CRA Insights: Life Sciences

CRA Charles River Associates

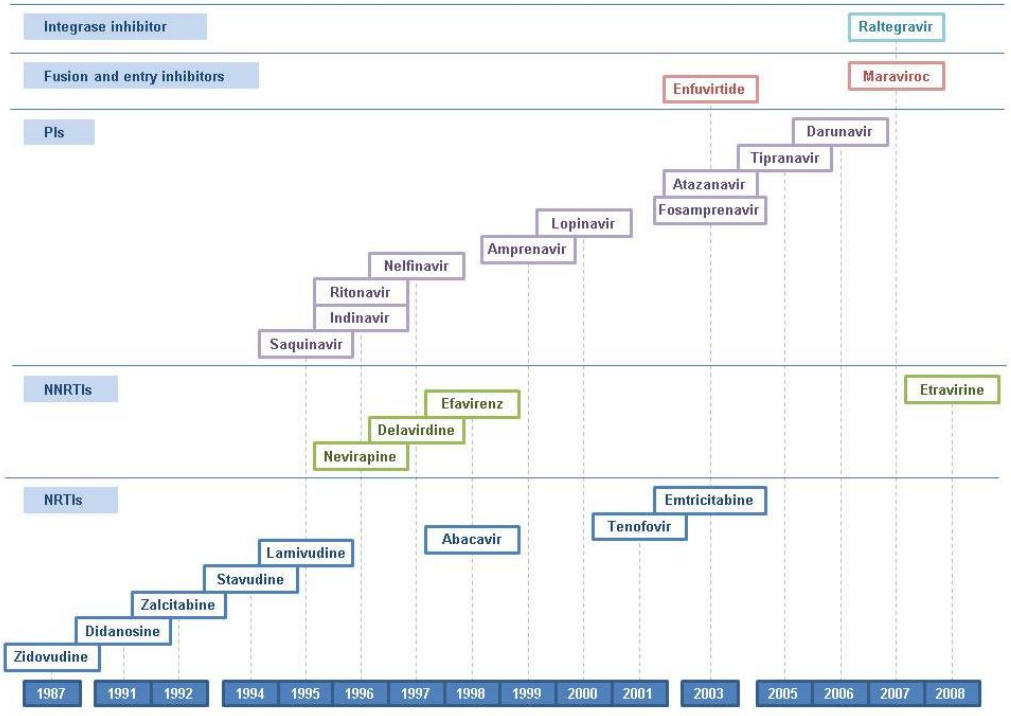
February 2012

Access to HIV/AIDS medicines

The value of partnership in ensuring access to medicines

Developing a strong evidence base is a fundamental part of the work of all life sciences companies, which is equally the case when addressing the most difficult policy challenges. We were, therefore, excited when the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) asked CRA to review the evidence on the developments concerning access to antiretroviral drugs (ARVs) for the treatment of HIV/AIDS over the last 10 years in low- and middle-income countries, the factors that have contributed to progress, and the lessons that these offer for the future.

Figure 1: Development of new ARV drugs over time by class



Source: CRA

Access first requires innovation

Firstly, we reviewed how the industry has responded to the challenge of HIV/AIDS. While the first treatments for HIV/AIDS were developed in the late 1980s, the most significant developments toward current antiretroviral therapy (ART) standards were achieved in the mid-1990s with the launch of protease inhibitors (PI) and non-nucleoside reverse transcriptase inhibitors (NNRTI). These newer drugs have since been used for combination therapies, known as highly active antiretroviral therapy (HAART). HAART typically comprises two nucleoside reverse-transcriptase inhibitors (NRTIs) plus one NNRTI or alternatively two NRTIs plus one PI (usually a ritonavir-boasted PI), resulting in reduced development of virus resistance to ARTs, one of the main limitations to the long-term efficacy of antiretroviral mono-therapy. As a number of new ARV medicines have become available, the set of treatment strategies employed by prescribers has multiplied, offering increased tolerability, reduced side effects, simplified dosages, and expanded the alternatives in cases when resistance to first-line treatment is developed.

Evidence not anecdote

To understand changes in access to these medicines, we selected seven countries (Botswana, Brazil, India, Mexico, Rwanda, South Africa, and Thailand) that are seen as having been relatively successful in improving access, but which represent a range of different economic, political, and demographic circumstances. For these countries, case studies were developed to illustrate some of the different approaches and strategies for combating HIV/AIDS, allowing an analysis of the various strengths and weaknesses of the efforts undertaken in each these countries. Research for these case studies included interviews with local industry, academics, non-governmental organizations (NGOs), and, where possible, government officials.

The insights gathered have been used to design a statistical analysis allowing us to test the relative importance of different factors in determining access to ART and prices of ARVs. This statistical analysis was performed using a wider set of low- and middle-income countries than the case studies, including those countries that have been relatively less successful in improving access to ARVs. The statistical analysis provided a basis for quantifying the importance of the policy interventions that were identified as potential drivers for improving access to ARVs over the last decade.

Significant progress has been made, but there remains much to be done

In the past 10 years, almost every developing country has substantially improved its population's access to ART, and approximately 50% of the HIV-infected population eligible for ART now has access, which represents an estimated five million people being treated. While this is a significant improvement from 2000 when less than 10% of people in need of ART in low- and middle-income countries had access, the other 50% of the population in need of ART still do not have access in these developing countries.

Contributing factors

From both the case studies and the statistical analysis, a number of conclusions can be drawn:

- The date when the universal ART programmes were initiated is clearly important and this reflects the relevance of political will and commitment. It is hardly surprising that programmes starting earlier—in Brazil and Botswana—have been the most successful in achieving high levels of access to ARVs. Political commitment to HIV/AIDS, encouraged by society and NGOs, has played a significant role in changing attitudes, committing domestic resources, and encouraging the industry to increase its contribution.

- Secondly, the speed at which it has been possible to improve access depends on the development of the domestic health infrastructure and associated programmes to address stigma. Building up necessary infrastructure takes time. It is one of the primary reasons that countries struggle to raise levels of access at an accelerated rate.

- Thirdly, the substantial increase in the resources from the international community that have been dedicated to promoting health over the last several years has begun to change the trajectory of the HIV/AIDS epidemic in the poorest countries, as evidenced by the case studies of Rwanda, Botswana, and South Africa. Only once the Global Fund, the President's Emergency Plan for AIDS Relief (PEPFAR), the Gates Foundation, and UNAIDS focused resources did access start to improve for the poorest countries. Middle-income countries have mostly funded their own programmes, although they have also been able to leverage the experience of multilateral agencies to their benefit.

- Fourthly, the innovative industry has contributed to the affordability of ARVs through differential pricing, which emerged as a common practice at the beginning of the decade, and more flexible licensing opportunities. Voluntary license agreements have played a significant role in the development of generics, particularly in South Africa, and are increasingly important to the provision of second-line medicines by Indian generics.

- Last, but not least, generic manufacturers have been important in the great majority of the case studies. In Brazil, Thailand, India, and South Africa, domestic suppliers have played an important role for first-line ARVs. In Botswana and Rwanda, Indian generics have played an important role through pooled and direct purchases. This has been clearly the case for first-line treatments, and they will play a similar role for second-line treatments in the future.

Underlying these contributing factors have been partnerships between different stakeholders, whether represented by the Global Fund itself or through partnership programmes, such as the Accelerated Access Initiative (AAI) established internationally in May 2000 to increase access in developing nations and high-burden, middle-income nations, or the African Comprehensive HIV/AIDS Partnerships (ACHAP), a public-private partnership between the Bill & Melinda Gates Foundation, Merck & Co. /the Merck Company, and the government of Botswana.

Conclusion

Good news and evidence of successful partnerships rarely make headlines, but there has been substantial progress in providing access to HIV patients over the last 10 years. ART coverage in low- and middle-income countries has increased from 12% in 2003 to 54% in 2009, measured according to the 2006 WHO guidelines. This is due to many different factors working together in often complex ways. Learning the lessons that have contributed to success and failure will mean that future efforts can continue to improve these critical efforts. It is also important to recognise that many challenges remain: there is a large underserved population and there are types of patient that are still particularly badly served, such as paediatrics. The case for maintained funding and developing innovative partnerships is as strong as ever.

Contact
Tim Wilsdon
Vice President
+44-20-7664-3707
twilsdon@crai.co.uk

Dr. Jim Attridge
Senior Consultant to CRA
+44-20-7664-3700
jattridge@crai.com

Hugh Kirkpatrick
Associate
+1-617-425-3177
hkirkpatrick@crai.com

About CRA and the Life Sciences Practice

CRA is a leading global consulting firm that offers business, financial and economic consulting services to industry, government and financial clients. Maximizing product value and corporate performance, CRA consultants combine knowledge and experience with state-of-the-art analytical tools and methodologies tailored to client-specific needs. Founded in 1965, CRA now has offices throughout the world. The Life Sciences Practice works with leading biotech, medical device and pharmaceutical companies; law firms; regulatory agencies; and national and international industry associations. We provide the analytical expertise and industry experience needed to address the industry's toughest issues. We have a reputation for rigorous and innovative analysis, careful attention to detail and the ability to work effectively as part of a wider team of advisers.

www.crai.com/lifesciences