



## Snakebite: How Sanofi slithered its way out of the neglected antivenom market

July, 2015

### The context

Snakebite is a neglected health issue, which kills anywhere from 20,000 to 95,000 people globally each year. In sub-Saharan Africa, it is estimated that between 4,000 and 30,000 people die per year, although figures are poorly reported. In Africa, over 50% of injuries from snake bite are not treated appropriately, with as many as 80% of snakebite victims consulting a traditional healer for treatment in some countries.

Across Africa, where access to healthcare can be very limited, the need for a single antivenom treatment that covers the bites of multiple different snakes is critical. Fav-Afrique, an antivenom produced by French pharmaceutical company Sanofi, is one of the few products which meets the needs of being able to treat the bites of many different snakes across Africa – a pan-African antivenom – while being of good quality and having proven to be effective in saving lives.

### The issue

In 2010, Sanofi made the internal decision to stop production of Fav-Afrique. The reason later cited for this was the lack of a lucrative market. This decision to stop production was only revealed in July 2013, when MSF requested information from the company. In January 2014, the last batch of Fav-Afrique was produced and very quickly sold out, leading to a shortage.

The expiry date – or the end of the shelf life – for the last batch of Fav-Afrique produced is June 2016. MSF's own stocks of the antivenom – which are currently being rationed amongst its operational programmes – are expected to be exhausted in early 2016.

While Sanofi decided to transfer the technology on how to produce Fav-Afrique to another company (called a tech transfer), the contracts for tech transfer are not expected to be finalised until the end of 2016 – six months after the last batch produced expires. And this means that the first batch of a replacement Fav-Afrique antivenom is not expected to be produced until the end of 2018 or early 2019 – two and a half to three years after the last Sanofi batch expires.

**“This is a public health failure that could have been avoided – Sanofi knew there were very few alternatives to Fav-Afrique and still decided to stop production. They’ve made an already insecure supply chain infinitely worse. We can’t predict every outbreak or emergency but we know without appropriate antivenom, death and disability associated with snakebite will get worse. By discontinuing Fav-Afrique, Sanofi is enabling the development of this desperate situation.”**

- Julien Potet, Neglected Diseases Advisor, MSF Access Campaign.

### What next?

With no supplies of Fav-Afrique, mortality rates from snake bites could increase. In MSF's Paoua project in northern Central African Republic (CAR), which receives 300–400 bites per year, the use of Fav-Afrique has shown mortality rates to be under 0.5%, or less than one in 200 people. Without it, it is estimated mortality would rise to 10% - one in 10 people.

Unfortunately, little is known about the safety and effectiveness of alternatives to Fav-Afrique. There are a few other suppliers with alternative antivenom products which are supposed to protect against the same range of venoms as Fav-Afrique. However, none of these products have been proven as safe and effective as Fav-Afrique.

Sanofi claim they can't make another batch of Fav-Afrique as they have since dismantled some of the equipment needed to produce it, and their manufacturing is now running at full capacity producing another neglected quality-assured product, rabies immunoglobulin. While there is insufficient capacity to produce rabies immunoglobulin at the global level, the bottom line is that Sanofi has taken a deliberate decision to leave the already neglected snake anti-venom market; have been glacially slow to enable another company to pick up the baton and produce a replacement product; and will leave a gap of perhaps three years before a replacement product is in place, but refuse to manufacture interim batches. Meanwhile, lives could be lost. Sanofi has a responsibility to do the minimum – continue to produce Fav-Afrique until another equivalent product is in place.

## What needs to happen?

### Sanofi should:

- Immediately begin interim production of Fav-Afrique – especially by starting to produce the plasma needed to convert into antivenom – until such time as an equivalent product can be produced; and
- Speed up tech transfer contract negotiations and quickly finalise a tech transfer deal.

### International donors and funders of neglected diseases should:

- Adequately fund the snakebite market; with a limited market, donors should fund quality, effective antivenoms such as Fav-Afrique for developing countries; and
- Provide a mechanism, such as the WHO pre-qualification program – by which the quality and safety of alternative antivenoms can be assessed.

### Other suppliers should:

- Conduct and publish the pre-clinical and clinical studies that will show how safe and effective their products are, and where they can be used.

## Timeline on Sanofi and Fav-Afrique

- 2010 – decision made to stop production of Fav-Afrique internally by Sanofi
- July 2013 – Decision to stop disclosed - only because MSF asked
- Jan 2014 – last batch of Fav-Afrique produced
- Nov 2014 – Sanofi reveals that decision to stop production was actually made in 2010
- Early 2016 – MSF stocks of Fav-Afrique expected to be exhausted
- June 2016 – last batch produced expires (end of shelf life)
- By end 2016 – Sanofi expected to finalise tech transfer contracts
- End 2018/beginning 2019 – replacement Fav-Afrique product expected to be launched

## MSF use of Fav-Afrique

- Paoua, Central African Republic – MSF treats 300-400 bites per year. Fav-Afrique is effective in this context (where the carpet viper is the main cause of bites) with low mortality, less than 0.5%; without the use of Fav-Afrique, mortality is estimated to be around 10%;
- Agok, South Sudan – MSF treats around 150 bites per year. Before introduction of Fav-Afrique in hospitals, people used traditional healers, resulting in higher mortality rates; since introduction of Fav-Afrique, people now understand the need to go to hospital for proper treatment, with a better chance of survival; and
- MSF wants to introduce Fav-Afrique in projects elsewhere; countries/projects of high incidence of snake bite are being identified.