

Bringing New Antiinfective Agents to Patients - Role of the Industry

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We have seen a dramatic shift in industry sponsored antiinfective research away from antibiotic research, but instead increasing antiviral research during the past decade. This is partially due to feedback to the pharmaceutical industry that society did not need new antibiotics. Additional factors have been rapidly increasing regulatory hurdles, and significantly increasing development cost and development time. A good example of this is Sanofi-Aventis new innovative antibiotic ketek which had its development lengthened substantially with requirement of more studies and in the end ended up studying some 24.000 patients before approval! Additionally, antibiotic therapy is typically short courses, all contributing to the area being financially relatively unattractive for big pharma.

Since the emergence of increasingly resistant/multiresistant strains of bacterias, calls for redoubled efforts in antibiotic research has been made. However, with substantial regulatory barriers remaining, the possibilities of putting in place stimuli of mainly financial character has been discussed. Several possibilities exist that would be attractive to both major pharma and biotech companies but so far no significant progress has been made.

New antibiotics with activity against multiresistant strains also risk being put "in reserve", further drastically decreasing the financial attractiveness, strong formulary controls with prior authorisation by specialist also work as a deterrent on industry.

Encouragingly, a number of biotech companies focused on antibiotic research has emerged on the scene in recent years. Their pipelines now contain antibiotics inlicensed from big pharma, some companies are formed directly as a spinout and

others have a more traditional biotech model, often formed based on university collaborations. This contributes to a slowly growing pipeline in the antibiotic area. However, young biotech companies, especially European biotechs, are vulnerable as access to funds is scarce. Although a relatively small peak sales forecast can still be attractive to a small company, you still need to see potentially attractive financial return to get access to further funds.

Developing countries also have huge medical needs for better antiinfectives to combat common diseases like malaria and tb. Collaboration between public institutions and private companies to pool expertise and resources have started, but needs to grow. Further build up of this R&D is vital!

New medicines, developed globally will by definition be relatively expensive; this needs to be understood and accepted also in the antiinfective field. Mechanisms to help developing countries afford improved medicines for major healthcare problems are thus needed; several proposals are being developed. With attrition, the cost of developing one new medicine is approximately \$1bn and typically 40-50 % of the patent life is already gone by the time approval has been received. To get even modest payback on this investment, when an antibiotic treatment course is perhaps 7-10 days, per unit price will be high.

Aggressive use of generics once patent has expired on all medicines as well as elimination of both traditional drugs where superior alternatives exist and herbal and other "alternative" treatments where no credible scientific documentation of efficacy and/or safety exist will create substantial financial savings which in turn at least partially can be used to finance new and better medicines.