Concerns over regulation of oral powders or gels sold as medical devices in Europe

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Oral powders or gels, sold as medical devices in the European Union (EU), aren't regulated to the same safety standards as those applied to medicines, reveals research published online in the *Archives of Disease in Childhood*.

As a result, these products, which look like medicines, can be marketed with very limited clinical data and accompanied by poor quality product information.

This is of particular concern for children taking them, say the researchers, who call for the regulation of these products to be revised.

To test the impact of the regulatory assessment and monitoring processes for MedDevs before and after launch, the researchers compared the product leaflet information for three soluble powder and barrier gel MedDevs for the treatment of digestive problems, including in children, with that provided for prescription drugs.

They scrutinised the information on product composition and ingredients; use/indications; clinical effectiveness; interactions with other drugs/foodstuffs; toxicity; and long term safety.

And they assessed the quality of the published clinical evidence available at the time and used to inform the launch of: gelatin tannate; gelatin tannate plus tyndalised probiotics (for diarrhoea); and a hyaluronic acid and chondroitin sulfate gel (for acid reflux).

They found that the product information—which is used by clinicians and patients—for these three MedDevs fell short of the quality required for medicines.

For example, there was insufficient or no information on: the derivation of the products; the ratio of the relevant constituents; toxicity; factors affecting absorption and potential interactions with other drugs; maximum safe doses; and potential long term harms.

Although no evidence of side effects associated with the three products has been published, there is no proof of safety either, note the researchers.

No age limit was specified for any of the three MedDevs, meaning that they could all be used in children from birth onwards, despite little or no published evidence of their safety and clinical effectiveness in children.

MedDev product information leaflets don't mention side effects, yet there are safety concerns associated with the active ingredients in each of the products, say the researchers.

MedDevs for use in Europe are regulated by a business arm of the EU called GROW, rather than the European Medicines Agency, and require only certification with a 'CE' (quality) kitemark before the product can be marketed.

This process doesn't require evidence of efficacy or safety from high quality clinical trials, as is the case for medicines.

It also means that these products can automatically be sold without a prescription across the EU, and actively marketed to patients and clinicians. Medicines are usually prescription only when launched, and can only be marketed directly to patients if and when they become 'over

the counter' products.

And the three MedDevs reviewed could easily be mistaken for medicines, helped in no small part by references to them as "paediatric drugs" or "drug treatments," suggest the researchers.

"We believe that that these products [MedDevs] could be perceived as medicines, likely because of their indication, formulation and repeated mode of administration similar as for a medicinal drug," they write.

A tougher monitoring system for MedDevs is under development, they acknowledge, but it still isn't as stringent as that applied to medicines.

"In conclusion, this analysis indicates relevant differences in the leaflets and standards used to certify MedDevs for oral use in children in the EU, when compared with medicines," write the researchers.

"We found that oral MedDevs requiring repeated ingestion to treat a medical condition (similarly as required for medicines) are hardly or not evaluated in children. This is likely because the regulatory requirements of MedDevs differ significantly from the registration standards for medicines.

"In our opinion, MedDev regulations need revision, excluding all substances for repeated oral intake," they say.

More information: Suzy Huijghebaert et al, Medical devices that look like medicines: safety and regulatory concerns for children in Europe, *Archives of Disease in Childhood* (2019). DOI: 10.1136/archdischild-2018-316391

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