Klinikum rechts der Isar
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HERA – A NEW TOOL FOR THE QUALITATIVE AND PHARMACOECONOMICAL EVALUATION OF GENERIC DRUG PRODUCTS BEFORE CHANGING BRANDS

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What was done?

A working-group of pharmacists from seven hospitals developed an Excel-based tool for the qualitative and pharmacoeconomical evaluation of generics before changing brands (aut-idem substitution) in hospitals:
"HERA – HTA-Evaluation of geneRic phArmaceuticals"

Why was it done?

Rising cost-pressure and increasing shortages have made generic substitution a common practice in hospital pharmacies.
To ensure constant treatment quality and patient safety, the equivalence of a potential new product with the current one must be guaranteed before changing brands.

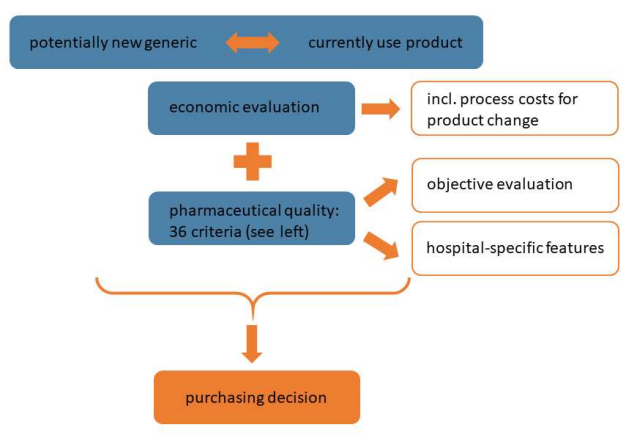
Table 1

Approved uses	
	legal status: drug product / medical device / dietary supplement
	approved indications
	approved administration routes
	pediatric marketing authorisation
	use during pregnancy
	use during lactation
Drug substance	
	drug substance (salt, ester)
	drug content in relation to dosage
	drug concentration of different strengths
Dosage form and excipients	
	potentially problematic excipients
	sustained release
	enteric coat
	special galenic features
	divisibility of tablets
	administration via enteral tubes
	compatibility data for intravenous products
Handling	
	ready-to-use dosage form
	dissolution behaviour of powders
	simpleness and safety of handling
	storage life after opening / reconstitution
	storage life of the ready-to-use preparation
	online availability of prescribing information
Safe Design	
	unique product name (no sound-alike)
	precise declaration of strength
	discernability of different strengths
	unique packaging design (no look-alike)
	precise labelling of primary packaging
	peel-off lable
	recognizability of solid oral forms
Packaging & Storage	
	bulkware or blisters with or without individual perforation
	suitability for automated picking machine
	anti-counterfeiting protection (securPharm)
	storage conditions
	shelf life
	quality and stability of packaging
	reasonable pack size

How was it done?

Within HERA's Excel-matrix a potentially to-be-used generic is compared with the currently used product (Figure 1).
The economic evaluation is based on unit-prices and prescription volumes, but also includes process-costs associated with the product change.
The assessment of pharmaceutical quality is based on 36 criteria from six areas (Table 1).

Figure 1



The objective quality evaluation is complemented by the assessment of hospital-specific features. Complex substitutions – e.g. those associated with a handling change – require involvement of the medical staff using the product.

The purchasing decision is taken based on the synopsis of pharmaceutical quality and economic evaluation (Figure 2).

Figure 2

generic with quality rating „1" (minor advantage) and potential annual savings of 6.300€, compared to the currently used product (data point generated automatically in the HERA-instrument based on data input)

What has been achieved?

Standardized evaluation of product differences before substitutions allows for early identification and mitigation of potential problems of brand changes, thus optimizing patient safety. HERA also guarantees reproducibility and transparent documentation of product changes.

What next?

The pharmacies of our purchasing group now routinely use HERA for the assessment of generics before intended brand substitutions. Each evaluation is conducted in one pharmacy and shared with the others via data-cloud.
We have published a paper on HERA and presented it at the German Hospital Pharmacists' congress in 2018. Our aim is to create a network of colleagues with shared access to all colleagues' HERA product-evaluations to reduce the workload for the individual pharmacies.

References

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