# 1NC

**I value morality, per the use of ought in the resolution, asking us to evaluate the moral obligations for both sides.**

**Since the resolution asks nations to take an action, our frameworks in this debate should focus on government action.**

**The only ethical framework policymakers can use is util**

Robert Goodin 90, [professor of philosophy at the Australian National University college of arts and social sciences], “The Utilitarian Response,” pgs 141-142, BE

My larger argument turns on the proposition thatthere is something special about the situation of public officials that makes utilitarianism more probable for them than private individuals. Before proceeding with the large argument, I must therefore say what it is that makes it so special about public officials and their situations that make it both more necessary and more desirable for them to adopt a more credible form of utilitarianism.Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices – public and private alike – are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. Public officials, in contrast, are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices, but that is all.That is enough to allow public policy-makers to use the utilitarian calculus– assuming they want to use it at all – to choose general rules or conduct.

**Thus, my value criterion is maximizing expected well-being.**

## SO21 – CP – Compulsory Licensing

**Counterplan Text: The member nations of the World Trade Organization ought to agree on specific conditions under which they could issue a compulsory license.**

**Even the threat of compulsory licensing increases access to essential medicine for developing countries**

**Ooms and Hanefield 19** (Department of Global Health and Development, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London, UK. Gorik Ooms is a human rights lawyer and a global health scholar, Honorary Professor of Global Health Law & Governance at the London School of Hygiene & Tropical Medicine, Adjunct Professor at the Law Faculty of Georgetown University, and Visiting Professor at the Faculty of Medicine and Health Sciences of Ghent University. Johanna Hanefield is an Associate Professor in Health Policy and Systems Research at The London School of Hygiene and Tropical Medicine.), “Threat of compulsory licences could increase access to essential medicines”, BMJ 2019;365:l2098, 5-28-19, doi: <https://doi.org/10.1136/bmj.l2098>, <https://www.bmj.com/content/365/bmj.l2098> NT

The power of compulsory licences is most obvious when governments use them effectively. However, compulsory licences also have power when governments warn patent owners that they will use them if necessary. For example, when the US faced the threat of terrorists using anthrax in October 2001, the US secretary of health and social services wanted to stockpile ciprofloxacin, which was the best available treatment for anthrax. Bayer, the patent owner, demanded the usual price for ciprofloxacin, but when the US and Canada declared they might issue a compulsory licence, Bayer reduced the price.22 Neither Canada nor the US needed the Doha declaration to threaten Bayer as there was sufficient manufacturing capacity in both countries (and the Doha declaration came a month later). Thus threatening to use a compulsory licence may be as effective as formally issuing one. The Doha declaration solution is cumbersome to apply effectively, but it does give countries— even those without domestic manufacturing capacity— the power to threaten to use a compulsory licence. This may have an influence on prices. For example, sofosbuvir is a relatively new and highly effective treatment for hepatitis C, but its high price in some countries has proved controversial. Sofosbuvir came to the market in 2007. According to Iyengar and colleagues, the price of sofosbuvir was $64 680 per treatment in the US and $539 in India in 2015.23 In 2015, no country had issued a compulsory licence for sofosbuvir. The first such licence was issued by the Malaysian government in September 2017.24 Why the disparity in the price of sofosbuvir in the US compared with India? The prices were set by the originator, or by generic manufacturers working with a voluntary licence given by the patent owner. Thus, the “discount” for India, given or allowed by the patent owner, was 99% before any compulsory licence was issued. This is similar to the price reduction of the classic combination antiretroviral therapy, attributed to generic competition.25 We cannot be certain that the risk of a compulsory licence was the main reason for the patent owner of sofosbuvir allowing a 99% discount, but there is no other obvious explanation. India has manufacturers that can produce generic equivalents of sofosbuvir, as does Malaysia. Can countries without manufacturing capacity use the same strategy? Before the Doha declaration, patent owners would not have been impressed by a threat to issue a compulsory licence from a country without domestic manufacturing capacity. **Since the declaration, such a threat would be credible**. Although the Doha Declaration solution has been used only once, this was enough to show that it can be done, as long as countries with manufacturing capacity are willing to cooperate. Low and middle income countries would be in a stronger position if they declared their commitment to cooperate to make the Doha Declaration solution work. One option might be for them to agree on specific conditions under which they would issue compulsory licences for export based on the Doha declaration, if required by another member of the alliance.26 This would increase the credibility of threats to issue a compulsory licence by countries without manufacturing capacity. It would also give a signal to generic manufacturers of the potential size of the market, if all countries participating in this alliance would buy from the cheapest provider within the alliance. We should not be naive. As Sell points out, “there is a dizzying array of extra intellectual property protection that is being imposed on developing countries, such as TRIPS Plus agreements, in the form of bilateral agreements, free trade agreements, and plurilateral negotiations such as anti-counterfeiting trade agreements.”27 The political pressure used by rich countries against poorer countries to dissuade them from using their rights under the TRIPS agreement and the Doha declaration has increased. **However, the governments of low and middle income countries with manufacturing capacity are not as powerless as before the Doha declaration. They can issue compulsory licences for all medicines needed to protect public health without violating the TRIPS agreement**. They can declare their intention to help low and middle income countries without manufacturing capacity and, by doing so, empower these other countries. Whether they have the will to confront the likely political pressure is a different matter.

## **Counterfeit medicines DA**

#### **IPP Law is essential for preventing the development of counterfeit medicines.**

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The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation of fraudulent and dangerous goods. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is much more complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licenses, as this is the most responsible way to bring their technologies to the world and safeguard global health. In addition, as the COVID-19 pandemic continues there has been a noticeable increase in the circulation of fake medicines around the world. According to the International Criminal Police Organization (Interpol), organized crime groups have been producing fake drugs and medical products and selling them for lucrative profits in developing countries.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to disastrous consequences, including worsened illness and death for the individual and the retardation of herd immunity for the population at large. Effective and proactive IP procurement is essential and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, putting millions of human lives at risk and reducing trust in vaccines.

#### IPP reductions promote counterfeit medicines and access is meaningless without quality medicine

**Lybecker**, Kristina. [Associate Professor of Economics at Colorado College] “Counterfeit Medicines and the Role of IP in Patient Safety.” IPWatchDog, 20**16**. <https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/> //CS

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated: “The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that **counterfeit products accounted for** up to 2.5 percent of world trade, or **$461 billion, in 2013**. This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount. Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1] As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While **the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods**, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines. **While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting.** **The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement**; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3] According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health **Organization presents** a much more modest number noting that **malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines** which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] **Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems**poised **to prevent** a series of **recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless.** Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need: inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives. If the United Nations is serious about addressing the critical need for access to medicines, the Secretary General must come to terms with the reality surrounding the challenges of access to medicine. Although the international patent system may be in need of improvement, it is overly simplistic to blame drug patents, international trade agreements and the global pharmaceutical industry for the access problem. The problem is far more nuanced and complicated than portrayed by the High Level Panel. As the WHO, OECD and Senator Hatch recognize, intellectual property rights are part of the solution. **To truly address the access problem, we must move beyond blaming IPRs and begin the difficult work of grappling with structural deficiencies and poverty.**

#### Counterfeit medicines are catastrophic for individuals, producers, and governments

#### OECD/EUIPO (2020), Trade in Counterfeit Pharmaceutical Products, Illicit Trade, OECD Publishing, Paris,<https://doi.org/10.1787/a7c7e054-en>.//AK

#### Impact on individuals Bad quality counterfeit medicines can affect individuals in a variety of ways (WHO, 2017c): · Adverse effects (for example toxicity) from incorrect active ingredients. · Failure to cure or prevent future disease, thereby increasing mortality, morbidity and the prevalence of disease. · Contributing to the progression of antimicrobial resistance and drug-resistant infections. · A loss of confidence in health care professionals, health programmes and health systems. · Increasing out-of-pocket and health system spending on health care. · Lost income due to prolonged illness or death. · Lost productivity costs to patients and households when seeking additional medical care, the effects of which are felt by businesses and the wider economy. As indicated above, people taking counterfeit medicine may be putting their lives at risk. Estimates show that between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs, and that fake anti-malarial medication might be responsible for an additional 116 000 deaths (WHO, 2017c). Renschler et al. (2015) estimate that each year over 120 000 under-five malaria-positive children may die across 39 sub-Saharan countries due to taking poor-quality anti-malarials, including counterfeit and substandard pharmaceuticals. In their rather conservative review of the published literature on the health consequences of falsified medicines, Rahman et al. (2018) analysed 48 reported incidents in which falsified medicines caused serious adverse effects to patients. These incidents involved approximately 7 200 casualties, including 3 604 deaths. The results of the study indicate that a similar number of incidents affect developing and developed countries alike, and the counterfeiters target all types of medications (Rahman et al. 2018). Forensic tests of suspect samples performed by the pharmaceutical industry also demonstrate that counterfeit medicines, in 90% of those cases tested, could cause harm to the patient (Novartis in Society Report, 2019). While many incidences of patient harm will likely go undetected, numerous examples have nevertheless been recorded. 1 For example, a recent UK survey carried out by Sapio research and commissioned by a private company INCOPRO, concludes that almost one-third (32%) of those who have bought one or more counterfeit medicines have suffered a health issue as a result (INCOPRO, 2020). There are numerous other documented cases in which patients have died or suffered harm due to an online purchase. As just one example, in 2013 people died after taking a counterfeit diet pill bought through an online drug seller. The pill, sold as a weight loss aid through many illicit online pharmacies, is actually a pesticide with lethal consequences for humans.2 The impact of counterfeits on legitimate producers are multiple, including lost sales, costs of protecting brands, loss of reputation, the potential cost of managing the disposal of counterfeits and litigation costs involving counterfeiters and possibly people who were unknowingly victimised by counterfeits. The challenges are alluded to in corporate reports, albeit in a general manner. For example, one of the five largest pharmaceutical companies – Pfizer – mentioned counterfeiting in its 2019 annual financial report , although not in its general annual report. In the financial report, the company includes a section on counterfeit products, containing general information on the challenges it faces, and noting the efforts it has taken to address the situation (Pfizer Inc., 2019a; 2019b): Counterfeit pharmaceuticals can result in squandered health resources, not only for individual patients, but also for international humanitarian organisations, NGOs and national government programmes (OECD, 2016). Counterfeiters divert resources away from genuine treatment, robbing limited health budgets of already scarce resources. At the same time, counterfeits can mean losses in corporate taxes and VAT, increased regulatory and enforcement costs for securing the supply chain, and higher health care costs to treat the adverse effects of fake drugs. With respect to taxes, EUIPO (2016) estimates that the cost to EU governments of revenues foregone from counterfeit medicines was in the order of EUR 1.7 billion.

#### Counterfeit medicines are a global public health issue and must be prevented by legal protection

**Brezovska, Katerina. [**[**Ss. Cyril and Methodius University in Skopje**](https://www.researchgate.net/institution/Ss_Cyril_and_Methodius_University_in_Skopje)**] “Counterfeiting of medicines as an infringement of the intellectual property rights.” Research Gate, 2016.**[**https://www.researchgate.net/publication/332638896\_Counterfeiting\_of\_medicines\_as\_an\_infringement\_of\_the\_intellectual\_property\_rights**](https://www.researchgate.net/publication/332638896_Counterfeiting_of_medicines_as_an_infringement_of_the_intellectual_property_rights)**//CS**

**Counterfeiting and piracy are one of the biggest issues of the global economy** in the last two decades, facing all industrial sectors, including pharmaceutical industry. **Counterfeiting of medicines** is a growing phenomenon affecting all type of medicines including both in- novative and generic **and represents a serious public health problem and a problem of the trade competition as an intellectual property right infringement.** In order to combat this problem, anti-counterfeit regulatory activities are undertaken on a global level through establishment of legislation, strengthening the regulatory activities, development of mechanisms for effective collaboration between the stakeholders on national and international level and communication for raising public awareness regarding the risk of using counterfeited medicines. **The role of the pharmaceutical manufacturers, wholesalers and retailers in the fight against counterfeited medicines is essential for securing the supply chain and providing quality, safety and efficacy of** the **medicine**s that reach the patients from one side and for protecting their brands and their profit from the other side.  Intellectual property represents the rights given to people over the creations of their minds, usually given as an exclusive right over the use of his/her creation for a certain period of time. **Intellectual p**roperty **rights** include copyright and rights related to copyright, with a main social purpose to **encourage and reward creative work**; and industrial property, **aiming to stimulate and ensure fair competition and to protect consumers, but also to stimulate innovation**, design and the creation of technology. Industrial property includes protection of trademarks and geographical indications, but also inventions (protected by patents), industrial designs and trade secrets. The social purpose is  to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities (WTO, 1994). The fast growth of the **counterfeiting and piracy** as an intellectual property infringement in the last two decades, **have created** one of the biggest problems facing all sectors of the global economy (OECD, 2011). The **damage inflicted on the businesses** can be seen **through: loss of income, product withdrawal, loss of the brands’ value** etc. Counterfeiting also causes social problems like: **indirect tax rises, market destabilization,** **criminal activity, downsizing of foreign investments**, expenses for exercising of intellectual **property rights etc.** (OECD, 1998).  **According to** the World Trade Organization (**WTO**), **counterfeiting is unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered**, with a view to deceiving the **purchaser into** believing that he/she is **buying the original** good**s** (WTO, 1994). Reports from the **World Customs Organisation suggest that around 10% from every product**/service **sold** all **around the world are falsified**. The data on counterfeiting **and** piracy presented in the 2013/2014 Illicit trade report, indicate that **more than half** of the reported cases **were** illicit **pharmaceutical products**, followed by electronic appliances, food, toys, games and school supplies; products representing a potential health and safety risk for the consumers. Compared to the data from 2012 there is a significant increase (from 10.21% to 76.42%) in the reported cases of pharmaceuticals. The data regarding the falsified medicines include reported cases of many different types of medicines indicating that no medicine is safe from being counterfeited, including both innovative and generic, from life-style medicines to medicines that are indicated in life threatening diseases such as cancer, malaria and HIV. In the last years there is a sig- nificant increase in counterfeiting of dietary supplements (especially sliming dietary products) and medical devices. The phenomenon is increasing in the last few years, due to the growth of the sophistication of methods of falsification, and increased quantity of the imported products. According to the World Health Organization (WHO) around 10% of the medicines are falsified on a global level, 30% to 60% are in the developing countries, around 1% of the falsified medicines enter in the legitimate distribution chain in the developed countries, and around 50% from the medicines sold over internet are falsified. Counterfeiting of medicines is a highly profitable business with an estimated profit of more than 75 billion USD per year globally, resulting in a significant percentage of loss of the income of the pharmaceutical industry (WHO, 2010; WCO, 2013; WCO, 2014; WHO, 2014).  Innovative pharmaceutical and biopharmaceutical companies usually spend an average of 15-17% of their annual incomes on the research and development fоr providing the quality, safety and efficacy of their products and for ensuring the best outcome of the use of the medicine, avoiding the risk to the health and lives of patients (Blackstone et al., 2014; OECD, 1998). Counterfeiting of medicines as an unauthorised use of the intellectual property of the pharmaceutical industry reduces the incentives for creation and innovation, resulting in the damage to the econ- omy, society and environment (Blackstone et al., 2014). From the other point of view, counterfeit medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging and are often produced by unqualified personnel and in very poor and unhygienic conditions, and may con- tain toxic ingredients or unknown impurities, posing a serious treats to the health and safety of the patients. Consequently, counterfeiting of medicines has negative influence  of the healthcare systems on an international level. Patients suffer from additional conditions due to the uncontrolled quality and quantity of the counterfeit medicine and there- fore must get additional care covered by the state’s min- istry of health, causing additional burden of the government’s funds (WHO, 2014).  The counterfeiting of medicines compromises the le- gitimate activities performed during the production, trans- portation and distribution, such as, infringement of the pat- ent rights (unauthorised production, theft, selling and im- portation of patented active pharmaceutical ingredient), implementation of patented process or method for produc- tion of active pharmaceutical ingredients, excipients or fin- ished products, unauthorised use of the name or logo pat- ented for the medicine, the colour and shape of the dos- age form, the packaging or any other characteristic that are subject of patenting. Counterfeiting of the medicines may involve unauthorized manufacturers, brokers, illegal/un- regulated suppliers, wholesalers, and unregulated internet sale (MHRA, 2012; OECD, 2007).  Anti-counterfeit regulatory activities on a global level  Counterfeiting of medicines is an organized crime, reaching truly global proportions, which violates the law regarding the medicines and medical devices, but also in- cludes infringement of the intellectual property rights of the pharmaceutical industry. The greatest concern regard- ing the counterfeit medicines is the risk to public health, therefore this problem should be considered primarily from a public health perspective, and secondary as an intel- lectual property concern (Council of Europe, 2013; WHO, 2014). The real extent of the problem with occurrence and distribution of counterfeit medicines vary from country to country. The lack of resources/skills to detect counterfeit medicines, weak medicines regulatory systems, the differ- ent definitions of counterfeit medicines in different coun- tries worldwide, the variations in the distribution systems, high prices of the authentic medicines and insufficient co- operation between stakeholders are factors which facilitate counterfeiting activities (WHO, 1999).  Since the problem with counterfeit medicines cannot be combated successfully with isolated measures, an inte- grated and multilateral approach is necessary; ensuring co- operation between the various authorities involved, such as public health authorities and medicines agencies, as well as customs and police authorities on national, regional and in- ternational level. The fight against counterfeiting of med- icines should also involve pharmaceutical manufacturers, distributors, health professionals, consumers and general public (Council of Europe, EDQM, 2013; MHRA, 2012; WHO, 1999).  The World health organization (WHO) in February 2006 founded the International Medical Products Anti- Counterfeiting Taskforce (IMPACT), by joining together  Maced. pharm. bull., 62 (1) 85 - 89 (2016)  Counterfeiting of medicines as an infringement of the intellectual property rights 87   all of the stakeholders (international organizations, regu- latory agencies, associations of pharmaceutical manufac- turers, regulatory bodies) in the fight against counterfeit medicine on a global level, with the main purpose to pro- vide the main principles and elements of the national leg- islation for combating this problem. IMPACT is focused on the establishment, implementation and enforcement of the legislation and regulatory infrastructure, development of the technology to prevent and to detect counterfeit med- icines and communication strategy for rising public aware- ness (WHO, 2008).  The Medicrime convention of the Council of Europe is a powerful tool against the counterfeiting of medicines, from the perspective of protection of the patients’ health. The Medicrime convention provides the guidance for in- troduction of common minimal standards for safety, effica- cy and quality of medicinal products, essential and proce- dural criminal law; administrative procedures and preven- tive measures as well as provisions directed towards im- proving the cooperation and exchange of information be- tween the entitled organs in the fight against counterfeit medicines (Council of Europe, 2013).  The intellectual property rights are mostly regulat- ed on the national level, but additionally from an interna- tional perspective, the Trade related Aspects of Intellectu- al property rights (TRIPS) Agreement is also applicable. The TRIPS agreement is a document that guides the im- plementation of a global system for protection of the intel- lectual property rights, developed by the WTO and estab- lishes minimal standards for legal protection of intellectu- al property rights (sanctions for criminal activities are not harmonized). The TRIPS agreement introduced intellec- tual property law into the international trading system for the first time and remains the most comprehensive interna- tional agreement on intellectual property to date. Specifi- cally, **TRIPS requires WTO members to provide copyright rights, geographical indications, industrial designs, patents, trademarks and undisclosed or confidential information. TRIPS specifies enforcement procedures, remedies, and dispute resolution procedures.** According to TRIPS, the protection and enforcement of all intellectual property rights will contribute to the promotion of technological in- novation and to the transfer and dissemination of technolo- gy, to the mutual advantage of manufacturers and users of technological knowledge, while maintaining the social and economic welfare, and balancing the rights and obligations of the holders if intellectual property rights (WTO, 1994).  Protection of the brand of the pharmaceutical industry  In order to protect their brands, many pharmaceuti- cal companies take measures for prevention of counterfeit- ing and for rapid and effective response to counterfeited products including: development of the strategy for pro- tection from counterfeit, establishment and protection of  Макед. фарм. билт., 62 (1) 85 - 89 (2016)  their intellectual property rights, developing standards for traceability of the authenticity of their products, and there- fore providing larger transparency of the distribution chain and early detection of counterfeited products. The compa- nies should continuously implement new anti counterfeit- ing technologies for securing the distribution chain and to protect their brands by using track and trace systems, se- rialization and by keeping electronic records for all stages of the distribution of their products. Many different anti- counterfeit technologies are applied by the pharmaceutical companies including human readable (overt) and machine readable (covert) safety features, use of sophisticated print- er inks and track and trace software (Abel, 2010; OECD, 2007). EU Directive 2011/62 provides for measures to pre- vent the entry into the legal supply chain of falsified me- dicinal products by requiring the placing of safety features consisting of a unique identifier and an anti-tampering de- vice on the packaging of certain medicinal products for hu- man use for the purposes of allowing their identification and authentication (Council of Europe, 2011). The new EU regulation 2016/161 sets out the system for identifica- tion and confirmation of the authenticity of the medicines (Unique Identifier, UI and Anti tampering device, ATD) in the distribution chain in order to in order to verify the le- gitimacy of the manufacturer (Council of Europe, 2015).  The pharmaceutical companies should establish test- ing laboratory units in different countries for examination of suspected counterfeit samples. Additionally, in the fight against counterfeit medicines the pharmaceutical industry should participate trough organizing trainings (for law en- forcement, government officials, pharmacists and official testing laboratories), but also attending educational pro- grams for detection, monitoring and reporting of counter- feit medicines; leading and supporting networks against counterfeiting for promoting knowledge and experience exchange, development of activities for communication, informing, education and awareness increase of the gen- eral public; establishment of cooperation between private and public institutions (Abel, 2010; OECD, 2007).  The wholesalers has also an important role in preven- tion of counterfeiting of medicines, by verifying the au- thenticity of the medicinal products in his physical posses- sion and in cases where the verification of the safety fea- tures of the medicinal product indicates that the product may not be authentic or its packaging has been tampered, to report it to the relevant competent authorities (Council of Europe, 2015).  The marketing authorisation holder, parallel importers or parallel distributors are also an important link in secur- ing the distribution chain of medicines and should share the responsibility with other stakeholders in the fight against counterfeiting medicines (Council of Europe, 2015).  88 F. Cvetanovski, K. Brezovska, A. Poceva Panovska, J. Acevska, J. Tonic Ribarska, Z. Sterjev, A. Grozdanova, K. Ancevska Netkovska  Conclusion  Counterfeiting of medicines is a crime carried out us- ing deception and other techniques typical of organized crime, posing a significant danger to global public health in developing as well as developed countries. Additional- ly, counterfeiting of medicines has negative influence to the health care systems as well as to the pharmaceutical industry, causing financial problems, loss of the value of the brands and reduced confidence in their products. Solv- ing this problem and preventing counterfeiting of med- icines require establishment legislation that will identify the counterfeiting of medicines as a serious crime and en- forcement of effective penalties proportional with the con- sequences of this crime, strengthening the regulatory ac- tivities for securing the distribution chain of the medicines, establishment and improvement of collaboration between health authorities, police, customs and judiciary and de- velopment of communication strategy for raising public awareness for the risk of using counterfeit medicines. The role of the pharmaceutical manufacturers, wholesalers and retailers in the fight against counterfeited medicines is essential for both securing the supply chain to provide quality, safety and efficacy of the medicines that reach the patients from one side and to protecting their brands and their profit from the other side.