

Policy Statement on the responsibilities of UK universities in access to medicines, vaccines and diagnostics Proposal for adoption at AW18 (Bristol)

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Introduction

“It’s a familiar, if tragic, pattern: A medical breakthrough is discovered at public expense, only to be licensed to a private corporation that earns billions of dollars by making it unaffordable for ordinary people”¹, argued Richard Eskow after a Zika vaccine developed by a US government-funded army research institute was licensed to a pharmaceutical company, without an agreement on pricing, effectively giving the company the monopoly power to set the price as high as they could. The development of medicines, vaccines and diagnostics very often runs this exact course. A publicly- funded institute, mostly universities, carries out the basic science and preclinical research associated with the development of new pharmaceuticals, and then either sells their patent or exclusively licenses their developed product to a pharmaceutical company, which completes the cost- and labour-intensive clinical trials leading up to regulatory approval. Upon approval, the pharmaceutical company is then able to charge whatever price they want for the product because the patent guarantees them years of monopoly, and the university that developed the original research did not include any requirements for price control in the licence. The end-result is that patients end up paying twice for life-saving treatments, once through taxes for the initial research, and again through either their taxes paying for the state-run healthcare system (like the NHS) or out of their pocket for the exorbitant prices charged by a pharmaceutical company with no obligation to set fair prices, and no accountability for their actions. Publicly-funded research should not lead to excessive private profit at the expense of the health and well-being of people.

SfGH Position

Students for Global Health (SfGH) believes that all people who need a medicine, vaccine or diagnostic should be able to access it affordably and equitably; and that the most significant barrier to access remains the high price charged by pharmaceutical companies for these technologies. SfGH recognises the critical role that universities play in the discovery and development process of medicines, vaccines and technologies. As a student organisation, SfGH urges universities to consider future access barriers to the end-products of their discoveries, and act through policy to ensure that licences explicitly address these.

Call to Action

1. Students for Global Health branches should:

- a. Urge their universities to build their capacity to take on more authority in the formulation of licensing agreements, including, but not limited to, the hiring of legal expertise for this purpose.
- b. Urge their universities to implement a university-wide policy on all interactions with the pharmaceutical industry.
- c. Urge their universities to assume the responsibility to regulate pricing, in order to improve global access to the medicines, vaccines and diagnostics that they have been integral in developing.
- d. Urge their universities to pass a global access licensing policy and designate an office to the monitoring and evaluation of the policy's implementation.
- e. Organise events and campaigns on this topic at their respective universities, in order to increase awareness amongst the student body and the general public and bring this to the attention of the university leadership.

2. Students for Global Health should:

- a. Affirm that universities play a crucial role in the research and development of essential medicines, vaccines and diagnostics; and should as such obligate the inclusion of reasonable pricing in a licensing agreement.
 - b. Organise national events and campaigns on this topic, in order to increase awareness amongst the student body and the general public, and bring this to the attention of the university leadership.
 - c. Advocate for the development of a global access licensing policy that addresses the access requirements of all patients.
3. The UK Government should:

- a. Hold a consultation with universities to discuss the current process of how medical inventions discovered at universities are licensed to pharmaceutical companies, and how this process may be improved to widen and accelerate access to the end-products of these inventions.
- b. Write legislation that requires that publicly-funded inventions, including those that result from research at a university, should not be the subject of an exclusive licence unless the licensor and licensee agree on reasonable pricing.

Background

A third of the world's population does not have access to essential medicines². The largest contributor to inadequate access is price, which is set by the company that sells the medication (or other health-related invention). Access to medicines is a tremendous problem all over the world, in low- and middle-income countries (LMICs) and high-income countries (HICs) alike. The proportion of total private and public health spending on medicines is immense, at 20% in HICs and up to 66% in LMICs³. Two out of five of the NHS's most expensive medicines were discovered using substantial public funding⁴. Furthermore, the NHS spent more than £1 billion on drugs developed from publicly funded research in 2016⁵.

It is widely recognised that introducing competition through generic manufacturers is the most

effective and sustainable way of driving down prices and thus increasing accessibility to life-saving treatments. However, in the current intellectual property system, patents grant the patent holder a 20-year period of exclusive market access that allows the company to set the price as high as they choose in a market void of competition. There lies much value in advocating against patent term extension mechanisms, and for waivers that allow generic companies to conduct research and begin building up production capacity prior to the expiration of the patent (Bolar exemptions). However, effort must also be spent on reducing the price of medicines, vaccines and diagnostics during the period of patent protection. Since almost a third of medicines originate from universities⁶, universities are in a powerful position to effect change that could improve access to the end- products of their research findings, and save many lives.

Global Access Licensing Policy

The Universities Allied for Essential Medicines (UAEM) network suggests that all technologies developed by a university that have the potential to be further developed into a medicine, vaccine or diagnostic should be licensed in such a way that affordable access in low- and middle-income countries is ensured. The process of developing and implementing a licensing agreement should also be made as transparent as possible. UAEM recommends that universities implement global access licensing policies that adhere to the following five principles⁷:

1. Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. This includes protecting access to the final end-product needed by patients (e.g. formulated pills or vaccines). Licence agreements must explicitly address access.
2. Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research.
3. Generic competition is the most efficient method of facilitating affordable access to medicines in resource-limited countries. Legal barriers to generic production of these products for use in resource-limited countries should therefore be removed. In the cases of biologic compounds or other drugs where generic provision is forecast to be technically or economically infeasible, “at-cost” or other provisioning requirements should be used as a supplement to generic provisioning terms but should never replace those terms.
4. Proactive licensing provisions are essential to ensure that follow-on patents and data exclusivity cannot be used to block generic production. Other barriers may need to be addressed for the licensing of biologics.

5. University licensing should be systematic in its approach, sufficiently transparent to verify its effectiveness, and based on explicit metrics that measure the success of technology transfer by its impact on access and continued innovation.

The global access licensing framework suggests a variety of strategies to improve access to the end-product in low- and middle-income countries. These strategies include patenting only when commercially necessary, using non-exclusive licenses, streamlining processes for technology transfer and reserving broad rights to use the licensed technology in future research. The global access licensing framework also recommends that licences make specific provisions for generics production in low-resource settings, including by encouraging pharmaceutical companies to use voluntary licensing to increase access in LMICs.

Universities often argue that by not patenting their discoveries in low- and middle-income countries, they are making a sufficient contribution to ensuring access. However, by not specifically including access provisions in licences to pharmaceutical companies, the company could still block access in low resource settings by filing follow-on patents and by enforcing data exclusivity periods that prevent generic companies from performing bioequivalence trials. Strategies to address the issues of follow-on patents and data exclusivity include non-assert clauses, sublicensing agreements, patent pools, data waivers, and grantback provisions⁸.

Price Control

The Global Access Licensing Framework is helpful in regard to improving access to the end-products of university discoveries in LMICs. However, barriers to equitable access to medicines, vaccines and diagnostics exist all over the world, and high-income countries also struggle to pay the prices set by pharmaceutical companies during their periods of market exclusivity. Universities should therefore include access provisions that apply to all countries in their licence agreements. Since non-exclusive licensing may not always be feasible, depending on the status of development, universities should always include price control in any licence agreement to ensure that pharmaceutical companies cannot solely determine the price of a product that was in part developed using public funding.

Conclusion

Universities play a critical, yet under-recognised, role in drug development. Patients all over the world struggle to access the medicines, vaccines and diagnostics they require to treat disease and keep them healthy. The brunt of the basic science research, and an increasing amount of preclinical and early clinical trials, are conducted at universities, which benefit from public funding. Universities subsequently license their discoveries to pharmaceutical companies, which go on to complete clinical trials and seek regulatory approval. Patients should not have to

pay twice for a medication, first to develop it, and then to stock it. Since universities play an integral role in drug discovery, they should assume more responsibility in the extent to which the end-product actually reaches those who need it. The Global Access Licensing Framework, developed by Universities Allied for Essential Medicines (UAEM), is a helpful tool for universities to develop their own global access licensing policies. While the Framework includes important suggestions on how to protect generics competition in LMICs, and thus help to keep prices low, universities should further seek to include access provisions, such as price control, in all their licences, in order to ensure that patients everywhere can access the treatments they need.

References

1. Eskow R. The Government Created This Zika Vaccine. Why Should Big Pharma Reap the Profits? *The Nation*. <https://www.thenation.com/article/the-government-created-this-zika-vaccine-why-should-big-pharma-reap-the-profits/>. Published June 20, 2017.
2. *The World Medicines Situation*.; 2009. <http://apps.who.int/medicinedocs/en/d/Js6160e/>. Accessed October 4, 2018.
3. Essential medicines and health products. WHO. http://www.who.int/medicines/services/essmedicines_def/en/. Published 2016. Accessed October 4, 2018.
4. Bulman M. NHS pays pharmaceutical companies millions for drugs developed with taxpayers' money. *The Guardian*. October 22, 2017.
5. Cohen D, Clifton H. Taxpayer-funded drugs "too expensive for patients." *BBC News Health*. October 22, 2017.
6. Kneller R. The importance of new companies for drug discovery: origins of a decade of new drugs. *Nat Rev Drug Discov*. 2010;9(11):867-882. doi:10.1038/nrd3251
7. *Universities Allied for Essential Medicines Global Access Licensing Framework*.; 2013. https://uaem.org/cms/assets/uploads/2013/03/Framework-V1_2.pdf. Accessed October 4, 2018.
8. Effort AE, Stevens AJ. The Critical Role of Academic Licensing in Promoting Global Social Responsibility. 2008.