

Irish PharmaChem

The Industry Buyers Guide 2007

Major Breakthrough

"CRANNAGH & CO.

cured a Major Headache for us, when they diagnosed, identified and successfully treated the malignant trade ailments we were having"



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IN ASSOCIATION WITH PHARMACHEMICAL IRELAND

CRANNAGH & Co.: THE PANACEA TO YOUR CUSTOMS AND TRADE PROBLEMS

Crannagh & Co. could be the one-stop answer to all your customs and international trade problems.

The challenges, costs and risks facing the PharmaChem industry today are at an all time high, with returns on investment facing erosion through many outside factors, including:

- Costs of getting drugs to market and the huge investment in R&D;
- Threats to security, public health and profits through counterfeit goods entering the supply chain;
- Increasing costs of compliance;
- Risks of acquisition;
- "Block-buster" products coming off patent.

In this environment, can a review of your trade compliance, duty costs and supply chain security benefit shareholder value? The answer is a resounding 'Yes', according to Fred Hassan, CEO of Schering-Plough: "In our industry, you are dealing with not only increasing globalisation but also the increasing influence of political agendas, legal issues, regulatory matters...CEOs must have the ability to tune into widely different issues and have peripheral vision...If there is one common thread in this evolution it's the ability to manage complexity." (Source: Great Expectations, NGP Europe).



The headquarters of Crannagh & Co. are located in Belturbet, Co. Cavan.



Crannagh Directors Michelle and Carol Lynch.

SECURITY IN THE SUPPLY CHAIN

Security and visibility in the supply chain is the most important issue on a company's agenda with the E-Pedigree system, RTID, Drug Safety and the increasing prevalence of Counterfeit Goods. You should endeavour to secure your supply chain, and by extension your standing in the industry, against litigation, while simultaneously protecting your shareholder value.

New EU Regulations are tightening up security, given the increasing perceived threat of a global trade incident in the movement of container traffic. Compliance with the new Regulations and the new "Authorised Economic Operator" (AEO) status being introduced will be vital from January 1, 2008.

AEO CERTIFICATION

AEO is a certification, which, if granted, gives you the status of being secure, reliable and verifiable operators in the international supply chain.

There is increasing concern to validate and secure container traffic being shipped internationally or within Europe. The US authorities have led a move towards audited controls on the safety and security of those operating in the supply chain and US companies have over-whelming signed up to this through the C-TPAT programme. This

secure supply chain concept is now being introduced into European Law through the AEO security regulations. The Revenue Commissioners have advised that the holder of an AEO certificate will be subjected to fewer physical and document based controls, and customs will focus their resources on those outside the AEO network. Your containers will be unlikely to get stopped at the borders for risk assessment and control once you are an AEO.

As companies sign up to the certification, the numbers who are likely to deal with non-AEO operators are likely to dwindle, as the costs in monitoring the supply chain become too high. Many US corporations have already indicated that they will refuse to deal with any companies who do not have AEO certification in the same way as they impose C-TPAT requirements on their US suppliers.

If you are a US subsidiary, an Irish company with US plants or you are currently trading with the US or plan to in the future, there will be 'downward pressure' to become compliant.

Finally, it will be unacceptable for companies operating internationally to fail to be AEO compliant. Many of your competitors are already in the process of preparing for certification: therefore, you should start now

"Our AEO team conduct in-house AEO workshops, together with managing project teams, to secure AEO certification from January 1, next year," notes Carol Lynch, MD, Crannagh & Co. "Together with the Irish Exporters Association and the Institute of Trade, we are also holding workshops across Ireland to prepare companies for this essential status." (See the enclosed leaflet for more information on these workshops.)

REDUCING COSTS

AEO certification is not the only service offered by Crannagh & Co., however. This boutique firm focuses on international and European customs and trade law, import/export taxes, excise duties, audits and disclosures, appeals, export licensing, AEO, ISA and C-TPAT, together with project management for set-ups.

"Our network of experts across the EU, the US and Asia can advise you on your import/export issues in any of these



Pictured on the Crannagh 3 are Lorna Guckian, Carol Lynch and Leanne McPhillips.

jurisdictions," notes Carol Lynch. "We work with a large number of the major PharmaChem global companies and can alleviate your trade headaches. We know your trade issues are often urgent and require priority attention. In this respect, we have a range of dedicated specialists with expertise in the areas listed above and in this we are unique in being able to match your business/trade issue with an experienced and knowledgeable consultant."

PLANNING A TAKE-OVER

"If you are planning a company take-over, you should be very aware of significant hidden liabilities," notes Carol Lynch. The costs of take-overs today are huge and reflect the industry focus on 'growth through acquisition'.

"However, in the competitive nature and high pressure deadlines associated with such deals, it is critical to ensure that your due-diligence work takes account of potential customs liability, trade litigation, and security risks," she explains.

While you may not consider these priorities in terms of the number of areas that need to be reviewed and the tight deadlines for same, failure to include these areas can result in significant liability transferring to the company at a later stage, something no-one will be keen to have on their plate.



Getting the right advice on international taxes and laws could help your products get to market quicker and cheaper.

TRADE REGULATIONS

Not every company can afford in-house trade lawyers, regulation experts and the like. However, new legislation hits the table every day, with Crannagh MD Carol Lynch noting how "the EU Commission is notorious for its bureaucracy in this regard!" She cites the recent REACH directive and the WTO agreement on TRIPS as two prime examples.

In terms of exporters, the Pharmachem industry is often confronted with numerous non-tariff barriers and obstacles, including (as recently identified by the EU Commission):

- Complex standards and technical regulations;
- Weak Intellectual Property Right protection;
- Unnecessary, burdensome or costly testing, registration, licensing and certification procedures.

All of these barriers have an impact on cost effectiveness throughout the PharmaChem industry. For instance, are you affected by the costs of bringing a drug to market or facing a money-spinning blockbuster drug soon coming off patent?



Leanne McPhillips, part of the team at Crannagh & Co. helping to organise the AEO workbooks (see insert for more details).

"As costs increase and profitability is impacted, the need to look at opportunities for savings wherever possible increases exponentially," notes Carol. "We advise our clients on numerous ways to use customs and trade law to reduce costs and save on payment on taxes in the supply chain."

According to Carol, these massive savings are to be found, in particular, in cases where:

- You import a new active ingredient not yet listed for duty free treatment under the WTO's Pharmaceutical Agreements. If you are at pre-registration, this should be looked at well in advance to save millions of lost duty.
- Your products should currently be on the list for duty free treatment but you aren't aware it exists or how to get on?
- You may be listed for a 0% duty rate by the EU Commission – do you know how?



Lorna Guckian and Carol Lynch, Crannagh & Co. MD, at the company's headquarters in Cavan.

- You pay customs duty on manufacture of pharmaceutical and chemical goods.
- You pay customs duties on import of capital equipment for new set ups.
- You are a supplier being forced into taking responsibility for importing goods on consignment and facing new Customs and VAT registration issues.



Crannagh & Co. are experts in international customs and trade laws.