SAFETY ASSESSMENT DECISION SUPPORT FOR EXCIPIENTS IN MEDICINAL PRODUCTS

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BACKGROUND INFORMATION

Some excipients in medicinal products could cause undesirable or harmful adverse events under certain circumstances. Therefore, information for safety decision support for certain excipients in medicinal products is needed.

PURPOSE

To provide pharmacists with safety assessment decision support for excipients in medicinal products during the dispensing process.

METHOD

We identified excipients used in medicinal products which could cause undesirable or harmful adverse events from the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. For each of these, a review of scientific literature and standard reference works is carried out.

Practical guidelines for safety assessment decision support

Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'

Review of scientific literature and reference works

Decision: is an alert in practice necessary and helpful?

If no: no practical guideline

If yes: development of practical guideline for safety assessment decision support

Implementation in Dutch Drug database G-Standaard

Implementation in Pharmacy Management Systems by software companies

In addition: practical tips and background information on website

RESULTS

Based on our review, we provide practical guidelines for safety decision support for excipients in medicinal products through the modules Allergy, Contraindication and Minimum Age in the Dutch drug database G-Standaard. This information is incorporated in electronic healthcare systems, which in relevant situations leads to an alert during the dispensing process. Such an alert could for example pop up when a medicinal product containing propylene glycol is prescribed to a child under 5 years of age or when a product containing aspartame is prescribed to a patient with phenylketonuria. In addition, we offer background information on our website.

CONCLUSION

Dutch pharmacists are provided with safety assessment decision support for excipients in medicinal products during the dispensing process through information in the Dutch drug database G-Standaard and through background information on our website.

Examples of safety assessment decision support for excipients in medicinal products

Excipient	G-Standaard module + specification	Advice in practical guideline (example, shortened version)
Aspartame	Contraindication – Phenylketonuria	Calculate amount of ingested aspartame and adjust diet if necessary
Propylene glycol	Minimum age – children under the age of 5 years	Calculate if child doesn't ingest more propylene glycol than treshhold value
Methyl parahydroxybenzoate / Methylparaben	Allergy – products containing methylparaben	No advise, only alert

G-STANDAARD

The above mentioned practical guidelines for safety assessment decision support are integrated in the G-Standaard.
The G-Standaard is the Dutch drug database, which is used by all parties in healthcare, including physicians, pharmacists, wholesalers, manufacturers, health insurers and the government. The G-Standaard supports the different processes in healthcare, like prescription, dispensing, ordering, reimbursement and decision support.

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