GSK's Position on the Anti-Counterfeiting Trade Agreement (ACTA)

The Issue

Discussions around a possible anti-counterfeiting Agreement, initially involving just Japan and the US, started in 2006. Textual negotiations began in earnest in June 2008 and included a broad group of participating nations[1]. Final agreement around the text was formally reached in Sydney in December 2010.

The primary objective behind ACTA was to establish international standards on intellectual property rights (IPRs) enforcement. The balance and safeguards embodied in the TRIPS Agreement are not affected by the Agreement, since it only deals with enforcement of rights, without altering the substance of those rights.

Given the importance of effective IPR enforcement to the pharmaceutical sector, GSK made every effort to monitor developments around the Agreement. This paper sets out our position on the final version and seeks to address certain misconceptions concerning its impact on the provision of healthcare.

GSK Public Position

- Adequate and effective protection of IPRs are pivotal factors in encouraging pharmaceutical companies to invest in research. Without IP laws, GSK would not be able to fund new R&D and to provide new innovative products which save the lives and improve the lifestyle of countless people. Nor would we be able to easily prevent third parties from counterfeiting GSK products.

- The value of IPRs is inextricably linked to their effective enforcement. GSK therefore fully supports any efforts aimed at ensuring strong enforcement of IPRs. The ACTA agreement is a recent example of these efforts.

- Counterfeiting of healthcare products represents an unacceptable threat to patients' welfare and is a particular concern for GSK. **We therefore welcome the Agreement's primary focus on counterfeiting and piracy.**

<u>Position in Relation to Patents</u>

- GSK supports the WHO's definition of a counterfeit product[2]. We accept and agree that the definition excludes violations or disputes concerning patents. In other words, even **illegal, patent-infringing generics should not be viewed as "counterfeits".** Likewise, we recognise that medicines not authorised for marketing in a given country, but authorised elsewhere, should not be considered counterfeits.

- **GSK would like to have seen the formal inclusion of patents in ACTA in relation to civil enforcement provisions.** Parties are instead free to decide whether or not to extend civil enforcements procedures to patents [Section 2; Footnote 2].

[1] Australia, Canada, the EU, Japan, Mexico, Morocco, New Zealand, Republic of Korea, Singapore, Switzerland and the US

[2] *A counterfeit product is one that is deliberately and fraudulently mislabelled with respect to identity and / or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, the wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.*

Sanctions under the Agreement

- Counterfeiting is a clandestine, often highly organised, criminal activity which, in the healthcare context, can have major implications for personal as well as public health. **GSK therefore supports the ACTA provision obliging Parties to the Agreement to provide for criminal procedures and penalties at least in cases of wilful counterfeiting.** [Article 23]

- GSK support for criminal sanctions against counterfeiters does not extend to similar penalties against patent infringers. **We therefore have no objection to the omission of criminal sanctions for patent infringers from ACTA.**

In Transit Provisions

- Criminals are becoming increasingly sophisticated in the way they distribute counterfeit and pirated goods, frequently using free trade zones and transhipment to disguise the origin and provenance of the products. Customs officials should therefore be given the right to control counterfeit products at any time when they are under Customs supervision, including on import, export, re-export, in transit/transhipment, in free trade zones of Customs warehouses and/or other suspensive procedures.

- **GSK fully supports the inclusion in ACTA of in transit provisions relating to counterfeit products.** That said, the text is insufficiently clear about the procedures that Parties should be encouraged to put in place. Use of terms such as "*may*" and "*where appropriate*" could be applied at the national level in such a way as to restrict the right holders ability to seek detention of suspect counterfeit goods by competent authorities. [Article 16]

- GSK recognises that the public health arguments supporting in transit action against counterfeit products do not necessarily extend to the detention of patent-infringing products. **We therefore have no objection to the exclusion of in transit patent provisions from the final Agreement** [Article 13, Footnote 6].

Customs Responsibilities

- GSK recognises the vitally important role that Customs Authorities play in stemming the flow of counterfeits and the workload this involves. However, we do not believe that Article 17 should be interpreted to mean that Customs are expected or able to make a decision regarding whether suspect product constitutes an infringement or not. Responsibility and liability for such a decision should lie with the Rights Holder in the first instance prior to a decision by judicial authorities.

Confidentiality Issues

- In the long term, successful prosecution of counterfeiters is key to tackling and reducing the practice. **GSK is therefore disappointed that the Agreement does not require the sharing of all relevant information relating to an alleged infringement with the Rights Holder.** We believe that all such information should be supplied to the Rights Holder who should be permitted to use it for the purpose of bringing legal proceedings.[Article 11]

De Minimus Provision

- The Agreement excludes counterfeits in non-commercial quantities, for example, counterfeits found in traveller's luggage and the recent surge in counterfeit goods distributed via the postal service. **GSK believes that this *de minimus* provision in the final Agreement sends out the entirely inappropriate message that "a little bit of crime is acceptable".** [Article 14]

- Such a *de minimus* approach also undermines future government attempts to raise awareness of the potential dangers and negative economic effects of purchasing counterfeit goods.

Adoption of the Agreement

- Widespread adoption of the Agreement will be key to its success in tackling counterfeiting. Detention of suspect product in one "signatory" country, while important, will only achieve so much. If corresponding enforcement rules do not exist in the "source" country then the effectiveness of the Agreement will be significantly undermined.

- The Agreement is open to all WTO Members to adopt. **A concerted effort should therefore be made by the negotiating parties to secure as many signatories as possible.** Particular effort should be directed at China, which - although it has taken steps to improve its IP protection and enforcement - is still widely recognised as a key source of counterfeit product. Key emerging markets, those with Free Trade Zones and those that contain known counterfeiting transit hubs should also be encouraged to adopt the Agreement.

Implementation of ACTA

- **Within Europe, support for ACTA should be confirmed via EU-wide adoption**. Adoption on an ad hoc basis by individual Member States and in a way that threatens to undermine national interpretation of existing EU Legislation (such as EC Regulation 1383/2003) could create confusion in the European market place.

- The Agreement is ambiguous in places and therefore can be implemented in many different ways at the national implementation stage. In view of this, when approaching the implementation stage, **GSK would urge signatory Governments to work with local stakeholders, including industry, to develop robust implementing legislation. GSK stands ready to support this process.**

BACKGROUND

International Cooperation in the Anti-Counterfeiting Arena

GSK rigorously investigates and where appropriate takes legal action against the manufacturers, distributors, retailers and other parties involved in counterfeiting our products. However, counterfeiters have little respect for borders. Our chances of success in this area are therefore significantly enhanced by international cooperation between governments and authorities. A harmonised approach that targets both the movement of counterfeits and their production is required.

Detention and destruction of counterfeit product is obviously vital in terms of safeguarding consumers in the immediate term; however, in the longer term, only successful prosecution backed by stiff penalties will ensure the practice is stamped out. Close international cooperation between Governments, Customs, rights holders and judicial authorities is therefore vital.

ACTA's Objectives and Scope

ACTA is aimed at establishing (among its signatories) agreed standards for the enforcement of intellectual property rights by increasing international cooperation; strengthening the framework of practices that contribute to effective enforcement of intellectual property rights; and strengthening relevant enforcement measures. The intended focus is on counterfeiting and piracy activities that significantly affect commercial interests, rather than on the activities of ordinary citizens.

In the context of promoting and protecting public health, those who negotiated ACTA clearly stated that it will be will be consistent with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and will respect the Declaration on TRIPS and Public Health.

The main elements of the Agreement are as follows:

Civil enforcement measures including the scope of IPRs to be covered by civil action; a definition of adequate damages for infringement; remedies, including the possible destruction of goods; and reimbursement for reasonable legal fees and costs.

Border measures including the scope of IPRs to be covered; a de minimus exception for travellers bringing in goods for personal use; procedures for right holders to request the suspension of suspect goods at borders.

Criminal enforcement including the role of criminal sanctions in cases of trademark infringement; the appropriateness and level of ex officio interventions by relevant authorities (ie to act in the absence of a complaint by a rights holder).

Greater international cooperation including agreement to share relevant information and to provide capacity building and technical assistance where necessary to help improve enforcement.

Institutional arrangements relating to the implementation of the Agreement, how and when to hold meetings of the Parties and other administrative details.

Final provisions including how to become a party to the Agreement, how to withdraw from the agreement and how to amend the agreement in the future.

December 2010