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### 515 Choice of fluids for resuscitation in children with severe infection and shock

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### 517 Oral bisphosphonates and oesophageal cancer

Evidence is inconclusive but cautious prescribing and active follow-up are advised, says Diane K Wysowski >>> Research, p 545

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### **Christmas 2010: Deadline for submissions**

Please submit your articles for consideration for this year's Christmas issue by 20 September.









Go to http://submit.bmj.com for more details about online submission. And remember to mention in your covering letter that your article is intended for the Christmas issue (it's not always obvious). No spoofs, please.

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The Editor, BMJ BMA House, Tavistock Square, London WC1H 9JR

Email: editor@bmj.com Tel: +44 (0)20 7387 4410 Fax: +44 (0)20 7383 6418

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#### PICTURE OF THE WEEK

On 16 September the Royal Mail issues a series of stamps illustrating medical breakthroughs, celebrating the work of British scientists. The stamps feature six medical specialties, including cardiovascular medicine, drug therapy, and parasitology.

**blogs.bmj.com/bmj** Neil Snowise has blogged about medical stamps

#### THE WEEK IN NUMBERS

**14%** Reduction in the risk of developing type 2 diabetes associated with eating more green leafy vegetables (Research, p 543)

**0.3%** Proportion of patients who died within 30 days of bariatric surgery (Research, p 546)

**2.24** Relative risk for oesophageal cancer in people with about five years' oral bisphosphonate use versus no prescription

(Research, p 545)

**50-70%** Proportion of patients in intensive care units who develop moderate to severe anaemia during their stay

(Clinical Review, p 547)

#### QUOTE OF THE WEEK

"Specialisation is promoting yet more medical tribalism, the gangs aggressively defending their clinical turf and unwilling to accept criticism"

Des Spence, general practitioner, Glasgow, on why we need an international moratorium and non-proliferation of medical specialisation (Views and Reviews, p 560)

#### QUESTION OF THE WEEK

Last week we asked, "Should people with dementia be allowed to vote?"

**52%** said yes (total of 402 votes cast)

This week we are asking "Should doctors regulate themselves?"

**bmj.com** cast your vote

#### **EDITOR'S CHOICE**

## Rosiglitazone: a cautionary tale

Europe's regulators ... should require a higher quality of evidence, including proof that new drugs are better than existing drugs

This week a *BMJ* investigation suggests that the diabetes drug rosiglitazone should never have been licensed and should now be withdrawn (p 530).

The tale of rosiglitazone is a cautionary one from which we must hope the main parties will learn for the future. Hailed as a much needed new approach for patients with type 2 diabetes, the drug was licensed 10 years ago with only limited evidence of its effectiveness and concerns over its safety. While allowing the drug on to the market, the regulators asked the manufacturer GlaxoSmithKline to do additional trials. This the company did while marketing the drug around the world. Millions of prescriptions later, the results of the open label RECORD trial are hotly disputed. GlaxoSmithKline says it shows the drug is safe and the European Medicines Agency seems to have taken this conclusion on trust. Officers at the Food and Drug Administration, however, prompted by concerns about GlaxoSmithKline's conduct (BMJ 2010; 340:c1848, doi:10.1136/bmj.c1848) and aided by the FDA's requirement for individual patient data, decided earlier this year to take a closer look. They uncovered errors in the way the trial was done that systematically favoured the company's drug.

Meanwhile the *BMJ* has discovered that the UK's Committee on Human Medicines advised the UK regulator, the Medicines and Healthcare products Regulatory Agency, in August that the risks of rosiglitazone outweighed the benefits and that it had no place on the UK market. But doctors received only a muted version of this guidance in a letter in August suggesting merely that they seek alternatives to rosiglitazone. The committee's much starker

conclusion would not have been known until later this month when the EMA meets to decide rosiglitazone's fate, and might not have been known at all if the EMA were to decide to keep the drug on the market.

So what should happen? Our editorialists (p 513) and commentator (p 535) and others quoted in the investigation are clear on a number of things, none of which is being said for the first time (*BMJ* 2009;338:b1025). Europe's regulators should be much more transparent. They should require a higher quality of evidence, including proof that new drugs are better than existing drugs before being licensed. And if they do ask the manufacturer to undertake post-marketing trials, they must do a better job of overseeing the way these trials are designed and done.

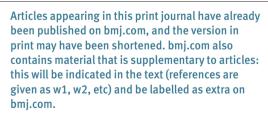
Will this put extra strain on what many see as an already over-regulated pharmaceutical industry? Certainly it will. So the patent for new drugs should be extended, from the current 20 years to perhaps 25 or 30. We all need the pharmaceutical sector to flourish and innovate. We should also seek to modify the increasingly destructive relationship between industry and the public. This would require concessions on both sides: far greater transparency from industry and the regulators, including access to raw data and funding for independent trials; and greater understanding from the public that there is no such thing as a completely safe drug.

#### Fiona Godlee, editor, BMJ fgodlee@bmj.com

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Career Focus, jobs, and courses appear after p 560

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Would you "steal" a book? Eight per cent of US university students say they have succeeded in downloading a textbook. The practice is on the increase, and the Association of American Publishers says that it must be combated to protect the creative energy of the publishing industry.

But not everyone agrees. "Copyright law has always included a right for the general public to have access to the content of books through the library system," says Andrew Robinson, free culture campaigner and leader of the UK Pirate Party. "Should students be forced to visit a physical library... or should we allow them to use modern technology to accomplish the same goal in a fraction of the time?"

student.bmj.com (*Student BMJ* 2010;18:c4099)