

CONSULTATION ON IMPLEMENTING THE NAGOYA PROTOCOL IN THE UK

Response by the Wellcome Trust

April 2014

KEY POINTS

- We believe that there is a risk that the Nagoya Protocol could be implemented by countries in a manner that could potentially be highly damaging to international research efforts to monitor, investigate and control pathogens of global health significance.
- We call on the Government to ensure that it does not implement the Protocol in a manner than limits the ability of UK researchers to participate in these initiatives; and does not inhibit UK preparedness for infectious disease outbreaks, epidemics and pandemics. We also urge the Government to work at an international level to guard against these risks.
- We are largely satisfied with the specific plans for the UK to implement its obligations under the EU Regulation, but stress that the provision of clear guidance for the research community will be crucial.

INTRODUCTION

1. The Wellcome Trust is pleased to respond to Defra's consultation on implementing the Nagoya protocol in the UK.
2. The Wellcome Trust's vision, as a global charitable foundation, is to achieve extraordinary improvements in human and animal health. To further this goal, we provide long-term support to biomedical research and related activities, both in the UK and in low and middle income countries, which aims to enhance our understanding and ability to control diseases and other causes of ill-health affecting human and animal kind.
3. Our response to this consultation focuses primarily on concerns in relation to the scope of the Nagoya Protocol, and the potential risks that it could be implemented in a manner that could have serious consequences for global health research – particularly in relation to work involving human, animal and plant pathogens. We recognise that this goes beyond the scope of the consultation questions, but felt it was important to flag these issues and seek clarification from Defra where possible. We also provide some more specific feedback in response to the questions in the consultation document.

THE NAGOYA PROTOCOL: POTENTIAL RISKS AND CONCERNS

4. It is clear that human, animal and plant pathogens would fall within the definition of 'genetic resources' under the Nagoya Protocol, even though we do not believe they are the type of resource that the Protocol is primarily intended to capture. Indeed, the extent to which a pathogen could be regarded as a valued part of an individual country's natural biodiversity seems highly questionable. Also, given the genetic variation across and between pathogen populations, it is not clear to us when a country could claim a 'right' over a particular organism, and which genetic variants of that pathogen it would apply to.

5. In short, pathogens clearly do not respect national boundaries and our ability to combat a wide range of global health threats depends on the rapid and effective monitoring and response to existing and newly-emerging infectious agents on a global scale. The introduction of any additional regulatory hurdles which limited the ability of researchers and other global health professionals to share both samples and data could have a crippling effect on these efforts.
6. The provisions in both the Nagoya Protocol itself and the European Regulation regarding public health emergencies and influenza preparedness are welcome and necessary. However, we are concerned that many key global health efforts might not fall under this definition. A few illustrative examples are set out below.
 - **Monitoring drug resistance** - the emergence of drug-resistant pathogens is a global health issue of paramount importance. Malaria is a case in point – where the spread of resistance to front-line malaria drugs (particularly artemisinin drugs) is a critical concern. Most existing global surveillance efforts in malaria are being led by researchers rather than by governments, and it is essential that they are able to immediately and openly share materials and information (including genome sequence data) on malarial parasites without either fear of sanction or the need to negotiate benefit sharing terms. Another example is the emergence of NDM-1 (extended-spectrum beta-lactamase) as a genetic element conferring resistance to a range of antibiotics, which can be found in several bacterial pathogens across multiple countries. It appears to have originated in India just a few years ago. It is unclear to us whether genetic elements of this type that emerge in the future might be covered by the Protocol, and their essential use in clinical diagnostics or research be subject to benefit sharing negotiations with the country of origin.
 - **Building capability to respond to outbreaks** – in order to respond rapidly to outbreaks and identify their source, the community requires pre-existing databases of extant global pathogen diversity. For example, the ultimate source of the strain responsible for the outbreak of E. coli derived hemolytic-uremic syndrome in Germany in 2011 could be traced to Africa based on genetic similarity, concordant with the public health investigation that implicated seeds from Egypt. This demonstrates that comprehensive genetic resources accessible in the public domain will allow source attribution to be effectively immediate, rather than retrospective (and after causing significant economic damage through false attribution) as was actually the case. We fear that the protocol could limit the scope to build such resources.
 - **Tracking pathogens in animal reservoirs** – influenza is clearly just one of a whole range of potentially harmful human pathogens that reside in animal reservoirs (where they may be non-pathogenic). Examples include Ebola virus (bat reservoir), Dengue virus (insect vector) and rotaviruses (swine). It is not clear to us why the genetic characterisation of these agents in their animal hosts (with the goal of building data resources for diagnostic development and surveillance) should be treated differently from influenza.
7. In general, effective global surveillance of pathogens and drug resistance requires open, comprehensive databases that source information from a very large number of different countries. Requiring individual agreements with each separate country to set up these databases could be so onerous as to make them impractical.

8. The examples above also highlight another area of uncertainty on the Protocol, which is whether it potentially applies to derived materials and data (such as DNA sequence information). Our understanding is that it applies to the resources themselves, but that this is an area of ongoing debate. It is essential that this issue is resolved and clear guidance is provided. If the Protocol did extend to sequence information, it would be a very serious concern.
9. We accept that the UK Government cannot control how other countries (particularly those outside the EU) choose to implement the Protocol. However, it is vital that the Government ensures that in implementing the Protocol it supports, rather than restricts, the key contributions made by UK researchers to global health research. Perhaps more importantly, we would call on the Government to advocate at a global level (including at WHO and in other key international forums) to help ensure other countries do not establish provisions that put global health research and surveillance efforts at risk.

SPECIFIC COMMENTS ON CONSULTATION QUESTIONS

10. We recognise that the Government has limited scope in terms of the implementation of the European Regulation and are largely content with the proposals set out. The key issues from our perspective is that there is clear and unambiguous guidance for the research community on when the provisions apply, that the process for attaining relevant permissions is as straightforward as possible, and that the process and steps for enforcement take account of the nature of the use and the likelihood of any financial benefit being derived.
11. We are pleased that the consultation document reflects these principles, but it is critical that they are delivered in practice. A key concern here is that the international clearinghouse provides clear information on requirements in individual countries. It is essential that the UK works with international partners to ensure this system functions effectively.
12. We agree with the focus on civil sanctions as the primary tool for penalising non-compliance. The intention seems to be that any action would take into account the scale and nature of any breach, and that warnings would precede any more serious penalty. In particular, we would suggest that it would be disproportionate to apply financial penalties or criminal proceedings where no financial benefit has been derived – unless previous warnings and sanctions had been applied.
13. With regard to specific elements that would need to be addressed in guidance for researchers (Q9), we would suggest that:
 - it needs to be stated unambiguously that these provisions do not apply to human genetic material;
 - it needs to be clear when the provisions would apply to research involving pathogens and which activities would fall under the public health emergency provisions;
 - there needs to be explicit guidance on whether the regulation includes derived materials and data (in particular genome sequence information);
 - it needs to be clear what level of 'due diligence' is expected of researchers, particularly when accessing materials from collections based outside of the EU (the provision concerning registered collections in the EU is welcome).

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