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Market release
19 May 2017

Further European approval puts Maxigesic on path to become leading global paracetamol-ibuprofen painkiller

AFT Pharmaceutical's flagship painkiller *Maxigesic* has now been approved for sale across most of the European Union member countries.

The company was notified overnight (NZ time) by the European Medicines Agency (EMA) of a decision to approve *Maxigesic* tablets in Austria, Belgium, Croatia, France, Germany, Luxembourg, Netherlands, Portugal and Spain. These countries have been added to the existing European countries where *Maxigesic* has been approved for sale.

Chief Executive of AFT Pharmaceuticals, Dr Hartley Atkinson, says that having regulatory approval for these 9 additional countries will open up significant opportunities for global *Maxigesic* sales.

"If you just take these most recent approvals, Austria, Belgium, Croatia, France, Germany, Luxembourg, Netherlands, Portugal and Spain, they are really key markets for us," says Dr Atkinson. "Collectively they have over US$1.8 billion of annual sales of paracetamol and ibuprofen tablets[1]," says Dr Atkinson. "Just to have regulatory approval for France on its own is significant for us because France is the second largest potential market in the world behind the United States. So approval across most of the EU is a crucial piece of the puzzle for *Maxigesic* in terms of ramping up international sales and significantly reducing the regulatory risk for *Maxigesic* tablets."

The EMA's decision immediately clears the way for *Maxigesic* product launches in countries where AFT Pharmaceuticals already has a license agreement in place: Belgium and Luxembourg (Therabel); Spain and Portugal (Kern Pharma); and Ireland (Stada).

This will add to the existing launches already made in United Kingdom (Stada) and Italy (Angelini) and planned launches in the Nordics (Weifa). The launch dates within each of the newly approved countries will vary as licenses need to be transferred in the national phase of the process.

The EMA decision will also likely accelerate licensing negotiations in EU countries where agreements are not yet in place. "Basically the decision has removed one of the variables in any pharmaceutical licensing agreement – will the product be approved by the regulator? We know that for most of the EU, *Maxigesic* has now been approved, and so we expect to make further progress in reaching licensing agreements in those remaining EU countries in this financial year"

In addition, the EMA's regulatory approval for Germany will have a 'domino effect' in term of licensing agreements with Swiss pharma company *Acino* that span 65 countries across the CIS, Middle East and Africa. In these countries, regulatory approval for a pharmaceutical drug in Germany effectively means that *Maxigesic* registration applications can now be filed in these 65 countries also.

Dr Atkinson says that the EU's overnight decision, together with the stage two US Food and Drug Administration approval for *Maxigesic* announced last week, means that *Maxigesic* is well positioned to become the leading paracetamol-ibuprofen combination in the world.

"We already have scale in terms of the 110 countries where *Maxigesic* is licensed. Plus, we expect further countries to be licensed on the back of the EU decision. Now having regulatory approvals and pending approvals for large parts of Europe, CIS, the Middle East, Africa and Central America, together with the promising developments in the US, means that we've now entered a new phase for *Maxigesic* where agreements will begin to translate into significant international sales."

Last week AFT informed the market that it anticipates registration and product launches covering existing agreements will occur on a phased basis according to the following approximate schedule: around one-third in FY2018, around one-quarter in both FY2019 and FY2020, and the balance in FY2021.

Sales growth going forward for *Maxigesic* tablets will be fueled by both these new country launches, growing sales from existing markets, and further line extensions such as *Maxigesic* IV (intravenous), Oral Liquid and Sachets.

[End of release]

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Footnote 1. IMS World Review Pack [Aug 2015] Paracetamol and Ibuprofen tablet markets.