Addressing UK TTO Common Concerns regarding GALF

There is a concern from certain universities that they do not contribute greatly to the drug pipeline and so will not be able to improve access to medicines through equitable-access licensing. How then is the GALF relevant to these UK universities?

It is UAEM's hope that every University in the UK pledges it support to global access licensing principles in their policies, even if a particular university might have little opportunity to utilise it practically because of the nature of the research being undertaken in that setting. We believe it is only through acting collectively that universities can encourage co-operation with their partners to maintain a new industry standard of ethical healthcare innovation licensing. We recognise that though industry might be resistant to certain terms, they do rely on universities as a whole to undertake early drug research and this has given universities negotiating power particularly if they stand united. (1) Indeed, recent history has demonstrated that universities can hold pharmaceutical companies accountable to global access licensing principles in the transfer of technology. (2)

Other universities have expressed their concern that they feel they cannot successfully influence access to a medicine where the majority of their research is in the very early stages of innovation of a drug.

UAEM recognises that pharmaceutical companies will often take out several more patents in the process of developing a drug, which might pose a barrier to generic manufacture, even if a university waives their patent rights over an aspect of a drug's development. For this reason UAEM has worked closely with intellectual property experts, to develop licensing measures regarding the use of their innovation which only give pharmaceutical companies rights to university innovation if access to the end product is ensured. (3)

Are patents really that important to drug access in the developing world? Surely, poverty and poor healthcare systems are the real problem.

Certainly, improving access to medicines is complex and requires co-operation on many levels. However, it is UAEM's assertion that patents do pose an important barrier to drug access considering the current evidence available and the expert opinion of those working in this field, which indicates that drug patents reduce drug affordability. Firstly, the most meticulous economic studies concur that in general patents significantly inflate drug costs by over 100% at least. (4)(5) Secondly, though critics point out that the majority of the drugs on the WHO 'Essential Medicines List' (EML) are currently off-patent. (6) those few drugs which are under patent now have a critical role in improving public health in the developing world. (7) For example, anti-retroviral drugs are essential in tackling the crippling HIV/AIDS burden yet, patents on these drugs continue to hinder drug-access and put millions of lives at risk. (8). Furthermore, with increasing demonstration of drug-resistance in treatments for diseases plaguing the developing world such as therapies for malaria and TB, and also increasing morbidity and mortality from chronic diseases, then patents on future innovative medicines are likely to be of key importance. (9) (10)

The GALF claims that the generic provision of drugs is the best way to improve access to medicines. However, is this really the best approach, or should we be more flexible and allow pharmaceutical companies to apply their own strategies to ensure drug access is achieved?

Market competition generated by generic provision of drugs is recognized as the most effective means of driving down prices and increasing access.(11) Below are the three key reasons that UAEM believes that generic provisions should be required in all licenses:

1. Generic provision enlists competitive market forces to develop the most affordable, most efficient ways to get drugs to patients and providers. Generic companies sustainably supply large volumes of drugs as cheaply as possible. In contrast, pharmaceutical companies' drug donation programs do not provide an effective long-term solution—charitable providers have fewer incentives to drive down costs and are not sustainable options for meeting continuous demand.(12)
2. Generic provision eliminates the measurement and enforcement problems inherent in "at-cost" approaches. (13)
3. Approaches that foster generic access, such as open licensing, can also foster important innovations specific to the developing-world. For example, such approaches could allow generic companies to create paediatric and heat-stable formulations of new drugs. (14)

UAEM is very conscious of the fact that the pharmaceutical industry operates like any other for-profit business, and thus must be primarily concerned with raising the revenue to satisfy share-holders. It is therefore our feeling that pharmaceutical companies are much more likely to improve their prices according to changes in the market, such as through generic drug competition, rather than through extensive altruistic measures that might compromise their profits. For example, the pharmaceutical company GSK has recently promised to drop the price of its drugs in certain developing countries to 25% of the price in developed countries. (15) However, the expected average price reduction is 45% compared to the 99% reductions achievable through generic drug manufacture (16) Moreover, given current global economic inequalities, even at these reduced rates, medicines will still be largely unaffordable to the destitute being targeted in the least developed countries. Also the 1.3 billion people living in poverty in middle-income countries have been excluded entirely from this measure (17)

Will parallel importation not be a problem?

It is UAEM's position that diversion of reduced price medicines from developing countries to developed countries is rarely observed and easily preventable. There is no strong empirical evidence that this is a common occurrence and indeed generic drugs have been produced in India for decades without apparently infiltrating or undermining Western markets. (18). Rather, UAEM considers that this perception that parallel importation is a significant problem, is more likely to stem from the fact that pharmaceutical companies which often cite this as a problem, and over-blown media reports of diversion. For example, it was widely publicised in the media that 36000 packages of HIV/AIDS medicines from GSK were found to have been diverted from West Africa to the EU. (19). Indeed GSK went on to sue a legal parallel trader named Dowelhurst for this violation. However, in the court case, it turned out that 99% of the packages handled by Dowelhurst were not part of GSK's charitable access initiative but rather ordinary commercial sales at prices approximating EU prices. Also, GSK did not label the packages as ineligible for sale or re-importation in the EU. (20)

In fact, the World Trade Organisation maintains that if adequate prevention measures are taken then parallel importation of medicines need not be a problem. It advocates the use of simple but effective measures such as the use of different packaging, pill colour, and pill shape in different countries to facilitate the identification of illegal imports (21). Interestingly, GSK has now begun to successfully practice such anti-diversion measures and the responsibility for multinational pharmaceutical companies to discourage diversion is being increasingly recognised. (22)(23)

It seems UAEM has had a lot of success in the US. However, have any other UK universities adopted an improved 'access to medicines' licensing policy?

The University of Edinburgh adopted a policy based on the GALF in 2009 after a 2 year campaign from the student group UAEM. (24) The University of Oxford also adopted such a policy in 2007. (25) Furthermore, several universities are negotiating global access policies such as Manchester University, the University of Bristol and Imperial College London.

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