# EDITORIAL

## Adapting medicines for children

The paper by Galicia-Esquivel and colleagues describes their experience with extemporaneous dispensing of formulations adapted for children in a large, tertiary care paediatric hospital in Mexico[1].

The laboratory concerned is staffed by chemistry graduates and technicians who are able to work in a pharmacy but are unlikely to have the same training in pharmaceutical sciences and, in particular, formulation science as pharmacists. There is no information on the source of formulations or recipes used, so their quality cannot be judged. The standards in the Mexican Pharmacopoeia and Good Manufacturing Practice were not followed and no evaluation of formulations was made through lack of equipment. Many of the drugs included in extemporaneous medicines were available as commercial paediatric preparations and they may have been prepared extemporaneously to reduce costs.

To many European and American pharmacists, this would be an unsatisfactory state of affairs. Before criticising, however, we need to have much more information about the healthcare system in Mexico to know why the situation in a large children's hospital is as described and we should also inspect our own practices to see how they measure up.

We in Europe do not know the cost of drugs in Mexico or whether paediatric formulations marketed in other countries are available in Mexico. The Mexican system of pharmacy practice is clearly different. In Europe, suitable paediatric preparations are marketed in some countries but not in others. European pharmacists have a tradition of importing paediatric preparations to satisfy their need, but this is easier in some countries than others. They continue to prepare extemporaneously even though suitable alternatives could be imported, often because they are unaware of their availability but also because of cost[2]. Pharmacists in the USA continue to prepare medicines such as trimethoprim syrup which have been available for years as authorised paediatric preparations in many other countries[3]. In the UK a recent survey suggested that 50% of formulations used in large children's hospitals did not have the expiry period reliably established. Standards for extemporaneous dispensing are only available in a few European countries. There are few bioavailability studies conducted with these medicines even though some are prepared and distributed on a large scale.

The situation in Mexico would appear to be unsatisfactory but the authors recognise the situation and must be encouraged to improve it to ensure that medicines delivered to their patients are safe, effective and of good quality. However, pharmacists in other countries should be looking at their own practices to ensure that suitable, authorised paediatric preparations are used wherever possible; that extemporaneous preparation is undertaken in accordance with agreed standards; that the best possible formulation or recipe is in use and that it's chemical, physical and microbiological quality has been assured. Testing of products and raw materials should be undertaken to further assure the quality of the individual medicine, particularly when batches are prepared for several patients[4].

Even with the current US regulations and forthcoming European regulations promoting research, development and marketing of paediatric medicines, there will always be a requirement to adapt some medicines to the needs of children. The pharmaceutical industry can assist by publishing extemporaneous formulations as part of their label or authorisation and by making available active ingredients. The industry could also pay more attention to the needs of children in different countries by examining the extent of extemporaneous drug preparation and importation and finding different ways of making their drugs available. We are often told by the industry that they now work in a global market but there is good evidence of inequitable distribution of medicines for children, presumably linked to economic viability.

More than thirty years on, Harry Shirkey's 'therapeutic orphans' are still with us[5]. Paediatric

pharmacists in most countries still have room to improve practice!

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## References

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