Only a few drug makers are actively targeting medicines needed in poor countries

By Ed Silverman @Pharmalot

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A girl gets tested for malaria in a South Sudan refugee camp. Most R&D focuses on developing treatments for malaria while other conditions are neglected, a new report says. Paula Bronstein/Getty Images

Amid growing pressure on the pharmaceutical industry to ensure people in low- and middle-income countries have access to needed medicines, a new report finds five large drug makers are doing most of the heavy lifting, but much of the R&D is focused on only five diseases, leaving many illnesses unaddressed.

Specifically, 45 different maladies have been identified as areas in which R&D should be a priority for developing medicines, vaccines, and diagnostics, but these represent only one-fifth of the total product pipeline numbering more than 1,300 projects. Most work, instead, is overwhelmingly focused on malaria, HIV/AIDS, tuberculosis, Chagas disease, and leishmaniasis. The least attention is being paid to maternal and neonatal health conditions, and to neglected tropical diseases.

Meanwhile, most of the priority R&D projects — 63 percent — are being conducted by five drug makers: GlaxoSmithKline (GSK1), Johnson & Johnson (JNJ2), Merck KGaA (MKKGY3), Novartis (NVS4), and Sanofi (SNY5), according to the report6 from the Access to Medicine Foundation, a nonprofit based in the Netherlands that each year ranks the progress made by the pharmaceutical industry in targeting needed medicines.

“The industry approach to access continues to mature and all of the companies are addressing access to some degree,” Danny Edwards, research program manager at the foundation, told us. “But a lot of the efforts are being undertaken by just a handful of companies in key areas. Pipelines from 20 companies we measured are not addressing priority needs at all. And there are no projects for 13 diseases.”
The 20 companies in scope are addressing 48 out of 139 priority product gaps. That means many much-needed medicines, vaccines, and diagnostics are likely not being developed, unless they are in early stages of development by, for example, academic research group or others in the private sector, especially diagnostics companies.

Edwards rattled off some areas of concern: a cholera vaccine for children younger than 1 year of age is not being addressed by any company, non-hormonal contraceptives are not being addressed at all, and there are a couple of projects for a trachoma vaccine, but remain in preclinical stages. In general, he noted that the median number of projects is just two for diseases that are being addressed.

Overall, 60 percent of the products in company portfolios appear on the World Health Organization essential medicines list. In compiling its report, the foundation assessed seven different criteria: general management of access to medicines; market influence and compliance; R&D; pricing, manufacturing, and distribution; patents and licensing; building capacity for partnerships; and product donations.

The latest report comes as public health officials and patient advocates continue to push drug makers to widen access to life-saving treatments in poor countries. This has been a sore spot for the pharmaceutical industry after sustaining reputational damage nearly two decades ago in South Africa over litigation surrounding access to costly AIDS medicines.

Despite signs of progress, much of the priority R&D is undertaken by Glaxo, which by itself accounted for about one-third of the projects that were examined. Of the 20 global drug makers whose pipelines were studied, two companies did not have any priority R&D projects: Boehringer Ingelheim and Novo Nordisk (NVO). Meanwhile, Eli Lilly (LLY) has just one, Bristol-Myers Squibb (BMY) has two.

And three companies — Astellas (ALPMY), Daiichi Sankyo (DSNKY), and AbbVie (ABBV) — have yet to develop an overarching approach for access and “tend to engage in access initiatives on an ad hoc basis,” according to the foundation. This trio of drug makers placed in the bottom quartile in at least three out of the seven areas of evaluation.

“The fact that the bulk (of the work) is concentrated among a small group of companies is dangerous,” said Jayasree Iyer, who heads the foundation. The concern, she explained, is that a void could develop if one or more drug makers exit certain research. “The only way to secure global health is if we can make sure governments and investors and companies recognize the fragility of the situation.”

A frequent example of such concerns is antibiotic research, since public health officials are increasingly worried about the emergence of superbugs that are resistant to available salves. Earlier this year, for instance, Novartis declared this area was no longer a “long-term strategic fit.” The move followed similar steps by such other large drug makers as AstraZeneca (AZN) and Eli Lilly.

Some other findings from the report:

- Of the 20 companies evaluated, the foundation identified 53 products that were described as “critical candidates” for access initiatives based on four criteria: patented products, first-line therapies, appearing on the World Health Organization essential medicines list, and targeting a disease in scope. The products are mainly medicines for HIV/AIDS or hepatitis C, and vaccines. However, the foundation found that 37 of the products, or 70 percent, are covered by at least one such initiative, and most are limited in scale and reach. In most cases, the approach relies on pricing strategies, and they apply in fewer than five of the countries where greater affordability is a priority. Glaxo and Gilead Sciences (GILD) account for more than half of the products with access strategies.
- The analysis indicates that the majority of the priority R&D projects are being carried out with public sector research organizations. But some drug makers are developing priority products on their own. One example cited is Merck KGaA, which is developing tests and treatments for schistosomiasis, a water-borne parasitic disease that affects around 252 million people.
- Most of the 20 drug makers are marketing cancer medicines that are on the WHO essential medicines list. The foundation counted 72 cancer treatments, and identified an access initiative — mainly pricing strategies — for more than half. But the foundation also noted that pricing initiatives for cancer products have limited reach, covering fewer than five key countries, on average.

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