

Paediatric pharmacy



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Over the years I've worked with many pharmaceutical companies based all over the world, and I'm lucky enough to have friends and colleagues working in most countries you care to mention. This, I think, gives me a global perspective on the industry, and just lately I've been giving a lot of thought to the differences between the various sectors. I believe it's true to say that from an international perspec-

tive there's probably more parity in the pharmaceutical industry around the world than ever before, but one area where the differences are particularly striking is in the practice of clinical paediatric pharmacy.

Two years ago, the European Medicines Agency (www.emea.europa.eu) took action to improve the health of children in Europe by publishing guidelines (based on US Food and Drug Administration rules) to regulate paediatric medicines. Their objectives were to facilitate the development and availability of medicines for children aged 0 to 17 years; to ensure that medicines for use in children are of high quality, ethically researched, and authorised appropriately; and to improve the availability of information on the use of medicines for children. The guidelines also specified that the objectives should be fulfilled without subjecting children to unnecessary trials or delaying the authorisation of medicines for use in adults. Additionally, to increase the likelihood of this legislation

being followed correctly, they included some incentives for manufacturers. For example, when a licence application includes results of studies in the paediatric population, once authorisation is obtained in all EU Member States and study results are included in the product information, the pharmaceutical company producing the product is eligible for a six month patent extension. Also, in the case of medicinal products which have been awarded "Orphan" status, the manufacturer can, by meeting the same requirements as above, benefit from an additional two years of exclusivity (on top of the original 10 years awarded under the EU Orphan Drug regulations). In other words, it makes good business sense for pharmaceutical companies to fine-tune their products for children. And from the hospital pharmacist's point of view, this means guaranteed efficacy, quality and appropriate doses for a wider age range.

I've noted in my travels around the Middle East that there are wide variations in the practice of pharmacy for paediatric medicine. For instance, when medicines specifically manufactured for children are not readily available, a pharmacist will often opt for 'the next best thing', which could mean using a lower dose of a medicine designed for adults or by changing the administration route (crushing up pills that are meant to be swallowed, for example) which can impact efficacy and increase the potential risk of side effects.

Even with the best will in the world and years of experience, this is an inexact science.

The paper 'Making Medicines Safer For Children – guidance for the use of unlicensed medicines in paediatric patients' recently written by a group of leading paediatric pharmacists in the UK, explores the options available to a pharmacist when they need a medicine that's not available locally. To read the full paper, see www.rosemontpharma.com and click on 'education' on the menu bar.

Another option for paediatric pharmacy in the Middle East would be to move away from making variations of adult medicines in-house towards importing quality-assured paediatric pharmaceuticals from regions where strict regulation is already in place. I believe that Europe now leads the way in the field of clinical paediatric pharmacy, making importation of paediatric medicines from Europe into the Middle East an extremely sensible option. Durbin PLC can source whatever you're looking for and offers a speedy delivery service that's second to none.

Finally, ensure that you're giving the children in your care the best treatment possible by keeping the BNF For Children (www.bnfc.org) handy. Based on information from hospital paediatric formularies, research studies and systematic reviews, it contains information on the use of drugs for neonates, infants, children and adolescents. No pharmacist's desk should be without one. **MEH**

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