
Axel Schnuch: Report/Recommendations to EP (Contract No. APS/12/2005)

- ▶ Consumer →
 - ▶ Complaint-based
 - ▶ Collection by companies, not in public domain
 - ▶ Verification and specification of UE??
- ▶ Patient →
 - ▶ (GP), Dermatologist:
adequate work-up with diagnosis of UE possible
 - ▶ Systematic collection of information?
- ▶ As identification of sensitisation risk associated with a certain substance is the objective: clear preference for **patient/dermatologist based** system!

The patient with cosmetic-related contact allergy



Clinical diagnosis of contact allergy: patch testing



The ideal in terms of post-marketing surveillance

- ▶ Dermatological consultation with
 - ▶ adequate documentation of history and skin changes
 - ▶ patch testing with commercial test series (baseline and special series, if appropriate) and possibly culprit product
 - ▶ additional break-down testing of product ingredients, using adequate dilution, vehicle etc.
- ▶ Feed-back of above results to manufacturer *and* a suitable “public body”

The reality . . .

- ▶ Incomplete consultation by consumers with adverse events (presumptive allergic contact dermatitis) due to cosmetics (< 30%)
- ▶ Partly insufficient work-up of patients consulting a dermatologist
- ▶ Limited availability of cosmetic ingredients for patch testing (beyond commercial test allergens)
- ▶ Very limited feed-back of diagnosis and patch test result

Legal Basis (in the EU)

- ▶ Cosmetics Directive, Article 7a, 1 **f**: “Provide to competent authorities . . . existing data on undesirable effects on human health resulting from use of the cosmetic product”
- ▶ *ibid*, **h**: “Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, Member States shall ensure that the information required under (a) and (f) shall be made easily accessible to the public by any appropriate means, including electronic means.”

Making the best of cosmetovigilance

- ▶ REVIDAL/GERDA
 - ▶ Established French network with intense communication/co-operation
 - ▶ Group of experts who publish their case collections (inter-)nationally
- ▶ IDOC
 - ▶ German system for the support particularly of SMEs when dealing with physicians' reports of UE, and requests for break-down patch test material
 - ▶ Publication partly hampered by confidentiality issues
 - ▶ Broad participation – varying medical quality

IDOC: Information and Documentation Center for Contact Allergies

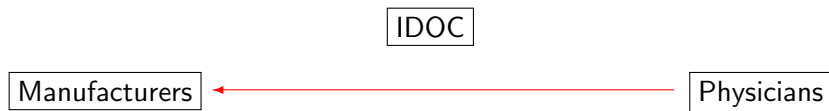
A project of the IVDK (www.ivdk.org) to assist manufacturers and physicians/dermatologist in the preparation of suitable break-down test materials for cosmetic products

IDOC

Manufacturers

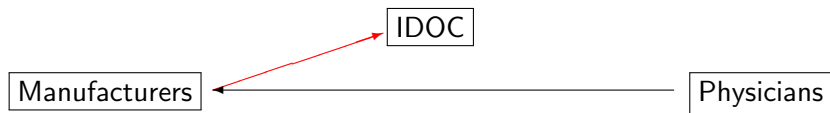
Physicians

IDOC: Workflow



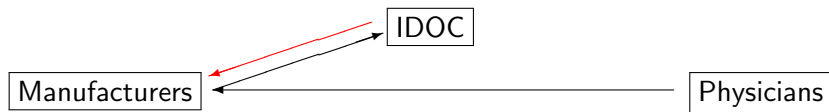
1. Request of Dermatologist

IDOC: Workflow



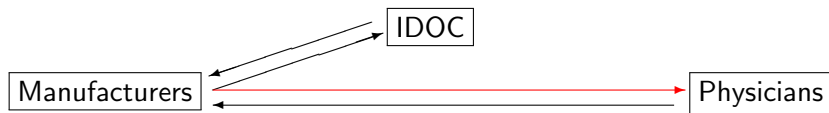
1. Request of Dermatologist for Break-down test material
2. ... passed on to IDOC with qualitative (INCI) ingredient info

IDOC: Workflow



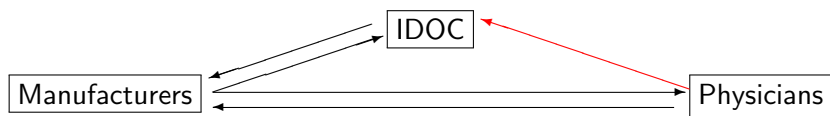
1. Request of Dermatologist for Break-down test material
2. ... passed on to IDOC with qualitative (INCI) ingredient info
3. recommended PT conc./vehicle returned to manufacturer

IDOC: Workflow



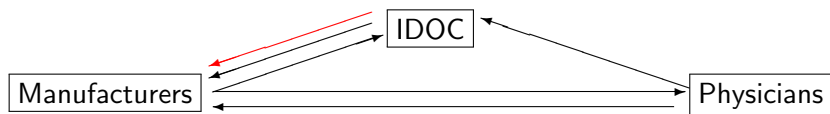
1. Request of dermatologist for Break-down test material
2. ... passed on to IDOC with qualitative (INCI) ingredient info
3. recommended PT conc./vehicle returned to manufacturer
4. material provided to dermatologist

IDOC: Workflow



1. Request of dermatologist for Break-down test material
2. ... passed on to IDOC with qualitative (INCI) ingredient info
3. recommended PT conc./vehicle returned to manufacturer
4. material provided to dermatologist
5. test result reported to IDOC

IDOC: Workflow



1. Request of dermatologist for Break-down test material
2. ... passed on to IDOC with qualitative (INCI) ingredient info
3. recommended PT conc./vehicle returned to manufacturer
4. material provided to dermatologist
5. test result reported to IDOC
6. communication of (commented) results to manufacturer

Main product categories (2006–2011)

Product type	distincts products	requests	%
skin care	(387)	578	21
oxidative hair colorants	(292)	468	17
wash lotion/shower gel/shampoo/soap	(235)	387	14
oxid. developers for hair colorants	(45)	273	10
other hair coloring products	(125)	245	9
permanent wave incl. fixatives	(87)	159	6
sun protection	(113)	119	4
deodorant	(68)	91	3
hair gel/setting lotion/hair lacquer	(49)	58	2
hair conditioner/hair care products	(42)	59	
hair bleach	(34)	48	
make-up	(40)	42	
others (eye liner, lip stick ...) or no information	(167)	216	8
	(1684)	2743	

Some experiences in the work of IDOC

- + Good cooperation with several manufacturers who shared their own experience with certain test preparations
- ± In case of mixtures used in products, the composition was often unknown, and mixtures were tested as such
- Inappropriate indication for patch testing (e.g., negative product test, no history, inappropriate product “positive”, such as household) detergents)
- limited quality of, and experience with, the patch test procedure in case of a few dermatologists (it is not a selected expert network!)
- Some “special” problems arised . . .

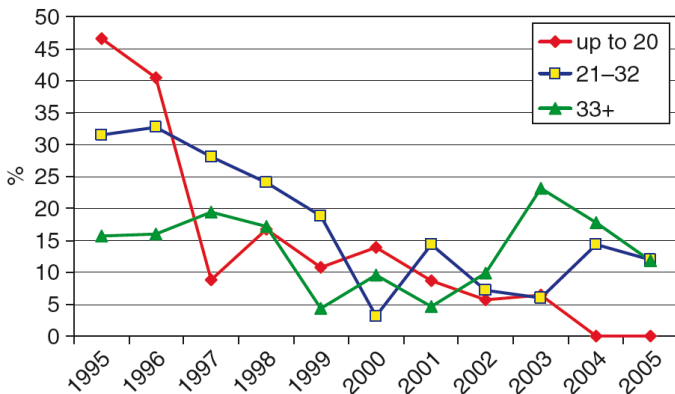
(Network) Patch test data

- Not as detailed as an ideal case documentation/report
- Naturally limited scope of *commercial* allergens tested
- ± Patients' own products, even break-down tests, may be recorded
- + Broad, representative data (on commercially available allergens)
- + Identification of time trends or subgroups at risk
- + Also useful to monitor the success of interventions

Downward trends reassure of a problem solved

GMTG-Trend in German hairdressers

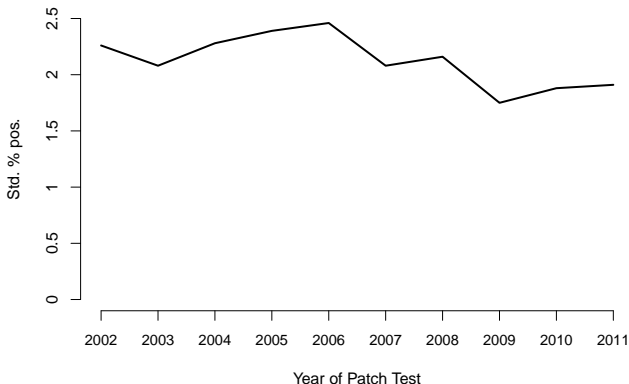
Contact Dermatitis 2006: 55: 54–6



(Largely) Persisting problems call for action

Hydroxyisohexyl 3-cyclohexene carboxaldehyde

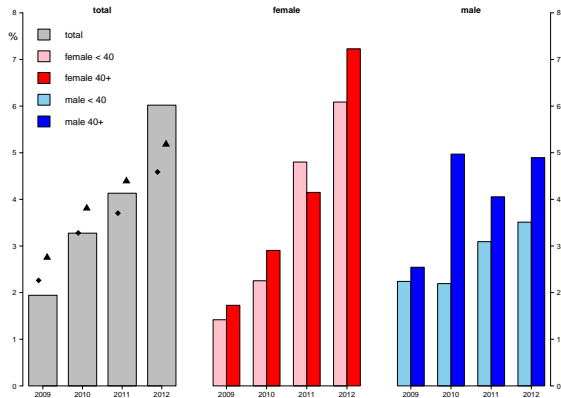
Contact Dermatitis 2012: 67: 47-9



Upward trends alert us of an emerging problem

Methylisothiazolinone

Contact Dermatitis 2013: in press



Future objectives

- ▶ More co-operation and communication between manufacturers, (networks of) dermatologists and competent authorities (national, EU)
- ▶ More standardisation of UE reports (see Resolution ResAP(2006), adopted 2006-11-08 by the Committee of Ministers)
- ▶ Centralised collection and continual analysis of case-by-case data with output to the public (*all* stakeholders)
- ▶ Continual discussion of epidemiological surveillance results (patch test data) involving all stakeholders

Thank you for your attention!

