Efficacy of generics depends on quality

Some pharmaceutical companies concentrate on developing new medicines, others on “copying” – producing more affordable analogues of original products. Richard Francis, Global Head of Sandoz, talked to RG (Rossiyskaya Gazeta) about how to ensure the quality and efficacy of generics.

1: Many Russians believe that originator medicines are better than generics. There is a preconception that generics are not the best option because of the legislation governing production in Russia. In other countries, biosimilars are actively promoted and generics are covered by insurance policies. Is that policy warranted? What are the advantages of generics, beyond price?

From a global perspective, generics (and biosimilars) offer the same quality, safety and efficacy as branded pharmaceuticals at a lower cost, increasing patient access to important, often life-saving, treatments. They contain the same active ingredients in the same concentrations as their reference product and can therefore be expected to produce an equivalent therapeutic effect – it’s that simple. Regarding the benefits of generics, cost savings are obviously critical. If we take the example of the US, an IMS study showed that the use of generics had saved the US healthcare system more than USD 1.2 trillion between 2003 and 2012. However, access is not just about cost savings – generic and biosimilar competition encourages originators to innovate and free up resources that healthcare systems can reinvest into more sophisticated treatment.

2: Generics are launched (approved) with a simple approach, without clinical trials. Some people believe this approach is not justified. What do you think in this regard?

The generic approval process worldwide is based on a simple principle: as the reference product has already been authorized for several years, there is existing and reliable information about the product’s safety and efficacy, and there is no need to repeat comprehensive clinical studies. However, regulatory systems worldwide define tests to ensure that the generic is safe and effective; usually including a bioequivalence study to show that there is the same quantity of the active substance in the human body whenever the same dose of the reference or generic medicine is taken over a defined period or periods of time. This tried and tested approach also prevents the unnecessary and unethical repetition of extensive experiments on humans and animals.

3: But there is also a problem of “second” and “third” copies – when the reference drug is not the original but a copy and the new copy is compared with generic medicine? This approach is allowed in Russia. Does anyone else have the same practice?

Under Russian legislation, as in other countries / regions, a bioequivalence trial for a medicine allows a conclusion to be drawn regarding generic bioequivalence to the reference product, in a specific form and dosage. The reference product has already demonstrated efficacy and safety, based on pre-clinical and clinical trials. However, the reality is that several bioequivalence trial results in Russia were accepted despite the fact that the generic was compared not to the reference product, but to another generic (already approved and marketed). Approving generics on this basis can cast doubt on the safety, efficacy and quality of all generics, and is not in line with international practice.
4: New original drug R&D is becoming more expensive. The generics market segment is growing while innovative companies’ incomes decrease. How can you save the innovative segment when profits will not cover costs for R&D and promotion?
At Sandoz as well as in all the Novartis Group, we believe that generics and patent-protected medicines are complementary. As the head of the generics division, I am probably not the best person to comment on R&D costs for producers of patent-protected medicines – though I am convinced that in order to continue leading the way in the global pharmaceutical industry, the company should relentlessly focus on innovation and meeting unmet medical need with wide usage of generics.

5: What can you say about the current position and perspectives of the Russian pharmaceutical market?
Over the past 10 years, the Russian pharmaceutical market has undergone substantial changes. The government has developed and is implementing its Strategy 2020, a federal program aimed at transitioning the Russian pharmaceutical and medical industry to an innovative development model. In the mid to long term this should increase the percentage of locally produced products in both generics and innovative medicines. We consider as very important the trend of collaboration and joint programs with local manufacturers. The Russian generic market is expected to develop more rapidly than the patent-protected market. We expect an estimated generic penetration rate of 77%, nearly as high as in the US.

6: What are the company’s plans in Russia? What about localization?
Since March 2012, the Novartis Group has been building a manufacturing site in one of St. Petersburg’s special economy zones, with a productive capacity of 1.5 billion units per year, comprising both patent-protected and generic medicines for the treatment of diabetes, cardiovascular, cancer and immunological diseases. To date, Novartis has invested about USD 140 million.

7: Recently in Russia there is a tendency for broad discussion about rules governing the production and usage of biosimilars. What is your position in this regard?
In the EU and other key markets, biosimilars are approved via a stringent regulatory pathway that is distinct to that used to approve small-molecule generics. Under current Russian legislation, follow-on versions of biologics are approved via a simplified procedure that is very similar to that used for small-molecule generics. We support planned changes to Russian legislation that will help to distinguish and regulate biosimilars as a distinct category of medicine. This will increase clarity for all Russian stakeholders, as well as helping to drive global agreement on the “biosimilar concept”: the idea that development of high-quality biosimilars is a robust and systematic process with two key steps:
- Technical development to achieve a “comparable” or “highly similar” molecule, which matches the reference product profile
- A targeted clinical development program, agreed case-by-case basis with health authorities.