

Dialogue between Members of the HMA-WG HMPWG and the Interested Parties AESGP, ECHAMP

Vienna - 17.10.2018

Flexibility Raw Material Suppliers

Factors influencing the quality of herbal raw material



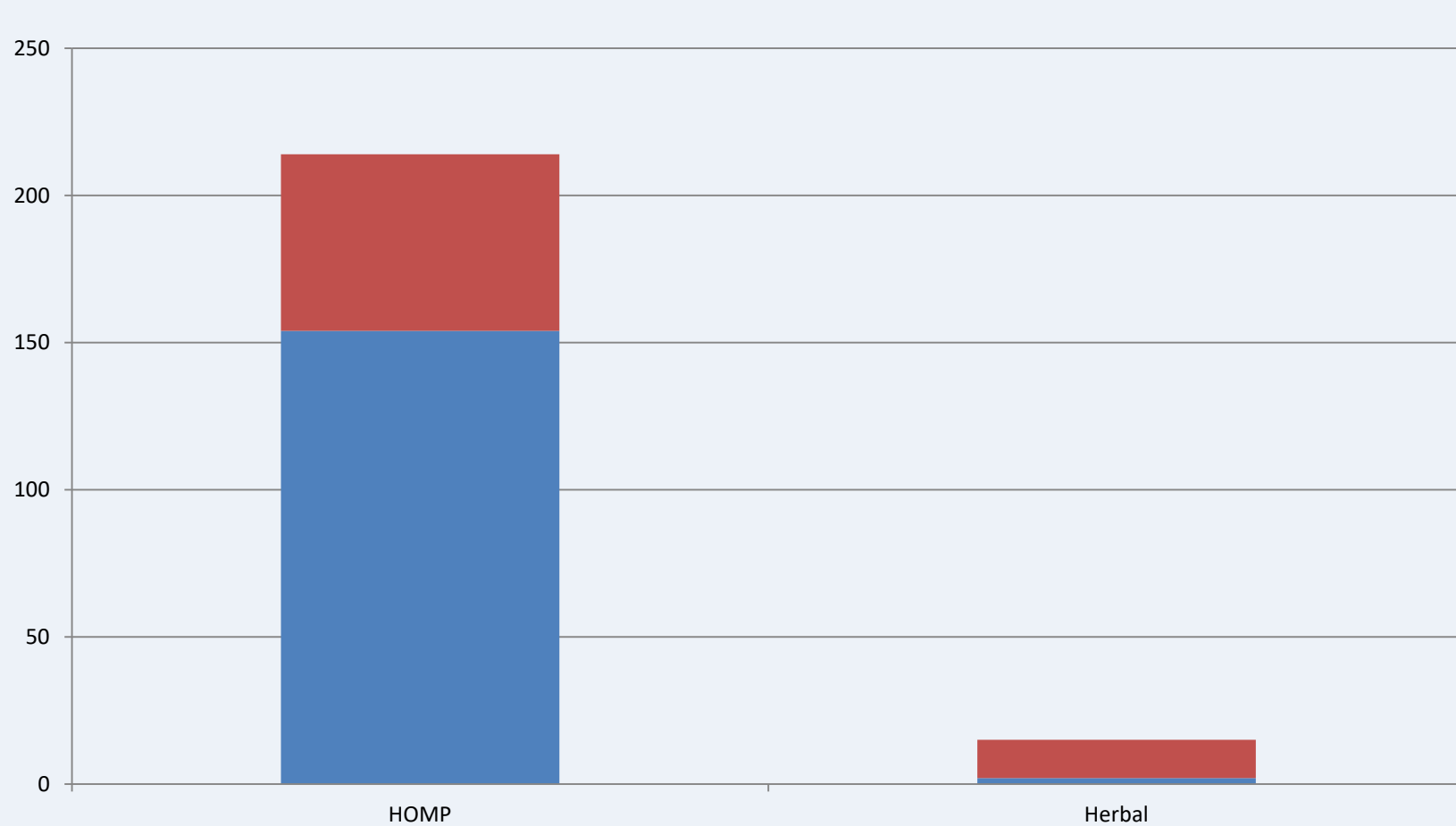
Special Situation of an Exemplary Homeopathic Compared to an Exemplary Herbal Manufacturer

Wide Variety of Materials

Homeopathic doctors need about 3,000¹ different raw materials for the therapy! Restrictions in the product range would result in severe restraint of this therapy.

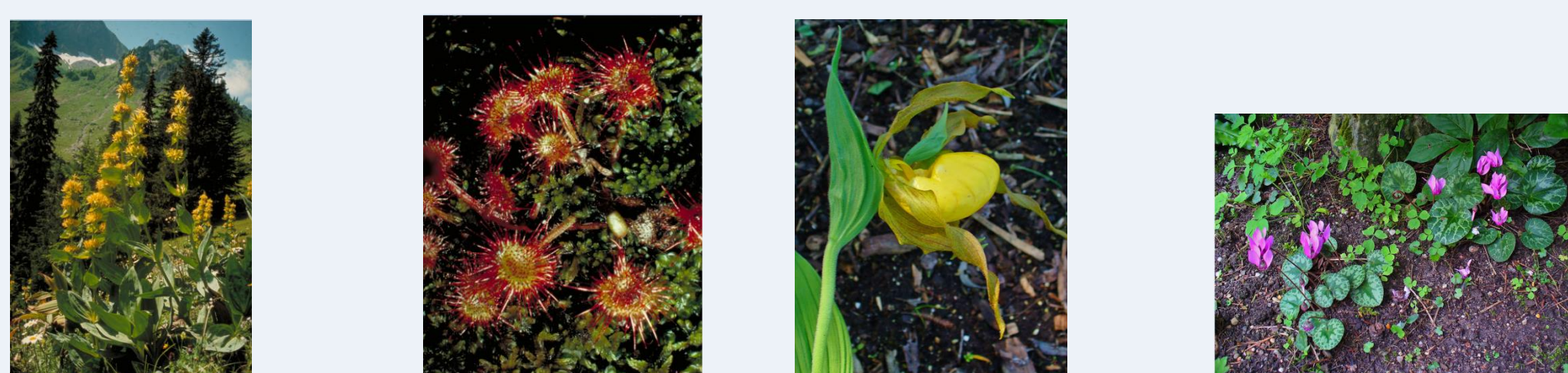
A comparison of the number of different plant materials processed within one year shows, that the number of different materials is about 14 times higher in homeopathy.

HOMP		HERBAL	
Number different raw materials 2016		Number Raw materials 2016	
Fresh Plant	154	Fresh Plant	2
Dried Plant	60	Dried Plant	13



Rare Species

In homeopathy a lot of rare plant species are used as raw materials, which are not cultivated in huge plantations → Supply is difficult, suppliers change more often.

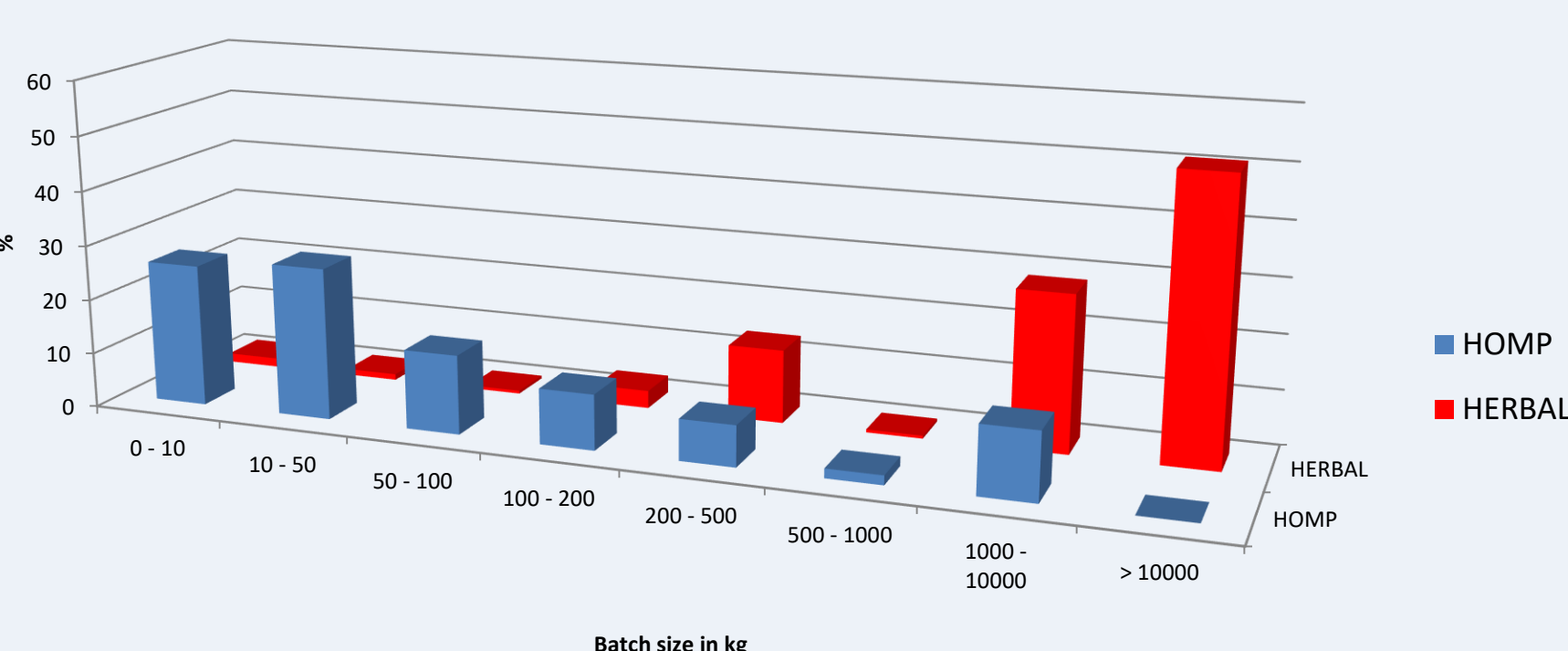


Gentiana lutea** Drosera** Cypripedium* Cyclamen*

Fotos: *H.Zell; **© Deutsche Homöopathie-Union

Low Batch Sizes

Batch sizes processed within 2016

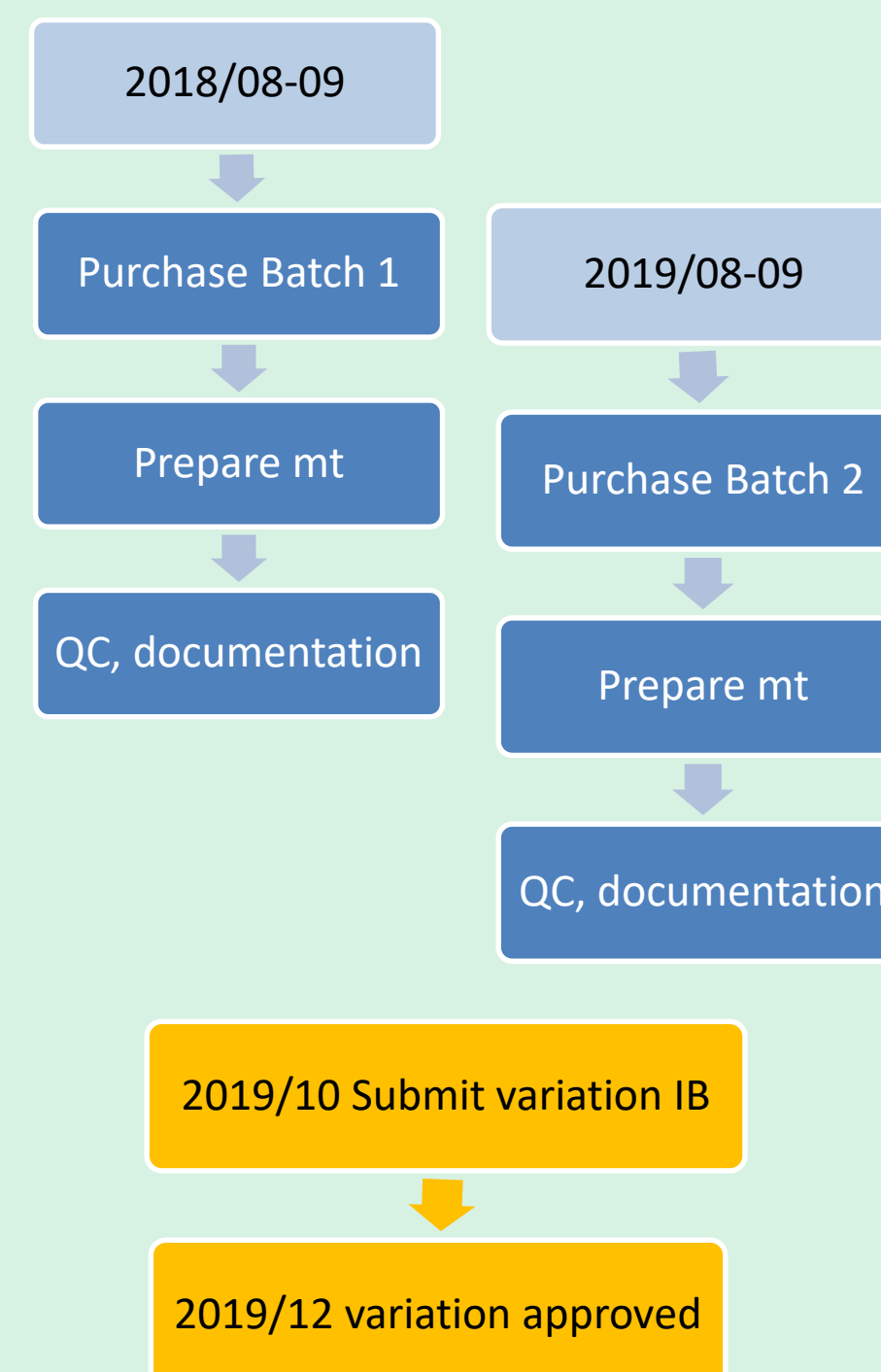


Variation Procedures for Change of Suppliers – How to handle?

According to HMPWG Q&A a change of supplier is classified as a IB variation. Authorities expect the documentation of at least two batches for a variation procedure (some even with stability data). However, suppliers of fresh plant material can mostly deliver only one batch per year.

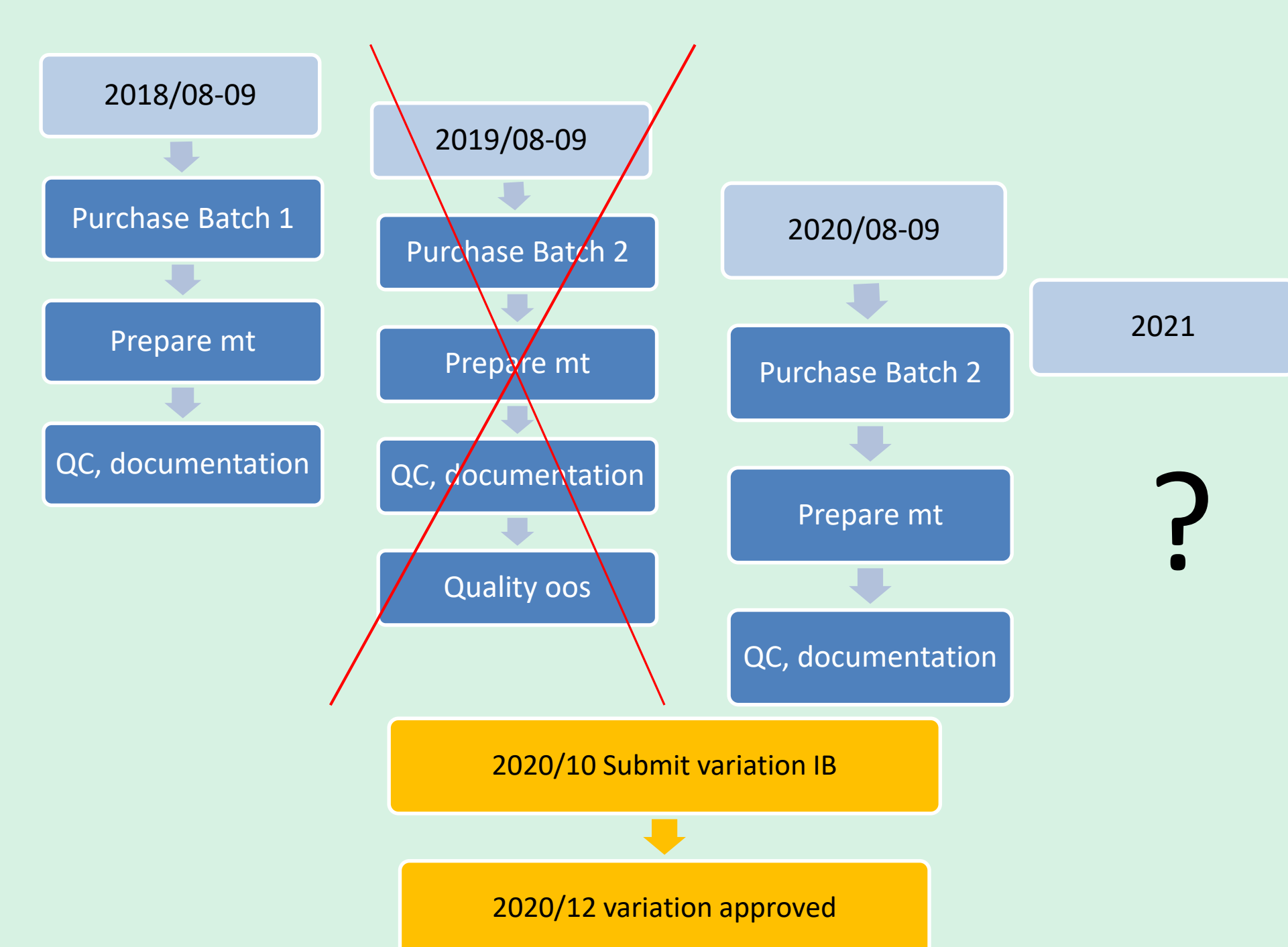
Case example 1

The supplier change is planned. The proposed supplier can deliver good quality material in two consecutive years



Case example 2

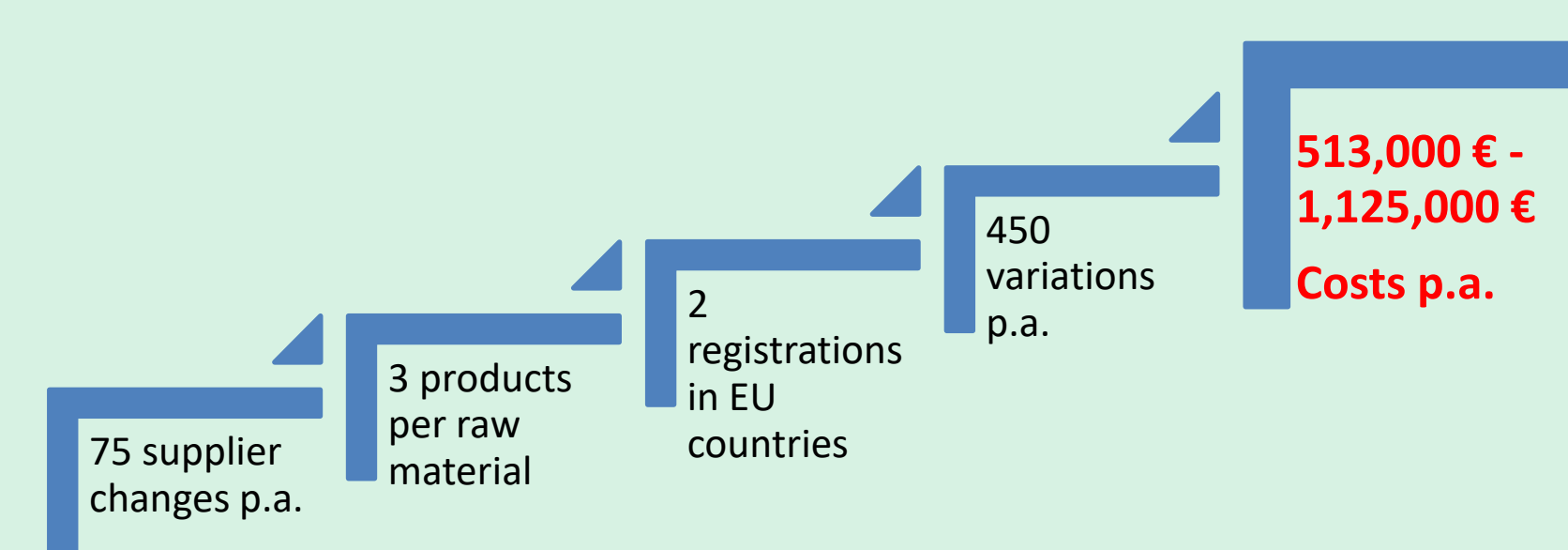
The proposed supplier can deliver good quality material only for the first batch. The 2nd batch (following year) is oos. So, the first batch of produced mother tincture cannot be used for production, before variation is approved. The manufacturer has to wait another year.



High Administrative and Cost Effort

Calculation (exemplary)

A typical homeopathic manufacturer has to handle about 75 supplier changes per year! With an average number of 3 products containing the same raw material With an average number of 2 EU countries where the same product is registered Resulting in 360 variation procedures Approximated costs per variation (IB): internal workload: 1000 €, fees 140 - 1500 € (variation type IB)



Facts

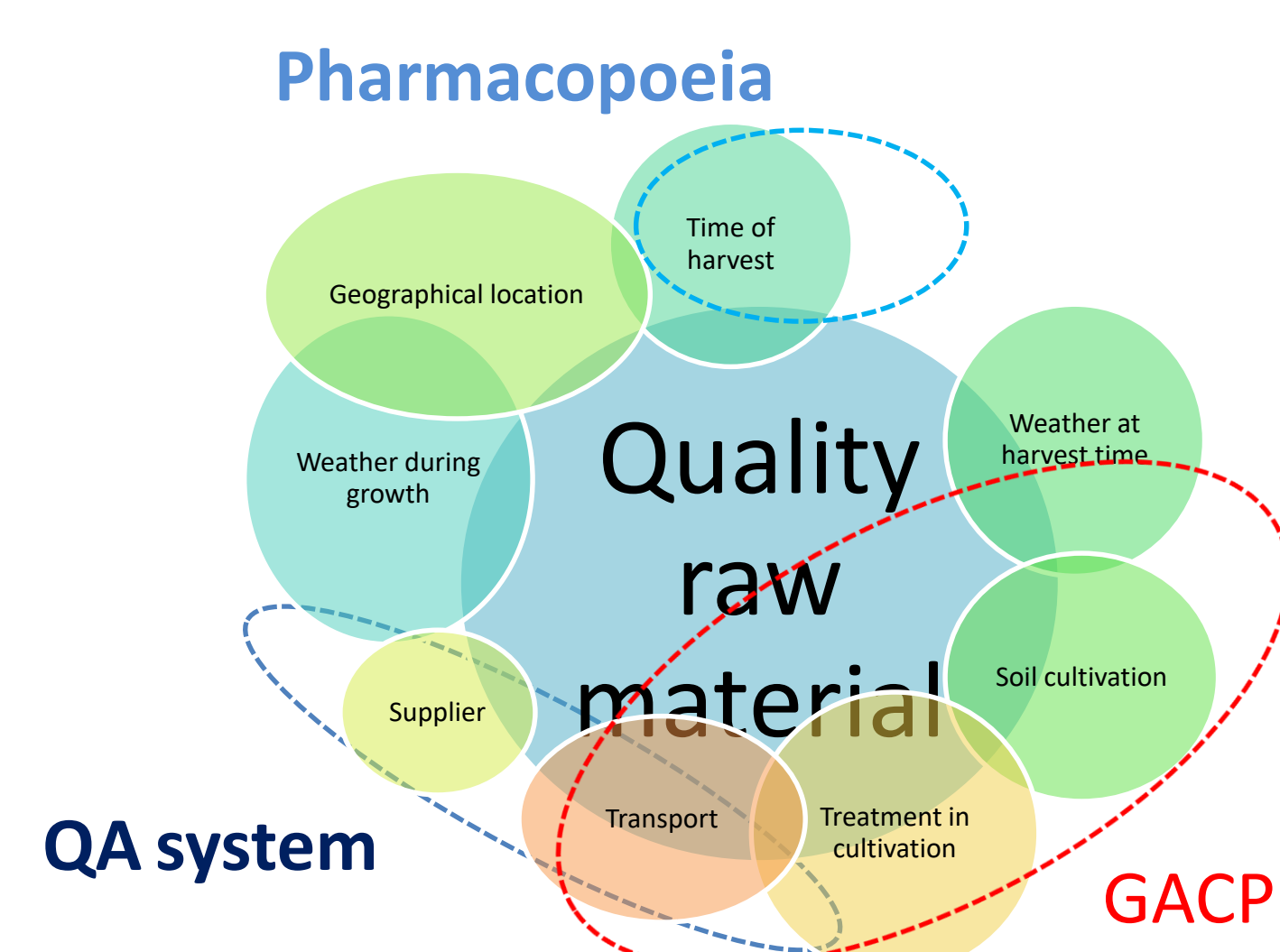
The homeopathic manufacturer is responsible for quality. Documentation (cultivation, harvest, transport...) is prepared by the supplier and checked by the manufacturer. Quality control (incoming control) is performed by the homeopathic manufacturer, not by the supplier. The homeopathic manufacturer bears the risk! GMP inspection takes place. Suppliers are not quality-relevant. Supplier fixing results in high efforts. Supplier fixing has no benefits.

Proposals for discussion

Specification (raw material and mother tincture) is fixed by pharmacopoeia and does not change with change of supplier. Quality is ensured by 1. GACP conformity (herbal supplier) and 2. QA system of the homeopathic manufacturer (incl. supplier audit) 3. Specification fixed by pharmacopoeia

Suppliers should be given in the registration dossier exemplarily, no variation requested!

Factors influencing the herbal raw material's quality are under control:



¹ European Committee for Homeopathy. Contribution to discussion at homeopathic workshop at EMEA on 27th Oct 2006. EMEA workshop on homeopathic medicinal products; 27/10/2006 [Internet]. European Medicines Agency [quoted on 13/02/2018]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2009/11/WC500012796.pdf