Impact Assessment of Policy Options for Combating Counterfeiting of Medical Devices and for Developing Safer Distribution Channels for Parallel Trade in Medical Devices

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TABLE OF CONTENTS

INTRODUCTION

The following report[1] assesses the impact of various policy options to regulate parallel trade in medical devices and to assist in combating the counterfeiting of medical devices. This study has been conducted by Europe Economics on behalf of DG Enterprise and Industry.

It has to be stressed that a similar study has been launched for medicine products, the results can be downloaded on the website of DG Sanco[2]. On that basis, a new legislative proposal has been adopted. This new legislation will apply to pharmaceutical products incorporated in medical devices.

[1] The following document is the executive summary of the report.
[2] http://ec.europa.eu/health/human-use/quality/fake-medicines/index_en.htm

I. PARALLEL TRADE IN SAFE MEDICAL DEVICES

A. The policy actions regarding parallel trade

The report contains an assessment of the likely impact of the following actions in relation to parallel trade.

Table 1.1: Policy actions in relation to parallel trade

OBJECTIVE 1: DEVELOPING SAFER DISTRIBUTION CHANNELS
Action 1: Clarify the different responsibilities of the medical device actors. Clarify the different responsibilities of the actors of the sector; for example, define manufacturers, distributors, importers, and identify respective obligations.
Action 2: Write Good Distribution practices (GDPs) in the field of medical devices. Development of written practices should give the opportunity to frame the general practices concerning the distribution of medical devices.
OBJECTIVE 2: REMOVING DIVERGENCES BETWEEN NATIONAL LEGISLATIONS
Action 3: Develop specific requirements in case of repackaging of medical devices. Development through legislation or guidelines of specific obligations in case of repackaging of medical devices by parallel distributors, in order to avoid that every Member State develops its own approach
OBJECTIVE 3: INCREASING THE COMPANIES' RESPONSIBILITY
Action 4: Involve parallel distributors in the fight against counterfeit goods by developing soft law mechanisms such as guidelines and/or a voluntary code of conduct. Although parallel distributors do not appear to be the main source of counterfeit medical devices, they might participate indirectly. Policy actions can try to develop dialogue with the parallel distributors in order to enhance quality control regarding their supply.
Action 5: Ask parallel distributors to register in a specific European database. If control over parallel distributors has to be increased, the best way could be to require in a legislative act that parallel distributors get registered in a specific database in order to increase the traceability of the medical devices trade.

B. Our method in reaching conclusions

To assess the impact of these policy actions we have used desk research and a survey of stakeholders to consider their economic, social and environmental effects. Based on the evidence provided by this analysis we have then considered the proportionality of the actions proposed. Administrative costs have been assessed using the Commission's Standard Cost Model based on a survey of manufacturers. These costs

are calculated on the basis of the EU 27 countries. Under this model costs imposed on the European Commission have not been included.

Our survey results suggested that parallel trade is relatively small in scale and that parallel distributors find it difficult to find suppliers of devices and buyers. In light of remaining uncertainty about the level of parallel trade we have used the following scenarios of parallel trade in establishing the counterfactual.

- Parallel trade currently very low;
- Parallel trade higher than visible in data immediately;
- Parallel trade low but presents a threat that drives price convergence;
- Parallel trade low and presents no threat that drives price convergence;
- Parallel trade low and currently presents no convergence-driving threat, but following broader progress to the internal market it would provide such a convergence-driving threat

C. Our findings in relation to parallel trade

Our findings are summarised in Table 1.2 overleaf.

Table 1.2: Summary of Impacts of actions for parallel trade

Policy Action Code	Action	Economic Effects	Social Effects	Environmental Effects
A1	Clarify Responsibilities	Small cost to regulator. Admin Cost of over €2.2 million for manufacturers. Indirect benefit on distribution.	Should foster greater certainty and in doing so improve safety with some consequent health benefits.	Not material
A2	Good Distribution Practice	Potentially significant cost to manufacturers and distributors. Could be admin costs of up to €88m one-off, €22m ongoing, in compliance. SMEs in particular could face a large cost. However, some economic benefits due to greater harmonisation of regulatory approach removing obstacles to the internal market. This could create benefits in relation to greater trade such as employment creation.	Could foster improved distribution practices and in doing so improve safety with some consequent health benefits.	Not material
A3	Repackaging Requirements	Potential significant effects. Parallel distributors may be forced to stop repackaging. Very difficult to monitor and thus to enforce.	Could be some health benefits in relation to improvement of packaging and where there may be particular importance to sterility and storage conditions for public health.	If repackaging decreases, then less packaging waste created
A4	Soft Law or Voluntary Code of Conduct	Minimal effect (this depends on the counterfactual). Admin costs of €50,000-€75,000	Not material as unlikely to be followed.	Not material
A5	Registration	Need for confidentiality of register or Parallel distributors may exit the	Potential employment effects. Potential benefits in relation to vigilance- e.g. tracking	Not material

		market. Admin costs of up to €50,000 for firms ongoing. Potential reduction in trade if confidentiality not respected. Potential effects on price dispersion through reduced competition if confidentiality not respected.	faulty goods. There are also potential benefits in greater harmonisation of the treatment of parallel distributors in relation to the internal market. Improved vigilance could improve patient safety with consequent health benefits.	

Administration costs

From Table 1.2 we can see that the administration costs are particularly significant for the good distribution practice guideline which may impose some changes for manufacturer and distributors in their current practice.

Other Economic effects

In general we found that the proposed actions could act as a restraint on parallel trade not only in imposing costs in relation to registration or best practice but more significantly in making parallel distributors more visible and thereby more vulnerable to losing suppliers due to actions by brand manufacturers.

Registration of parallel distributors could confer benefits in relation to vigilance and greater information although there are risks that unless the anonymity of parallel distributors can be safeguarded by regulators, parallel distributors may become clandestine with possible unintended effects.

Social effects

We did not consider that the actions would have very significant social impacts (e.g. on health) apart from the case of repackaging requirements (Action 3) which may foster some benefits where there had been inadequate repackaging. In this respect we note that the impact of such a measure would depend on the importance of ensuring the sterility of products and storage conditions to the particular product. In light of this we consider that such effects would only be significant for higher risk devices.

Environmental effects

We did not consider that the actions would have significant environmental effects.

D. Conclusions and recommendations in relation to parallel trade

Having looked at the economic, social and environmental effects of the actions we have then considered their general effectiveness and coherence, in order to form a final view on whether the actions are proportionate. In making judgements about proportionality we take benefit from the findings of our survey which did not suggest that parallel trade was having any detrimental health or other impacts.

Action One: Clarification of responsibilities

<u>Recommendation</u>: Action One should be implemented to provide for greater regulatory certainty in the sector.

Our survey revealed some confusion both about the definition of parallel trade in the sector and whether such trade existed at all. In this there seemed to be some variance across the Member States. Given this, and the fairly limited costs that this may involve, we consider that greater clarification in this area would be beneficial.

This would not be costly to undertake and could lead to greater regulatory certainty in the sector and would therefore appear to be a proportionate measure provided that it was not implemented in a manner which opposed significant costs.

Action Two: Good practice guide for distribution

<u>Recommendation</u>: Action Two should not be implemented if such distribution practice guides were to lead to costly changes in firms existing practice.

A Good Practice Guide (if it leads to a change in the actions of Distributors) may impose significant direct costs to parallel distributors and other stakeholders. These appear at first glance to be disproportionate to the gains which such a Guide may foster. However, we are aware that variance in the regulatory approach to parallel trade in medical devices across the Community may foster intangible barriers to such trade, and insofar as a good distribution guide may reduce such asymmetry of approach it could increase parallel trade and confer subsequent trade and employment benefits.

Action Three: Repackaging requirements

<u>Recommendation</u>: Action Three would only be proportionate for higher risk types of medical devices.

We also consider that repackaging requirements may be proportionate for higher risk medical devices, or for devices where packaging conditions in relation to sterility and

temperature a particularly vital, but not for other devices given the lack of evidence that parallel distributors (i) are significant in scale; (ii) that they repack items; or (iii) that such repacking is creating adverse health impacts.

Action Four: Soft Law mechanisms

<u>Recommendation</u>: We have concerns that Action Four would be ineffective as parallel distributors would be unlikely to cooperate with such mechanisms. However we could see some benefits in inexpensive awareness raising measures.

Soft law mechanisms may have some benefits in raising awareness about the possible risks of poor distribution practice or of counterfeits, but we think it unlikely that parallel distributors would seek actively to cooperate in such schemes, given their concerns about increased visibility. Such measures would only be proportionate therefore to the extent that they did not impose significant costs.

Action Five: Registration of parallel distributors

<u>Recommendation</u>: Our recommendation regarding Action Five comes in two parts. First, we consider those medical devices that present special issues of storage and transport, particular to the medical device industry and going beyond normal issues of sterility and the proper treatment of products in storage and transport that apply to many other products. (We are advised by DG Enterprise and Industry that this constitutes the majority of medical devices.) In respect of these medical devices, we recommend that Action Five should only be implemented if the register is confidential to regulatory authorities and the anonymity of parallel distributors is ensured. Subject to this caveat we consider that the measure could have useful social benefits in relation to vigilance.

Next, we consider those medical devices that do not present any special issues of storage and transport. In respect of these medical devices, we recommend that Action Five should not be implemented (even with robust confidentiality requirements), as it would end opportunistic parallel trade, the threat of which is, in our view, a key element preventing the segmentation of the Single Market.

We have concerns that registration of parallel distributors would be disproportionate apart from where there are special issues of storage or transport. Even then it is imperative to ensure confidentiality of the register.

II. COUNTERFEIT MEDICAL DEVICES

A. The draft policy actions

The report contains an assessment of the impact of the following policy actions in relation to combating counterfeit medical devices:

Table 1.1: Policy actions in relation to combating counterfeit medical devices

OBJECTIVE 1: DEVELOPING SAFER DISTRIBUTION CHANNELS
Action 1: Develop a best practice guide for medical devices in order to tackle counterfeit issues. Better adaptation of Guides and/or Draft Conventions which presently exist for medical products at the European (Council of Europe) and international level (IMPACT WHO) to address the specificities of medical devices.
Action 2: Write a code of conduct for every company selling medical devices in order to report any case of counterfeiting Because the development of future European approach to counterfeiting depends on a better understanding of the scale of the problem, a code of conduct developing the obligation for companies to report any counterfeit case to their national authorities would be very useful in this context.
Action 3: Enhance the collection of information about counterfeit medical devices by developing a specific database accessible to the Commission and to the Member States Encourage Member States to report back any counterfeited cases, which would be added to a European database managed by the Commission. Each case would be analysed in order to learn more about specific problems and information shared between Member States.
Action 4: Increase traceability by developing a unique device identifier (UDI) for medical devices at the European Union level Following recent developments in US legislation, UDIs will soon become compulsory in the EU medical devices market in order to access the US market. Some Member States are developing national UDI types, which could result in important barriers to trade. Therefore a common reflection with all stakeholders to define an optimal European approach to the establishment of a European UDI would be important.
Action 5: Build up reflection about actions which can be taken regarding sales on the Internet Development of a targeted regulatory approach in order to take into account the increased risk of counterfeiting through internet sales.
Action 6: Establish a code for procurement (public and private) in order to foster controls over distribution channels The development of a code of conduct to enhance the obligation regarding product origins could be an efficient tool to tackle counterfeit goods and decrease the possibility for them to enter the market through this channel.
OBJECTIVE 2: BUILDING LINKS BETWEEN NATIONAL ADMINISTRATION AT THE NATIONAL AND INTERNATIONAL LEVEL
Action 7: Improve relations between National Custom Authorities and National Competent Authorities dealing with medical devices

Since most of the counterfeit medical devices come from outside the European Community, fostering links between National Customs Authorities and National Competent Authorities would help to give customs authorities the information they require in order to target potential counterfeit goods (e.g. sets of security measures such as indicators and country-specific risk analysis).

Action 8: Collect best practice and disseminate them among other national administrations

An exchange of best practices between Member States can help States benefit from the more advanced approaches to controlling counterfeit medical devices, and close existing discrepancies between Member States regarding legislation and awareness levels.

Action 9: Increase co-operation between NCAs dealing with medical devices

Common controls between NCAs would enable them to ask each other to intervene in order to secure the distribution channels of medical devices. This would be achieved by request of intervention sent by one NCA to another in case a company is not established in a Member State where a problem occurs.

Action 10: Adopt a Directive regarding counterfeit medical devices

This would increase harmonisation between Member States and therefore enhance the quality and level of controls among Member States. The Directive could develop some minimal harmonisation regarding controls and sanctions related to counterfeit medical devices.

OBJECTIVE 3: ENHANCING INTERNATIONAL CO-OPERATION

Action 11: Increase international co-operation and promote international regulation

This action would mandate general research into potential fora where the issue of anti-counterfeiting can be raised, such as through the development of international guidelines with the WHO, or discussion at the GHTF or AHWG.

Action 12: Develop joint actions with third countries

In order to better concentrate controls to the main source of the problem of counterfeiting specific bilateral agreements could be signed with third countries which have been singled out as the main origin of counterfeit medical devices.

Action 13: Foster co-operation inside the GHTF

Establishment of a specific ad hoc working group on counterfeit medical devices to gather information about the EU's main partners would help identify potential common actions in the field of counterfeit and medical devices, as well as examine the development of Good Marketing Practice on a global level.

Action 14: Encourage European companies to establish in third countries common contact points to deal with counterfeit products

Promote a mechanism for mutual assistance between European companies to help each other in case of the identification of a counterfeit product in a third country. This would reduce the cost induced by controlling counterfeits and in addition considerably help SMEs which may not have adequate resources to tackle this problem.

B. Our method

To assess the impact of these policy actions we have used desk research and a survey of stakeholders to consider their economic, social and environmental effects. These have been considered for the whole of the EU 27 countries.

To facilitate an efficient IA of the different possible measures we have put similar actions into groupings.

These are summarised in Table 1.2 overleaf.

Table 1.2: Policy Action Groupings[3]

Combating Counterfeit of medical devices
UDI : Group One
B4: UDI
Collecting more information: Group Two
B2: Obligation to report
B3: European database
B5: Sales on the internet
Best Practice Guides: Group Three
B1: Best Practice Guide for medical devices
B6: Code of procurement
Cooperation related: Group Four
B7: Improve intra-national cooperation
B8: Dissemination of best practice
B9: Cooperation between NCAs
B11: International Cooperation
B12: Joint actions with third countries
B13: Cooperation inside GHTF
B14: Common contact points with companies in third countries
Directive: Group Five (not analysed in detail)
B10: Adopt a Directive (This action ruled out at rationale stage and subsequent IA is not conducted)

Source: Europe Economics

We have then modelled their likely impact on rates of confiscation of counterfeit goods and therefore their effectiveness in reducing the level of counterfeits. Based on the evidence provided by these analyses we have then considered the proportionality of the actions proposed.

Assessing the scale of counterfeits

A key issue in establishing the impacts of the different policy options was the current and likely future level of counterfeits. In accordance with the principle of proportionality, a higher scale of counterfeits, and a higher level of consequent social impacts- such as health costs, could justify more a more significant level of regulatory intervention.

[3] We have not included Action 10 in any grouping as we did not consider it proportionate to analyse the impacts of this action in detail.

Our survey results suggested a fairly low level of counterfeits relative to counterfeiting in other areas (such as medicine) with only a few reported incidents each year. However, a few respondents expressed concerns that such reporting was artificially low due to a lack of effective monitoring.

The use of scenarios in establishing the counterfactual

Given this uncertainty we have used the following scenarios of the scale of counterfeiting in assessing the impact of the above actions:

- Counterfeits currently at the average level of international counterfeiting as believed by the OECD;
- Counterfeits currently at much lower than the average level of counterfeiting;
- Counterfeiting currently at much lower levels than average, but rises to average level internationally following other international and European moves to remove obstacles to trade.

Administrative costs

Administrative costs have been assessed using the Commission's Standard Cost Model based on a survey of manufacturers across the EU 27.

Other economic effects

We considered that the policy actions may have effects in relation to trade in medical devices and we have calculated these in relation to impacts on the level of counterfeits on the whole of the EU 27 countries through our modeling. We also consider that measures such as the UDI may impose significant (non administrative) costs for example in new machinery and capital equipment.

Social effects

We have not attempted to calculate numerically health impacts of different levels of counterfeits, but have taken account of the potentially serious nature of any incidence of counterfeits in our assessments.

Environmental effects

We do not consider that these actions would have significant environmental impacts.

C. The results of our analysis

Having looked at the economic, social and environmental effects of the actions we have then considered their general effectiveness, coherence and proportionality

Table 1.3: Summary of IA in relation to actions to combat counterfeit medical devices

Code	Action	Economic Effects	Social Effects	Environmental Effects
B1 Group 3	Best Practice	Costs involved in drafting the Code estimated at over €60,000. Cost to companies in familiarisation with guidelines. Potential reduction EU companies' competitiveness and therefore trade flows as well as higher prices.	In raising awareness about the level of counterfeits and in promoting greater harmonisation of approach this measure may reduce the share of counterfeits with consequent positive health benefits.	No material effects.
B2 Group 2	Obligation to Report Counterfeits (Code of Conduct)	Effects depend on level of reporting but familiarisation with the Code alone would result in admin costs of over €700,000.	Possible long term effects on share of counterfeits and therefore health impacts. Positive health effects depend on number of counterfeits in market.	Not material
B3 Group 2	European Database	Costs borne by European Commission	Increased transparency and cooperation. Potential positive health effects if confiscation enforced. Positive health effects depend on number of counterfeits in market.	Not material.
B4 Group 1	UDI	The cost of implementation is substantial and would impact all firms, hospitals and public authorities involved in development and implementation.	Positive health effects if counterfeits decrease. Increased patient safety and various other benefits.	May be some due to increased production of readers and database machinery.
B5 Group 2	Sales on the Internet	Businesses would incur costs depending if a portal or charter is adopted. One-off costs €253,440 for portal and €253,440	Increased transparency and awareness of trade over the Internet contributing to safer internet trading.	No material effects.

		for charter.		
B6 Group 3	Procurement Guide	Costs to companies and procurers in following the Code, and to authorities in writing the Code (estimated at over €60,000). Potential increase in barriers to supplier entry. Potential barrier to counterfeiters. Potentially higher prices. Potential reduction in parallel trade where parallel distributers could not meet procurement requirements.	Increased awareness of counterfeits and barriers to counterfeits leading to a reduction in the level of counterfeits with consequent health benefits.	No material effects.
B7 Group 4	Improve intra-national cooperation	Not material – mainly entails additional meeting time.	Potential for increased confiscation and knock on health effects from a reduction in counterfeits. Raising awareness of future levels of counterfeits leading to some positive effects on health. Could be significant if level of counterfeits reduced	No material effects.
B8 Group 4	Dissemination of Best Practice	No material effects as information already shared and existing structures could be used to disseminate information.	Raising awareness of future levels of counterfeits leading to some positive effects on health. Could be significant if level of counterfeits reduced.	No material effects.
B9 Group 4	Cooperation between NCAs	No material effects as information already shared.	Raising awareness future levels of counterfeits leading to some positive effects on health. Could be significant if level of counterfeits reduced.	No material effects.
B11 Group 4	International cooperation	Could be significant depending on type of action adopted-unless existing cooperation mechanism was used.	Raising awareness future levels of counterfeits leading to some positive effects on health. Could be significant if the share of counterfeits is reduced.	No material effects.

B12 Group 4	Joint actions with third countries	Could be significant unless existing cooperation mechanism was used.	Raising awareness future levels of counterfeits leading to some positive effects on health. Could be significant if the share of counterfeits is reduced.	No material effects.
B13 Group 4	Cooperation inside GHTF	Some costs in set-up linked to additional meetings	Raising awareness future levels of counterfeits leading to some positive effects on health. Could be significant if the share of counterfeits is reduced.	No material effects.
B14 Group 4	Common contact points with companies in third countries.	Many companies have contact points but some costs in full utilisation.	Raising awareness future levels of counterfeits leading to some positive effects on health. Could be significant if the share of counterfeits is reduced.	No material effects.

Table 1.3 above summarises our findings in relation to actions to combat counterfeit medical devices.[4]

Variance across Europe

The Community regulatory framework for medical device sector is made up of the following Directives: the Active Implantable Medical Devices Directive (AIMDD), the Medical Devices Directive (MDD), and the In Vitro Diagnostic Medical Devices Directive (IVDD)[5]. These Community acts set out the framework for pre and post-marketing requirements which medical devices must comply with in order to be placed on the Community market.

A key finding was that although this broader harmonisation has taken place the regulatory practice in relation to counterfeit medical devices and the market more generally was varied across the Member States.

Modelling results

We have modelled the likely effects of policy actions on the scale of counterfeits. A summary of our results is set out in Table 1.4 below.

[4] Action 10 in relation to a new Directive is not considered in the more detailed analysis.

[5] Council Directive 90/385/EEG of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices 20.07.1990, OJ L 189/17. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices 12.07.1993, OJ L 169/1. Directive 98/79 of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices 07.12.1998, OJ L 331/1. Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma, OJ C 13.12.2000, L 313/22.

Table 1.4 Likely effects of policy actions on confiscation and the scale of counterfeits

Policy Option in IA	Range of plausible effects on the probability of confiscation/ detection % point increase		% point reduction in the market share of counterfeits		
			Scenarios for levels of counterfeiting.		
	Low	High	Medium	Low	High
Action B1	0	1	0.04	0.01	0.06
Action B2	0	0.5	0.02	0.01	0.03
Action B3	0	1	0.04	0.01	0.06
Action B4	0.5	2	0.08	0.03	0.1
Action B5[6]	0	0	0	0	0
Action B6	0	1	0.04	0.01	0.06
Action B7	0	1	0.04	0.01	0.06
Action B8	0	0.5	0.02	0.01	0.03
Action B9	0	0.5	0.02	0.01	0.03
Action B10[7]	0	0	0	0	0
Action B11	0.5	2	0.08	0.03	0.1
Action B12	0	0	0	0	0
Action B13	0	0.5	0.02	0.01	0. 03
Action B14	0	0.5	0.02	0.01	0. 03
Total	1	10.5			

Source: Europe Economics

From Table 1.4 we can see that under our modelling assumptions the likely effectiveness of different options on the scale of counterfeits depends to some extent upon the current level of counterfeits.

Under Scenario One, where the level of counterfeits is normal (compared to other goods) at 3 per cent of total goods, then the effect of the regulatory measures- based on an initial increase in the confiscation of good, is 0.04 percentage points for every likely increase in the confiscation rate — so, for example, if the confiscation rate were to rise 10 per cent then the level of counterfeits would fall from 3 to 2.6 per cent.

Under Scenario Two where there is a low level of counterfeiting (one per cent) then this effect falls to 0.01 percentage points.

Under Scenario Three where the level of counterfeiting is high (five per cent) then the reduction is higher at 0.6 percent for each increase in the confiscation rate.

[6] Given low level of internet trading currently we have not forecast any impact of a portal on the share of counterfeits.
[7] We have not considered it proportionate to assess Action B10 in detail.

Under each scenario we can see that the effects of the regulatory actions, even if taken as a whole are likely to be modest in relation to the level of counterfeits. However, it is important to understand that even a small change in the level of counterfeits may have health impacts.

D. Our conclusions and recommendations in relation to the policy actions

In general we consider that, compared to the administrative costs of such options, their likely effects on the level of counterfeits are small in scale and this suggests caution in moving forward to expensive regulatory solutions in the absence of further evidence that counterfeiting of medical devices is becoming a major problem. This also underlines the importance of ensuring high quality information about the level of counterfeits in setting an appropriate regulation.

Action 1: Develop a best practice guide for medical devices in order to tackle counterfeit issues.

<u>Recommendation</u>: We consider that this action could be an important cost effective measure and method of raising awareness of counterfeiting and may act to improve the level of information about counterfeits and the future targeting of anti-counterfeit measures and we recommend that it be taken forward.

We consider that a Best Practice Guide for dealing with counterfeits at international level would not create significant costs, although there would be non trivial costs in drafting the Guide and we could envisage also non trivial costs in finding agreement about such a Guide.

Whilst such a Guide could be an important step towards later measures, we do not consider that it would by itself reduce the level of counterfeits significantly. Although we do recognise that there may be benefits in fostering a more harmonised approach across the Member States and also social benefits in reduction of the harmful health impacts caused by counterfeits.

However, given the importance of such a Guide in raising awareness of the issue of counterfeits we consider that its benefits would outweigh its costs. Further the action could improve the information available to regulators and facilitate more effective future targeting of anti-counterfeit measures.

Action 2: Write a code of conduct for every company selling medical devices in order to report any case of counterfeiting.

<u>Recommendation</u>: Whilst we understand that an obligation to report counterfeits through a code of conduct may impose non trivial one-off costs we nevertheless recommend that this action be taken forward as it would raise awareness of counterfeiting and may act to improve the targeting of future anti-counterfeit measures. However, in order to ensure that such obligations did not impede cross border trade or create new barriers to the internal market for medical devices we consider that they should be uniform across the Member States. This would act also to reduce the current asymmetry in the national approaches taken.

We find that the obligation to report counterfeits may result in non-trivial administration costs, not least in the initial stages of communicating the obligation to stakeholders. In increasing transparency and certainty in relation to the number of counterfeits, and more generally the incidence of counterfeiting, we consider that such a measure would indeed have a positive impact, albeit modest, on the likelihood of confiscation of counterfeiting and therefore in the level of counterfeiting. This would confer social benefits for example in reducing the level of adverse health impacts caused by counterfeits.

Once again this impact depends to some extent on the current level of counterfeiting, with a low level of counterfeits suggesting both a reduced burden of reporting (communication of the obligation notwithstanding) and a reduced impact on the level of counterfeiting.

We note the views of stakeholders that in most cases incidents of counterfeiting are thought to be already reported and that where counterfeits are identified by customs authorities there appear already to be cooperation mechanisms in place between such authorities and health regulatory bodies.

However, we would consider on balance that this obligation is proportionate at this stage of regulatory development. The communication of the reporting obligation itself would bear benefits in raising awareness of counterfeits and the obligation itself would act to increase regulatory certainty in the sector, in particular around the possible scale of counterfeiting which remains in some doubt. Further the action could improve future targeting of anti-counterfeit measures.

However, we would also consider that it is important that such obligations should not be imposed in a manner which may create any barriers to the internal market for medical devices.

Action 3: Enhance the collection of information about counterfeit medical devices by developing a specific database accessible to the Commission and to the Member States.

<u>Recommendation</u>: We consider that a European database of counterfeits could be important in improving transparency about the level of counterfeits and thereby in facilitating better targeting of future anti- counterfeit measures and we recommend that it be taken forward.

Our findings suggest that a European database would impose non trivial costs in set-up and maintenance. At first glance such costs may seem disproportionate when compared to the low level of counterfeits which our survey appears to suggest.

However, given the serious impacts which even a low level of counterfeiting may create in relation to public health and given the possibility that counterfeit of medical devices may become more attractive over time relative to other forms of counterfeiting, we consider that (in tandem with compulsory reporting of counterfeits) such a move at European level would be proportionate.

Further, such a database would allow for a better consideration of future measures if the problem of counterfeiting becomes more serious. In this respect, the action could raise awareness about the issue of counterfeits and improve the information available to regulators and thereby improve targeting of future anti-counterfeit measures. This could have future social effects for example in relation to reducing health impacts caused by counterfeits.

Action 4: Increase traceability by developing a unique device identifier (UDI) for medical devices at the European Union level

<u>Recommendation</u>: Given the significant costs involved in setting up a UDI system we do not consider that it could be justified purely on the basis of its benefits as an anti-counterfeit measure, but recommend that a broader IA be undertaken on the issue.

Respondents to our survey were clear that implementation of UDI, even at batch level, could involve significant costs for firms and users and would require a timescale of three to five years. In particular this may impose significant costs on SMEs.

They also suggested that whilst such a UDI would be a nuisance to counterfeiters, evidence suggested that they would be able to mimic barcodes or other UDI within a short period and that it would not be decisive by itself as an anti counterfeit measure.

Our analysis, therefore suggests that, given these substantial costs, the introduction of UDI could not be justified if it were undertaken only for the purposes of combating counterfeiting of medical devices.

This is particularly the case under the scenario of fairly low level of counterfeiting of medical devices relative to general levels of counterfeiting.

However, we note that there are other more significant benefits claimed for UDI which lie outside the scope of this study- including public health, vigilance and inventory management benefits. Whilst we have not quantified these in this report, we consider that it is plausible that when such benefits are considered the introduction of UDI at a European level in a format which is consistent with the US and other global systems could be a proportionate and cost effective measure.

Action 5: Build up reflection about actions which can be taken regarding sales on the Internet

<u>Recommendation</u>: Our analysis suggests that an internet portal for sellers could act to improve transparency for purchasers of devices, and we recommend this. This could also provide a vehicle for best practice and accreditation of sellers and a safe harbour for known and trusted suppliers. However, we do not recommend that there should be regulatory intervention in this area for example that regulatory bodies be asked to monitor internet sales or that companies be required to register on an internet database.

We consider that the actions in related to internet sales could impose non trivial one-off costs on regulatory authorities in particular. Further, we note that were regulatory authorities to attempt a broader monitoring of internet sales then this could be extremely costly and unlikely to be effective.

Our survey results suggest that consumers do not currently procure medical devices in bulk purchases over the internet. However, we recognise that even if consumers purchase one faulty or unsafe medical device over the internet that this may have serious health effects.

Further, clinicians and hospitals have concerns over reputational risk, which may outweigh perceived cost efficiency advantages in purchasing over the internet.

However, we could also imagine a scenario where some pharmacies or smaller retail outlets may be tempted to purchase devices on the internet where these are much cheaper than alternatives.

In light of this, attempts to impose a register on internet sales of medical devices are unlikely to have a significant immediate effect on the level of counterfeits and could be disproportionate, but there is a case for increased awareness amongst purchasers of the risks of buying from unknown suppliers over the internet.

Further we recognise that an internet portal could provide an opportunity for legitimate suppliers to demonstrate their quality to buyers, for example through a certification by regulators or purchasers. Such a mechanism may also improve information across national borders providing for increased cross border trade.

In light of this we would recommend a move towards an internet portal.

Action 6: Establish a code for procurement (public and private) in order to foster controls over distribution channels

Recommendation: We recommend that a code of procurement be taken forward.

We consider that drafting and implementing a code of procurement may impose some non-trivial costs for regulatory authorities and also procurers in becoming fully compliant with such a code.

Our survey suggests that in some Member States hospitals tend already to have such best practice codes and that the added value of such a measure in these countries may be limited. However, we are aware also of considerable variance in the practice in the Community and that such a Code may be useful in establishing good practice in some Member States and in reducing barriers to cross border trade.

Given this, we find that, though the likely effects of such a code may be limited in some Member States, such a code may increase awareness of counterfeits and of the need for vigilance in purchasing. In this respect we could see some social benefits of it in reducing the health impacts of counterfeits, particularly in some Member States provided that it did not impose significant costs on SMEs or impede effective competition. In reducing barriers to the internal market, this measure should also foster increased trade and employment.

Action 7: Improve relations between National Custom Authorities and National Competent Authorities dealing with medical devices.

Recommendation: In general we consider that such cooperation is very useful in increasing awareness of the level of counterfeits and the facilitating the targeting of future anti-counterfeit measures. In light of this where such cooperation may not be established in the Community we would recommend that it should be undertaken. However we recommend that any increases in such cooperation take place within existing cooperation structures in relation to counterfeit manufactured goods.

Our survey results suggest that the costs of meetings between customs authorities and health authorities are not material to the bodies concerned. It appears from our survey that cooperation between these bodies often already exists, although we accept that there may be some variance in this good practice across the Member States and that such cooperation is sparked off in some cases by related discussions in the medicines fields and in others by specific incidents of counterfeit devices.

In one respect we can see that frequent meetings between these bodies may not always have taken place due to the low level of confiscation of counterfeit medical devices. In this respect it could appear to be disproportionate to put in place extensive bureaucratic arrangements on top of a natural level of cooperation driven by the discovery of consignments of counterfeiting.

Given this, whilst we consider that it is important that customs authorities and health authorities communicate regularly and that the issue of counterfeit medical devices are part of this discussion we would not wish to propose a set number of meetings or specific arrangements.

Whilst there are clearly extreme forms of such cooperation that might significantly reduce the level of counterfeiting quite directly (such as the placing of a medical devices expert at every customs point) these would appear to be highly expensive and disproportionate.

We would therefore conclude that any increases in cooperation take place within existing cooperation structures in relation to counterfeit manufactured goods.

Action 8: Collect best practice and disseminate them among other national administrations

<u>Recommendation</u>: We recommend dissemination of best practice which could raise awareness of the level of counterfeits and facilitate the better targeting of future anti-counterfeit measures. However we would recommend that any increases in such cooperation take place within existing cooperation structures.

Respondents to our survey noted that there is already a high level of cooperation in the medical devices field at European level. Yet we note that there is a remaining variance in the approach adopted by the Member States to this issue.

Awareness of the issue of counterfeit medical devices compared to that of counterfeit medicines remains quite low and we consider that it is important the counterfeit medical devices are not overlooked in the general discussion of counterfeits and that best practice in handling issues of counterfeit devices is given full attention. Dissemination of best practice may therefore lead to greater awareness of counterfeits and a better targeting of future anti counterfeit measures. This may in turn create social benefits in reducing the level and adverse health impacts of counterfeits. Further, in acting to reduce regulatory asymmetry it may also remove barriers to the internal market with consequent employment and trade impacts.

Action 9: Increase co-operation between NCAs dealing with medical devices

<u>Recommendation</u>: We recommend increased cooperation between regulatory authorities within existing structures which could raise awareness of the level of counterfeits and facilitate the better targeting of future anti-counterfeit measures. This could also act to reduce the current regulatory asymmetry between the Member States. However we recommend that any increases in such cooperation take place within existing cooperation structures.

National Competent Authorities already cooperate in a number of European bodies and in some cases bilaterally. In this respect cooperation has been driven largely by other issues related to health in general or medicines in particular.

In this context gaining greater focus or time for the issue of counterfeit medical devices may be simply a matter of including it in meeting agendas or setting up additional subcommittees to review it.

Action 10: Adopt a Directive regarding counterfeit medical devices

We do not consider that such a measure could be justified following our analysis in Step One of the Impact Assessment and have not analysed it in detail.

Action 11: Increase international co-operation and promote international regulation

<u>Recommendation</u>: We recommend greater international cooperation on this issue which could increase awareness of counterfeits and facilitate better targeting of future anti-counterfeit measures. However, we consider that this cooperation should come within existing discussions about the problem of counterfeits.

The costs of greater international cooperation are again felt largely in gaining space for the discussion of counterfeit medical devices within existing cooperation mechanisms. There are some additional administrative costs but we would not regard these as material.

The benefits of such cooperation could be significant were they to lead to action in those countries where the manufacture of counterfeits seems most likely to occur. These appear to be outside the EU. However, it is perhaps unrealistic to envisage early gains from such cooperation, particularly when the issue of counterfeiting can become conflated with that of generics manufacture, and when, in any case, even if cooperation was to lead to active enforcement of anti-counterfeit measures, the counterfeiters may simply move elsewhere.

Nevertheless, it could be argued that greater cooperation could lead to greater awareness about the level of counterfeits and better targeting of future anti counterfeit measures.

Given the fairly low level of counterfeits suggested by our survey we do not consider that it would be proportionate to create a new system for such cooperation but that any increases in such cooperation take place within existing cooperation structures in relation to counterfeit manufactured goods.

Action 12: Develop joint actions with third countries

<u>Recommendation</u>: We recommend that where there are joint actions with other countries (outside the EU) in relation to counterfeits, medical devices are included in these actions. However, we consider that this cooperation should come within existing actions in relation to the problem of counterfeiting.

The process of agreeing and implementing joint actions with other countries could create costs for regulatory authorities in relation to the set up of the actions (bilateral meetings etc.). However, in general these would be in relation to existing arrangements with third countries.

As in the case of greater international cooperation in general, if these actions proved effective then they could, in principle, lead to higher exposure of, and actions against counterfeiters, in third countries. However, given the inherent unpredictable nature of what these actions might be we have not attempted here to foresee their exact nature, apart from noting that they are a possibility.

Nevertheless such actions could lead to greater awareness about the level of counterfeits and better targeting of future anti counterfeit measures.

Given the fairly low level of counterfeits suggested by our survey we do not consider that it would be proportionate to create a new system for such actions but that any increases in such cooperation take place within existing cooperation structures in relation to counterfeiting.

Action 13: Foster co-operation inside the GHTF

<u>Recommendation</u>: We recommend that continued and further cooperation takes place on this issue in the GHTF which could increase awareness of counterfeits and facilitate better targeting of future anti-counterfeit measures. However, we consider that this cooperation should come within existing discussions about the problem of counterfeits.

Clearly there are some costs involved in greater cooperation in the GHTF, although these are likely to largely involve additional meetings in relation to counterfeit medical devices and agenda space for the issue compared to other issues.

Measuring the effects of progress in the GHTF is difficult in isolation. However, in raising awareness of the issue of counterfeit medical devices and in facilitating the move towards more effective regulation and enforcement of medical devices we can impute some significance to the GHTF process.

Action 14: Encourage European companies to establish in third countries common contact points to deal with counterfeit products

<u>Recommendation</u>: We do not recommend regulatory action to create additional common contact points with companies outside the EU.

In practice many of the larger firms supplying medical devices operate globally and have now outsourced their manufacturing operations to countries where counterfeiters operate. For these companies there would already be internal points of contact.

However, we would have some concerns about the potential impacts on SMEs of imposing regulatory obligations in this respect, although we recognise that they may be less likely to be active outside the EU.

In light of this we would not consider that such a policy would be proportionate as an additional alert to counterfeits.