Web pharmacies and ciprofloxacin:

A field study Roger Bate Abstract 244 treatment packs of the broad spectrum antibiotic ciprofloxacin were sampled from a stratified sample of 61 web pharmacies. Each sample was analyzed for active pharmaceutical ingredient content (API) and 11 (4.5%) were found to be grossly (less than 80%) under content. Most of the 11 came from non-certified sites, but two came from certified sites. None of the failures appeared to be a falsified medicine (packaging appeared correct and contained over 50% API). All failures were made by Asian manufacturers (7 Indian and 4 Chinese). All the failures regardless of source are a risk to patient health, and could accelerate population level resistance to this crucial antibiotic. Background In previous work on internet sourced medicines (Bate et al 2010 and Bate et al 2013) my colleagues and I analyzed five well-known branded medicines and used a precise raman handheld spectrometer to assess deviations in quality. In this new effort we assess the active ingredient content of the broad spectrum antibiotic ciprofloxacin.

One reason for this is that this allows measurement of generic products, which was not possible given earlier assessment techniques. In different earlier research (Bate et al 2015 and Bate et al 2016) we found that ciprofloxacin lost its patent protection in countries around the world over the last 15 years and so most patients get pills. We bought ciprofloxacin in several dozen cities over the past decade, 9 per cent of the roughly 2,500 samples failed basic quality tests (about 100 samples were patented innovator products and none failed). Seven per cent of which were substandard, products made by legal manufacturers, and two per cent were fake, products made by criminal groups. When a subset was subjected to more stringent tests we found three per cent more substandard medicines (no more fakes), so roughly ten per cent of the ciprofloxacin was substandard. Methods Following the protocol established in Bate et al 2010 we procured from three types of online pharmacies: tier 1 are US-based and certified by the National Association of Boards of Pharmacy (NABP) or LegitScript.com, tier 2 are certified by
PharmacyChecker.com or the Canadian International Pharmacy Association (CIPA) but not by NABP or LegitScript, tier 3 are not certified by any of the four agencies. Most tier 2 and tier 3 websites are foreign. We bought 28 samples from 7 tier 1 pharmacies, 88 samples from 22 tier 2 pharmacies and 128 samples from 32 tier 3 pharmacies.
We tested the samples with the protocol outlined in Bate et al 2015. All medicines were assessed following the Global Pharma Health Fund (GPHF) e.V. Minilab® protocol to identify substandard or falsified medicines (Jahnke 2001).

The results for this study closely echo previous studies, with one worrying change. Even the credentialed sites (tiers 1 and 2), which in prior studies only sold high quality medicines, sold a couple of medicines with insufficient ingredients. Both of these samples were Indian made medicines approved by FDA. Of course far larger samples would be required to make a proper assessment of any problems with these medicines and the sites selling them. As expected the tier 3 sites had the largest problems.

And as in previous studies on ciprofloxacin, the source of the problem was once again Asian (Indian and Chinese) made medicines. Conclusion With a rise in antimicrobial resistance it is essential that all medicines are of the highest quality and when it comes to ciprofloxacin that is simply not the case. It is especially concerning that if people buy medicines from non-credentialed (tier 3) sites, that they risk their own lives and could encourage population level resistance to an important antibiotic. References Bate, Roger and Kimberly Hess, (2010) "Assessing Website Pharmacy Drug Quality: Safer Than You Think?"

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