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Subject: Possible approaches for training courses on cosmetology and chemical labelling in Brazil

Dear Dr Masson,

Further to our meeting at your office in Paris on 17 December, kindly organised and attended by our mutual friend Chantra Eskes, and as a follow-up to my email and course examples I sent you on 24 December, I have the pleasure to share with you some thoughts on possible course elements of training courses we could offer to ANVISA, Brazil.

Course coverage:

- Legislation of cosmetics, toiletries, household cleaning products, etc.:
 - EU Legislation
 - North American Legislation
 - Legislation in other countries
- Fundamental aspects of safety assessment and labelling of cosmetics, toiletries, household cleaning products, etc.:
 - Hazard identification (what adverse effects could happen?, which tests and studies are relevant? Which non-animal tests are available?)
 - Hazard characterisation (at which doses do these effects occur and does the seriousness increase with increasing dosages or increased periods of use? Are animal studies essential?)
 - Exposure assessment (occupational, consumer, and environmental, exposure modelling and exposure measurements)
 - Risk characterisation and assessment (bringing hazards and exposure elements together)
 - Risk management (risk characterisation, risk reduction, risk monitoring)
- Risk communication:
 - Labelling for consumers
 - Labelling for professional use during production and transport (Safety Data Sheets)

- Government communication to consumers (internet, advertisements, education)
- Dossier development and evaluation
 - Guidance to industry how to produce a scientifically sound dossier with the required level of detail
 - Guidance to regulatory authorities how to evaluate the dossier: completeness, animal and non-animal studies, GLP's, etc.
 - Communication between dossier submitters and the authorities: meetings? In writing? How to avoid bias, commitments, involvements and still provide adequate guidance?
- Practical training
 - Dividing the course attendants in sub-groups, giving them assignments based on what has been explained and evaluate the outcomes in plenary sessions.
 - Working through case-studies: evaluating an example dossier first in break-out groups, followed by plenary evaluation

Furthermore, it seems important to discuss with the authorities (ANVISA) how to organise the courses. Basically there are three options, all equally valid but all with certain advantages and disadvantages:

Option 1: One single (3-4 day) course, participants from regulatory authorities, industry and interested academics.

Advantages: fully transparent, exactly the same information to all parties, most efficient use of resources (only one course)

Disadvantages: participants may be less open and active as they run the risk of exposing their (lack of) knowledge to the other parties, strategies cannot be discussed as a strategy is unique for each party (in particular the authorities vs the industry)

Option 2: First a course for regulatory authorities (2-3 days), focussed at their needs and responsibilities, followed by a second course (3-4 days) for all parties (authorities, industry and academia)

Advantages: mainly for the authorities as this provides ample opportunities to discuss strategies to be used to get the best dossiers out of the industry. Moreover, there is no revealing to other parties of what the level of knowledge of the authorities is.

Disadvantages: Industry may consider this unfair treatment and may become suspicious. This approach is less transparent and more costly (2 courses)

Option 3: Two subsequent and separate courses, one for the authorities and one for industry, followed by a third course open to all (authorities, industry and academia)

Advantages: both tailor-made courses (to authorities and industry) can be very focussed and interactive with broad participation of all. Neither the authorities nor the industry can claim bias as they are treated equally but with different emphasis. The 3rd joint course will be more general and less in-depth but allows interested academics to participate and, most importantly provides an opportunity for both

the authorities and the industry to double-check if the earlier course was similar for both.

Disadvantages: three courses are the most uneconomic approach (more expensive than options 1 and 2) and the most time-consuming.

Finally, a few words about costs involved:

- In accordance with World Bank definitions, Brazil is an upper-middle income country (emerging economy), hence Orange House Partnership cannot provide its services and training totally for free.
- Orange House Partnership would charge expenses (economy fare travel, modest but clean and safe hotel and meals) and a modest daily allowance for each expert trainer.
- Orange House considers that 5-6 trainers per course would be sufficient.
- It should be considered to ask for a (modest) registration fee for industry participants.

I hope this information provides you with a good basis for your discussions later this month with the Brazilian authorities. Please feel free to contact me if you need more details or additional information

Kind regards

Herman B.W.M.Koëter,
Managing Director

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