Malta Chamber of Small & Medium Enterprise

25th April 2008

GRTU – POSITION PAPER

Public Consultation – combat counterfeit medicines for human use

GRTU, the Malta Chamber of Small and Medium Enterprises, encompasses in its midst all the Pharmacy Owners in Malta, all full line wholesalers, plus all those companies involved in repackaging of pharmaceuticals and parallel traders in Pharmaceuticals.

In the past, GRTU was at the forefront in proposing legislation to support all these activities, and GRTU also spearheaded the necessary modifications to the Pharmaceutical Registration Systems in Malta in order to make registration easier in view of such a small market. Pharmaceutical registration in Malta post accession was overtly complicated and costly and Malta ran the serious risk of ending up with a reduced list of pharmaceuticals registered, mainly the fast moving ones. This would have caused serious problems in our National Health Service.

Malta, along with Cyprus, is unique in not having a full reimbursement system or even a co-payment system that encompasses all the pharmaceutical needs of its population. Patients suffering from a limited list of conditions, mainly diabetes, heart disease, and some mental health conditions are however given free medicines by the State Health System. There is no means testing for this, and the qualification is the condition rather than any monetary income or assets held by the patient.

Many medicines in Malta are registered in line with article 4(2) of the Medicines (Marketing Authorisations) Regulations in accordance with article 126(a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004.

Although such registration is necessary, yet it does not absolve the entity placing the product on the market from abiding with National Legislation. This means that it is usually necessary to change the package insert into one that is in English or Maltese. A number is also placed on the outer box as well as the PIL itself, and frequently a sticker has to be applied over the foil blister in order to comply with local patient safety standards.

Malta is also well served by the Parallel Import companies, who have by necessity to repackage their product to comply with national requirements. The PI industry provides a level of competition in a country of such small proportions that the normal factors that make competition effective are not present. There are a few importers, actually a handful, that distribute for a large number of pharmaceutical companies, and this in itself creates a virtual monopoly that can only be challenged by Parallel Importation and the repackaging of PI goods. The competition is there because PI goods invariably are cheaper. But whereas in the rest of the EU, the consumer does not directly “feel” the savings made due to reimbursement, in Malta, the opposite is true. The large majority of patients have to buy their medicines out of pocket, so to speak, and as such the cost savings made are directly felt by the consumer. To compete, the direct importer has to reduce his consumer price, and that has created a price war between the direct

GRTU Malta Chamber of Small and Medium sized Enterprises, Exchange Buildings, Republic Str, Valletta
Tel: (+356) 21232881/3 Fax: (+356) 21246925
Email: abigail.mamo@grtu.org.mt Website: www.grtu.org.mt

importers and the Parallel Importers, with the consumer being the ultimate winner. Malta is a very brand driven market, and consumers demand brands at a cheaper price. PI is giving them that choice, and enhancing it. Generic penetration is still very low in Malta, with consumers still opting for brands, be they direct imports or PI, over cheaper generic versions of the same drug. This is an area of concern that can only be addresses by empowering the patient through education.

As such, competition between all players in Malta is cut-throat and is frequently marked by incidences of borderline unfair practices by the direct importers and their principals in order to keep market share. The target, even in tiny Malta, is the fledgling PI industry and the Generics distributors.

If what DG Enterprise would like to proposes becomes reality, then the patient in Malta will suffer a lack of choice and higher medicine prices at the pharmacy. In one fell swoop competition in this field in Malta will be removed, leaving only the major importers to reign. This would mean again going back to the times when all medicines in Malta were imported and distributed by a handful of companies.

GRTU is saddened to see that DG Enterprise went to the trouble of embarking on this consultation with so tainted motivations.

The consultation is about identifying risk factors in the pharmacy supply chain that may facilitate entry of counterfeit medicines, and about measures that could help preventing this to happen.

This is a patient safety issue and should exclusively be handled by DG Sanco and not by DG Enterprise, which invariably takes an industry oriented position in this issue. DG Sanco possesses expertise, experience and the necessary set-up to pursue patient safety, whilst DG Enterprise's resources and expertise seem to lie elsewhere.

From the outset, GRTU strongly encourages the new Health Commissioner to take the initiative in this issue. This is DG Sanco's duty to the patients in the EU, and it seems that that they have not only not been sufficiently motivated to take their rightful lead position in spearheading the fight against counterfeits but they have allowed their place to be usurped by another DG, which does not have the remit for patient safety. The lack of involvement of DG Sanco is disturbing, to say the least, because patient concerns should come before industry concerns in the list of priorities.

Nonetheless, GRTU really does welcome initiatives that may lead to measures to enhance the safety of the supply chain. However this consultation has already set off on the wrong foot by needlessly attacking and in the process irritating the repackaging industry, which is one of the most regulated and sophisticated industries in the EU. The ideas set out in the consultation are already finding the repackaging industry guilty without the benefit of a trial. The proposed ban on repackaging is designed to kill this industry off. We state from the outset that we believe that the real reason for this is not the fear of counterfeit product penetration into the supply chain. The driving force here is far more dangerous and subtle in action. The ultimate target is the Parallel Distribution of Pharmaceuticals. This is an assault on one of the basic tenets of the very pillars of our treasured set of beliefs and freedoms, that is, the free movement of goods across the whole borderless market of the EU. That anyone or anything should attack this basic tenet is shocking. That the attack should be coming from within the Commission is wrong, and we say this with the greatest responsibility and concern. DG Enterprise and the Commissioner responsible should think very carefully about the far reaching

consequences of such an action, not just in the pharmaceutical sector, but across the Union we hold so dear.

We will now review certain key statements the consultation paper contains. The consultation paper cites that:

"Generally speaking, in order to successfully infiltrate the legal distribution chain, counterfeiters seem to veil the source of the product by selecting highly complicated distribution concepts. At the end of this "journey" counterfeiters tend to target traders who accommodate the packaging for the market of destination."

This statement is one of the mainstays of the document prepared by DG Enterprise. We are greatly saddened and concerned that this generalisation even made it into the document. There is absolutely no evidence to substantiate this claim, indeed, no evidence has been presented and from contacts we have made, it is doubtful if such evidence exists at all. It MAY exist in the writings of several so called patient safety groups. Invariably, one will find that these patient groups are not transparent in either their funding or their member base. Although everyone's opinion counts, yet opinions spurred by funding that is not transparent are in themselves tainted at source. It is a known fact that the major producers have a strong well funded lobby that can turn the tide of even US presidential elections, let alone patient safety groups. We have no need to look for evidence of this lobby in the EU. It exists to further its own interests. That is its right. But it has no right to trade in influence in such a way as to impinge on our shared European beliefs.

We should remember that in themselves, wholesalers and repackagers already have a very sophisticated setup that ensures the quality and safety of products they deal with and repackage. Indeed, it is well known that the recent cases of counterfeit were discovered by repackagers during preliminary checks on the products they handle, products originating from normal bona-fide licenced wholesalers. This is corroborated by the UK MHRA's own statements. The case of the counterfeit Zyprexa that infiltrated the UK supply chain in May 07 was discovered by the QP of one of the importers concerned and reported to the manufacturer and the authorities. The product in question came from a normal wholesaler.

Far from risky, repackaging of products ensures a second, independent audit on the products handled, all to the greater benefit of the patients. But this is just one of the many benefits of repackaging of Parallel Imports. There is clear, tangible, indeed everyday evidence, that repackaging operations are replete with checks and balances governing their operations, all in the interests of patient safety. Parallel importers who operate their own repackaging facility are as highly regulated as pharmaceutical manufacturers and are subject to the same inspections by the Medicines Agency as manufacturers. Parallel Distribution and repackaging companies must, by law, employ a Qualified Person (as stipulated in the relevant Directive) whose role is to ensure the implementation and functioning of the quality control system required for pharmaceutical manufacturers, and to ensure the quality, safety and efficacy of any product leaving the facility. The checks made on these companies are every bit as stringent, and so it should be. With the rigorous checks under the QP supervised quality system, parallel importers add a layer of safety to the supply chain. They can detect false, damaged, or eventually even counterfeit medicines entering the chain at a repackaging plant much easier than a regular wholesaler ever could. The only improvement we would venture to propose is NIR testing of products pre and post repackaging using the appropriate monographs.

There is also, however, an economic argument that militates against counterfeit targeting of parallel imports. A counterfeit product would not normally ENTER via a parallel importer, because he will not pay the price of the import market but instead a much lower one to cover his own costs; the counterfeiter cannot make a profit in this way. All of the counterfeit products identified in the UK legal supply chain over the past few years came in via ordinary wholesale operations. This is what the MHRA states when it reported the facts of this case.

In a nutshell, GRTU maintains that repackaging as it has evolved over the last 30 years and under the instructions and auspices of national drug regulatory authorities is safe and should not be gratuitously challenged. The way it is currently practiced is perfectly safe. There is absolutely no need to change the basic rules. Exchanging the PIL and replacing it by one that can be read and understood in the destination market, is a must in the interests of patient safety. In our particular market, there are serious economic considerations as well. Banning repackaging will mean killing off both Parallel Imports and generics in Malta. The consequences of this will be disastrous.

The only discussion in this proposal should be better regulation of all players and traceability. It is indeed prudent to note that all wholesalers in the EU are obliged to "shake hands" first when they start dealing with each other by exchanging licences, QP declarations and Pharmaco-vigilance declarations. This is a good thing. However there do exist a number of traders, brokers and middlemen who do not have an EU standard Wholesale Dealers Licence, and are therefore not inspected. GRTU welcomes amendments in the legislation to bring in line anyone handling pharmaceuticals. They should be handled only by registered inspected licenced wholesalers, even when the transactions involved are not actually physical but back to back transactions, for example, when a broker is selling on behalf of a manufacturer.

GRTU also welcomes measures of track and trace, but only under the specific condition that data gathered and held in such databases be kept out of reach of manufacturers as the risk for commercial misuse of such data, and the temptation to misuse it is simply too high. There is a clear concern that such data would be used to penalise wholesalers that could be identified as supplying "export" to markets inside the EU, or outside the EU. There is the fear that "big Pharma" has in the past used data in an improper manner for commercial gain. Instances similar to this have happened in the past (e.g. the GSK Seroxat case).

GRTU however is in principle in favour of a system of mass serialisation of individual medicine packs. One has to see how this will work in practice. The ideal thing would be to integrate all players into one system. Thus, besides the manufacturers' barcode or 2D imprint, they will also put on a unique ID number and have the IT systems in place to link up the manufactures' number with the repackager's number, ensuring direct and traceable links all around the system. GRTU believes that all entities, even the warring parties in this exercise should at least co-operate to make traceability work with no party using this new spirit of co-operation in an underhand way.

It is rather obvious that DG Enterprise has not sufficiently "analysed" this fact, but instead cites "recent analyses" to back its claims. It would be helpful and also fair if these analyses would be made available to everyone. We will then be able to audit the

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conclusions reached, but, more importantly the credentials of the persons drawing up such analyses.

In the absence of such glaring lacunae in the consultation paper presented by the commission, it is therefore difficult not to come to the conclusion, therefore, that there is some determination to implement this ban on repackaging, come what may, by DG Enterprise. DG Enterprise is aware that repackaging, be it re-labelling or re-boxing, is necessary for parallel distribution. It is the lifeblood of this industry and has proven to be safe for the 30 odd years it has been in existence. The obvious conclusion is that DG Enterprise is trying to ban parallel distribution. There is no other logical raison d'etre for this whole exercise. Repeated requests both from GRTU as well as from other concerned entities in the EU to DG Enterprise to list the "evidence" it claims it possesses that counterfeiters are targeting repackagers in the EU have fallen on deaf ears. The conclusions are obvious. There is no evidence that this is the case.

The only entity to benefit from this is what is generally known as the Big Pharma Lobby. Despite its many legal losses over these last 30 years, where it has lost every case in the ECJ challenging Parallel Distribution, this lobby will persist in finding new ways and suborning new entities to its will in its never ending quest to stop Parallel Distribution. We are saddened that of all entities, the Commission, which is the bastion of all that is the EU, has lent its attention to this lobby's entreaties.

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Attached is a handout for MEP's prepared by the EAEPC on the issue.