Antibiotics: Europe or a Tapestry of Nations?

By David Shlaes — December 3, 2019

The United States is not the only country where drug pricing is disjointed. Referring to Europe, ACSH advisor Dr. David Shlaes writes that it is "definitely still a tapestry of nations or even the Wild West." Especially in the world of antibiotics.

I spend a great deal of time in Europe. For drug regulation, in terms of approval for market authority, there is a centralized European agency and procedure. I have been involved, at least peripherally, in drug pricing discussions with various European national authorities where each has its own rules, regulations, and policies that govern such negotiations. In 1987, Flora Lewis wrote a wonderful analysis of Europe as it considered its future. The book is entitled, “Europe, a Tapestry of Nations.” When it comes to drug pricing, it is definitely still a tapestry of nations or even the Wild West and not Europe.

While the European Commission has no direct control over pricing within the various national authorities, it does exercise some control over transparency in pricing considerations within the national authorities. It also has undertaken a number of initiatives over the years thinking (not so much doing) about innovation, access, and other common issues. (For details, see this link [3].) The World Health Organization recognizes this as a problem in Europe as indicated in this 2018 policy [4] brief. The brief notes that collaborations already exist among and between various
European national authorities in the realm of drug pricing. The brief apparently does not explore the idea of a centralized European process for key medicines.

Given the emerging crisis of antibiotic resistance and the front and center role being played by economic considerations for antibiotics, each European country seems to be taking a different tack. Most are doing little or nothing to solve this economic problem. In the UK, a pilot program leading to upfront drug purchases that will depend on the drug’s value to the UK population is being undertaken. John Rex has uploaded a recent set of slides from a NICE webinar on their plans for this program.

The problem for me and for all of us is that this may well be too little too late. Even if the UK succeeds in establishing its program, how many other countries will do the same and how long will that take? The time it will take to provide a meaningful return on investment (if that occurs at all) will not save a number of small companies that are currently struggling with impending bankruptcy. A raft of such bankruptcies will probably occur in the near future. This will further aggravate the death spiral of investment in antibiotics R&D.

The other issue I find with all of these efforts is the math. The UK will base its program on the value of products to the UK population (see this announcement). But given the number of resistant infections in the UK, how much money will their upfront purchase entail? How many products for a given type of resistant infection will qualify for the program? The number of resistant infections even taking all developed countries together are not enough to drive a sufficient return on investment for companies marketing these therapies – especially if there is to be more than one product for each key resistance type. For these reasons, I support pull incentives that are somewhat divorced from patient numbers.

Given previous European initiatives, it surprises me that Europe is not playing a more active role here. I could find nothing in the European Charter or elsewhere that prohibits Europe from doing so. I conclude, therefore, that it is the national authorities themselves that are adverse to some centralized pricing procedure even for areas where the marketplace is failing to provide reasonable access to needed new medicines like antibiotics. But if we are to have truly valuable pull incentives, a centralized European approach will be required.

Some, including me, have argued for years that the US, though its irrational drug pricing policies have supported pharmaceutical innovation for the rest of the world. The US still accounts for about 50% of the total pharmaceutical market and is the largest single country contributor to pharmaceutical company profits in general. PhRMA argues that any change to, say, a US national negotiation for drug prices as is done in most other countries and as has been recommended by many including the National Academies, will reduce innovation. They are correct. Given that large pharmaceutical companies generally base their R&D budgets on yearly profits, a large change in profits would occur if the US adopts a more rational pricing policy, which would result in lower R&D investments and, consequently, less innovation.

I would argue that it should be the turn of other countries, including those in the EU, to better support innovation. One opportunity for Europe to lead in this regard would be to provide
substantial pull incentives for needed new antibiotics. This would require a dramatic change in the way EU countries work now, but for the sake of our future, I think they should consider this approach. Maybe the US would even follow their lead . . .