Published on *Treatment Action Campaign* (http://www.tac.org.za/community)

High Court rules in favour of the Medicines Control Council

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Created *2011/11/17 - 2:26pm*
17 November, 2011 - 14:26 ? moderator

The North Gauteng High Court in Pretoria has ruled in favour of the Medicines Control Council (MCC) and others in a matter concerning Adcock Ingram?s resistance to the MCC?s decision to cancel the registration of drugs containing dextropropoxyphene (DPP). The MCC made the decision in April 2011 after coming to the conclusion that the risks posed by such medicines outweigh their benefits.

In particular, the MCC concluded that the drugs present a danger to the public as they may cause serious damage to heart muscles, inhibiting the heart from supplying blood to the rest of the body at normal doses and deadly heart failure in higher doses. Death seems to occur before patients can be hospitalised and there is no antidote.

Concerns over the safety of DPP have previously prompted stringent drug regulatory authorities in the European Union, the United States and the United Kingdom among others to withdraw DPP-containing medicines from the market. Adcock Ingram is one of the primary manufacturers of drugs containing DPP in South Africa, selling the following branded drugs: Synap Forte, Lentogesic, and Doxyfene.

In an attempt to keep the drugs on the shelves, Adcock Ingram appealed the decision, arguing that the effect of its action was to suspend the MCC?s decision. The MCC disagreed, continuing to implement its original decision. On 28 September 2011, it finally distributed a Dear Health Care Professional (DHCP) letter in which the decision was explained to doctors, pharmacists and other professionals.

After failing to convince the MCC to withdraw the DHCP letter, Adcock Ingram made an urgent application to the high court in which it essentially sought two things: first, that it could continue marketing the drugs pending the appeal; and second, an order compelling the MCC to withdraw its DHCP letter.

The state attorney, purporting to act on behalf of the MCC and others, entered into a settlement with Adcock Ingram that allowed the company to continue selling the drugs. This settlement was made an order of court. The state attorney also released to Adcock Ingram the transcript of the MCC meeting at which the decision to deregister DPP-containing medicines was taken. The state attorney made both these decisions in the mistaken belief that he was authorised to do so.

Not only did the MCC and others not authorise the settlement, but express instructions to oppose the application had been given to the then head of legal services in the Department of Health. In the case of the Minister of Health and his Director-General, this instruction was given twice. In addition, the MCC had previously resolved not to hand over transcripts, as the law entitles it to do. Yesterday?s decision to rescind the settlement agreement means that DPP-containing medicines may not be prescribed or sold pending the outcome of the appeal.

Representing the MCC and the other state parties, Advocates Gilbert Marcus SC and Adila Hassim based their argument on two main points: first, the MCC was not legally allowed to settle the matter (and therefore, neither was the state attorney); and second, that the settlement was manifestly contrary to the interests of the MCC and the public, being so far-reaching and damaging that it would require a special mandate. Counsel also highlighted that the state

attorney entered the settlement without any authority to do so and contrary to express instructions to oppose the matter.

After studying the papers and hearing argument from both sides, Judge Bertelsmann ruled from the bench and set aside the settlement:

?What is clear is that the MCC has made a decision in its specialist, expert capacity and has seen its decision unfortunately undercut by [Adcock Ingram and the state attorney].?

Judge Bertelsmann also commented that ?it is a most unfortunate outcome and one that one hopes will never occur again?. He added: ?After all, the state attorney is the custodian of state funds.?

In his oral argument, Marcus argued:

?On one side of the equation you have R182 million worth of turn over [in Adcock Ingram?s sales of drugs containing DPP]. On the other side you have the dangers to the public that Adcock relegates to irrelevance. One cannot take chances with lives in face of the dangers [the judge] has been presented with.?

Marcus, supported by Hassim, methodically proceeded through a damning argument against Adcock Ingram. A worn paperback copy of the Constitution and a tall stack of affidavits from medical experts, government officials and MCC members rested on the table in front of the team. In response to questioning from the bench, Marcus referred to portions of the several hundred-page record by specific page and paragraph many times. Judge Bertelsmann attentively followed the argument and flipped to the relevant sections of the record.

Marcus also referred to and quoted from multiple cases in support of his argument, including a judgment authored by Bertelsmann himself. He further quoted from Adcock Ingram?s pleadings and pointed to misrepresentations of MCC meeting records made in them. He asserted: ?This is a warning to our learned friends at Adcock Ingram: these statements are egregious misrepresentations.?

Approximately 30 members of the Treatment Action Campaign (TAC) attended the hearing. The activists rallied outside the court before the hearing and during the break. After the ruling, Hassim and Marcus emerged from the courthouse to loud cheers and dancing from the activists. As Adila Hassim descended the courthouse steps they sang in Zulu ?UAdila lo abamaziyo abazange bambona!? meaning ?It?s Adila [Hassim] whom we know, and they don?t know her, but we know her well!? Hassim and Marcus thanked the activists warmly for their support.

Andrew Mosane, Gauteng Provincial Secretary for TAC said ?TAC supports this outcome ?. Today is a victory for TAC, SECTION27 and many others.?

Mark Heywood of SECTION27 spoke to the crowd of cheering activists:

?Today?s judgment means that the medicines must be taken off the shelf immediately. Judge Bertelsmann affirmed that the MCC has a statutory duty to protect the health of the public. And he also affirmed that the state attorney must do a proper job of defending people?s rights. TAC and SECTION27 must take this matter up. This is not the end of the story but the beginning.?

The case is important because it has resulted in the removal of products from the market that the MCC and other stringent drug regulatory authorities have deemed unsafe. Importantly, it also reaffirms the MCC?s statutory and constitutional duties to protect public health by ensuring that medicines are safe and basing its decisions on the available evidence. The judgment in favour of the MCC rightly places the health and safety of the public over the profits of the pharmaceutical company.

Click here to read TAC's statement on the case .

Source URL (retrieved on *2018/04/26 - 1:50am*): http://www.tac.org.za/community/node/3200