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A monthly information service for PSST customers and friends

No	No. 5 January 2016	page

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Cover story : Global Harmonization Of Combination Product Regulation: EU vs US

By A Wenzel adapted from an article of in scrip regulatory

Wherever you are in the world, the regulation of many different drug/device combination products is highly complex and costly. Yet the number of products being developed in combination is soaring. In this article will be reviewed the likelihood of global regulatory harmonization in this area, focusing on the differences between the EU and the US.

Historically, individual jurisdictions have attempted to address the regulation of combination products largely through the use of their own unique pre-existing regulatory concepts and controls for medical devices, pharmaceuticals, and biological products.

To illustrate just one aspect of the complexities of harmonizing combination product regulation, this article compares the definitions and basic regulatory thinking for combination products in the US and the EU. In terms of opportunity – when it comes to the global harmonization – there are many similarities in the types of products considered combination products in the US and EU. As such, there is a fundamental basis to find common ground for a harmonized definition of "combination product".

However, there would be many specific and nuanced definitional issues to overcome.

In particular, the level of regulation applied to various components of a particular type of combination product differs greatly in some instances between the US and EU. Among the most relevant differences between the US and EU regulatory approach is the definition and regulatory status of combination products.

The definition and regulatory status are completely absent in the EU legislation. Also, the approval pathway for combination products in the EU may involve two different authorities and follow different rules for medical devices and medicines which are part of the same combination product.

Comparing EU vs US

In the US, all combination products are regulated by the FDA.

The US has a fairly well-developed regulatory scheme for combination products. The US Congress has enacted legislation addressing the regulation of combination products, and the FDA has promulgated implementing regulations. The FDA's definition of a "combination product" is quite complicated. In the EU, meanwhile, where a specific EU combination product regulatory status does not exist, combination products are regulated by a complex and fragmented regulatory framework, largely reflecting regulatory concepts and controls for medical devices, pharmaceuticals, and advanced therapy medicinal products.

The FDA definition of combination product is very broad, covering physically integrated products at one extreme and, at the other extreme, products that are merely labeled or otherwise

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represented for use together for a single therapeutic or possibly diagnostic purpose. As such, a very large and diverse group of medical products constitute combination products in the US.

The US Congress directed the FDA to assign an agency center to primarily regulate a combination product based on the product's "primary mode of action" (PMOA; 21 U.S.C. § 353(g)(1)).

The FDA defines PMOA as "the single mode of action of a combination product that provides the most important therapeutic action of the combination product."(21 C.F.R. § 3.2(m)). The definition also states that the "most important therapeutic action is the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product".

Less certainty in EU

As opposed to the US system, no single EU regulatory authority is entrusted with the duty to determine the classification of the product nor to confirm its regulatory status. Although, such products are discussed by the European Commission's Medical Device Expert Group, which has published a *Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices.* Depending on the type of combination product, a different approval pathway must be followed. For the combination products the medicinal product is governed by the MPD and authorized by the competent medicines agency, while the device must be CE marked under the medical device directives.

Finally, there is no definition for companion diagnostics in the EU legislation yet. Most companion diagnostics are self-certified by the IVD manufacturers.

The EU's new medical device and IVD regulations are expected to be adopted in 2016, some say most likely in the first half. These will see the introduction of new rules for device type combination products and for companion diagnostics. There are also ongoing discussions that may impact products currently regulated as drug-type drug/device combinations. But how, exactly, these will operate remains to be seen and we hope it will do little to close the existing gaps between the US and EU regulatory approaches in this area.

This full and original article has also been published in Scrip Regulatory Affairs. ***Neil O' Flaherty is*** *the medtech regulatory affairs editor for Clinica Medtech Intelligence, a sister publication of Scrip Regulatory Affairs. You can read the whole article including its tables on Scrip Regulatory Affairs' website.*

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1. EMA 'Disappointed' With Use Of Art. 58 Procedure For Non-EU Drugs

By A Wenzel adapted from an article in scrip regulatory

Would a regulatory procedure for new drugs that was used only eight times in a decade be deemed a success? Hardly. Which is why the European Medicines Agency has described as "disappointing" the pharmaceutical industry's use of the "Article 58" procedure, under which the EMA can give a positive recommendation on new medicines intended for use outside the EU.

Article 58 was introduced in 2004 to allow the EMA's scientific committee, the CHMP, to give scientific opinions on medicines intended for use in low or middle income countries (LMICs). The national regulators in those countries could use the CHMP's opinion to support their own approval evaluations. An Article 58 opinion is given in collaboration with the World Health Organization.

But with only eight products having completed the process in 10 years, the EMA and the European Commission decided it was time to assess why it wasn't being used, and what could be done to make it more attractive.

"Core Barriers"

It found there were five "core barriers" to Article 58 realizing its full potential:

- Manufacturers are unclear about or unconvinced of its benefits, and are reluctant to use the procedure because of the lack of successful precedents.
- For many manufacturers, the fee is burdensome or prohibitive (particularly the annual maintenance fee).
- Many national regulatory authorities (NRAs) are unaware of the Article 58 process or consider it a lower-grade review as it does not confer EU marketing approval.
- Even where opinions are well accepted, the pace of national assessment is no quicker than with other stringent regulatory authority approvals.
- Poor co-ordination between the EMA and the WHO – in terms of general logistics and the management of variations and pharmacovigilance – limits the potential impact of their collaboration for both NRAs and manufacturers.

Another perceived drawback of the process is that alternative pathways for achieving the same aim have come along, such as the US Food and Drug Administration's priority review voucher and significant fee waivers.

Rough Direction

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The EMA has released some information on the broad direction that this strategy will be taking, though. It says that in addition to the measures described in the work program, the "action plan" will focus on the following:

- **Communication activities**: developing communication tools to better explain the procedure and the agency's capacity-building activities, looking at "re-branding" the procedure to find a more attractive way of promoting it, developing "Questions and Answers" to help sponsors and other third parties, simplifying messages about the procedure and its advantages, etc.
- **Stakeholder communication**: improving communication and awareness with stakeholders such as NGOs, product development partnerships, and regulators in Africa and other target LMICs.
- **Regulator interactions**: improving interactions with the WHO, ensuring greater involvement of local regulators from target LMICs, and better understanding UK visa entry requirements for LMIC experts nominated by the WHO.
- **Regulatory issues**: clarifying regulatory options in association with the commission relating to the study's findings and recommendations, to be included as appropriate in the revision of the Article 58 guideline from November 2005.

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Source: *Ian Schofield*, Scrip Regulatory

No. 2

2. Next Steps For EU Medtech Reform, Deal Likely In June

The Council of the European Union's plans for adoption of the EU regulations on medical devices and IVDs will likely become clear by June 17.

That is the date for the second of two formal meetings of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) during the Netherlands' current six-month presidency of the council.

Before that date, the council will be taking part in a heavy schedule of trilogue meetings[1] with the European Commission and European Parliament in a bid to reach agreement on the proposed Medical Device Regulation and IVD Regulation. Last month, the commission called for a deal on the regulations to be reached by mid-2016

The three EU institutions thrashing out the details within the trilogue have a tough job ahead in a variety of critical areas, such as reprocessing of single-use devices and the regulation of high-risk innovative devices, although progress is beginning to be made on the latter, according to latest reports.

What Lies Ahead?

So what do we know about the likely discussions ahead for parliament, the council and the commission?And can we make any assumptions about the level of progress made during the trilogue discussions (now officially referred to as the “informal trilogue discussions") held under the previous Luxembourg Presidency?

Even though the institutions have not made public exactly what has been discussed during the trilogues to date, with conflicting reports circulating, a picture is emerging.

This article summarizes the main political issues that were covered in the trilogues and the position as it is understood to be at present. But it is important to note that nothing should be understood as agreed until the texts are finally adopted.

It is not yet clear whether the future trilogue discussions will continue to treat the issues within the blocks, or whether a new, more topic focused agenda will emerge under the Dutch Presidency. A table (which you can find in the original article) summarizes all discussion points.

Second reading?

Following the next set of trilogues, the objective is for the texts to be adopted during an "early second reading".

A source close to the commission indicated that to achieve an "early second reading" adoption, this would require the co-legislators to reach agreement during the ongoing informal trilogues and for the council to adopt the results as its position at first reading and transmit this to parliament. Parliament would then finalize the procedure by adopting, as its second reading position, the council's position at first reading (with which it is already in agreement) without amendments. This would be the fastest route to adoption.

How much longer?

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Serge Bernasconi, chief executive of Europe's medical device and IVD industry associations, Eucomed/EDMA, has already highlighted the extent to which companies are suffering because of the length of time it is taking to reach a deal on the regulations.

"This wait and see situation is not good for industry," he said in a recent interview[2]. The unstable and unpredictable environment is causing companies and investors to go elsewhere, he warned.

The next country to take the helm of the Presidency of the council will be Slovakia, which takes over on July 1, 2016.

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Source: *Amanda Maxwell*, Scrip Regulatory

No. 3

3. EU Drug Regulators Urge SMEs to Seek Scientific Advice 'Again And Again'

By A Wenzel adapted from an article in scrip regulatory

"Companies should plan a strategy to engage in dialogue with regulators early, should use early access tools [like the forthcoming PRIME and adaptive pathways] and should seek scientific advice again and again," recommends Melanie Carr, former head of the European Medicines Agency's SME Office and now head of the EMA's corporate stakeholder department.

In return, investors explained some of the issues that are affecting their businesses in Europe. Biopharma executives from the emerging cell and gene therapy sector described the progress of their work.

Informal Entry Points

Carr noted that it can seem quite daunting for academics and small- to medium-sized enterprises (SMEs) approaching the EMA for advice. For that reason, several informal ways of interacting with the agency have been set up, including the Innovation Task Force, where novel technologies can be discussed in an informal way with a multidisciplinary team. "The task force can be approached by individuals as well as companies, is free-of-charge, and it doesn't matter if you are inside or outside the EU," Carr explained.

Another "entry door" to the EMA is the SME Office that can facilitate the progress of a smaller company through the regulatory process, translate documents if required and apply reductions in regulatory fees. There are now 1,450 SMEs registered at the SME Office, and in 2014, 120 of those sought scientific advice and 160 sought regulatory assistance.

"I can't emphasize enough that companies, particularly small ones, should seek scientific advice from [the] EMA," Carr said. The process generates a written letter of advice, in which the agency responds to questions asked by the company within 40 to 70 days. The CEO of an EU company explained that Merck & Co had asked them about orphan drug designation, fast-track status and discussions with the EMA and the US Food and Drug Administration "before it entered a 2012 licensing agreement with us".

But some small European biotechs, particularly those with a single wealthy major shareholder, are not considered SMEs by EMA's definition, and are excluded from the benefits that having SME designation confers. For example, the German biotech AiCuris is backed by the family office of the Strüngmann brothers, ex-owners of Hexal AG, that has a large portfolio of biotech investments in Germany.

Cell/Gene Therapies Coming Of Age

The design of clinical studies for the rapidly emerging cell and gene therapy sector is likely to be different from the Phase I-to-Phase III paradigm of conventional therapeutics. Keith Thompson of the not-for-profit Cell Therapy Catapult – an independent company set up to support the UK cell and gene therapy sector – pointed out that the shelf life of cell-based products might only be a matter of hours, and regulatory processes would have to adapt to the products' different properties.

But automation and industrialization of cell manufacturing is improving regulatory certainty, so the "velocity of product development" is increasing, Thompson noted

Another European company, Belgium's TiGenix, expects to submit the first allogeneic expanded adipose-derived stem cell therapy product, Cx601, to the EMA's Committee for Advanced Therapies (CAT) in the next several months, reported CEO Eduardo Bravo. The intralesional injected product has met its primary endpoint in a pivotal Phase III trial in Crohn's disease patients with complex perianal fistulas.

Bravo recommended that companies in the cell and gene therapy sector need to plan large randomized clinical trials for their products. "It's no use doing a 30-patient open clinical trial, you lose three years and get nowhere," he commented. Bravo was also concerned about companies and/or hospitals in some parts of Europe using "hospital exemption" regulations to manufacture cell-based products without going through EMA's regulatory processes.

A Phase I/II study of a replacement trachea manufactured by UK-based Videregen Ltd. is expected to start next year after a three-year search for finance, explained CEO Steve Bloor. The regulatory path also has challenges – there are no preclinical models, no formal control group, and manufacturing controls are uncertain; the product involves removing cells from a donor trachea so that only a cellular "scaffold" is left, and then reseeding the tissue with autologous cells before implantation into the recipient.

Not Enough Capital

But unfortunately for innovative biotech companies, there was "not enough capital to fund the therapies of tomorrow, particularly in Europe," said Joep Muijrers from the European investment firm, Life Sciences Partners. "We get around 800 serious proposals every year, and invest in 1-2% of those," he noted.

There are several funding gaps in Europe, but one that Muijrers particularly highlighted was that affecting smaller stock market-listed biotechs, that attract little interest from European public investors. Compared with the US, there are few "crossover" investors, large financial institutions that invest both pre- and post-IPO, pointed out Vincent Ossipow from the Boston-based international investment company, Omega Funds.

The lack of capital may also be contributing to the high attrition rate of products in Phase II in Europe, much higher than in the US. EU biotech companies are heading off to NASDAQ to list, or area being snapped up by US companies, causing an "innovation drain" for Europe, noted seminar attendees.

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Source: John Davis, Scrip Regulatory

4. Spain Simplifies Clinical Trial Approval Process Pending New EU Rules

By A Wenzel adapted from an article in scrip regulatory

The Spanish government is taking steps to streamline its procedures for authorizing clinical trials, ahead of the implementation of the EU's Clinical Trials Regulation. The move means trial sponsors will have to jump through fewer hoops to get a study under way in Spain.

At present Spain is involved in around 18% of all clinical trials conducted in Europe. The country "has a competitive position in the clinical trials market, but it is necessary to maintain and strengthen this position as the new Regulation is being implemented," the ministry says[1].

Under the Regulation, whose provisions are expected to apply in a couple of years' time, sponsors wanting to run a multinational trial in the EU will have to submit one application through a central portal, rather than to all countries involved in the study. However, each country will still need to issue its own authorization, consisting of a combined approval by the regulatory agency and an ethics committee.

At present, for a trial to go ahead in Spain, it must be approved not only by the Spanish medicines agency (AEMPS) but also by an ethics committee in each of the centers where the trial is to be run. So, for example, if there are 20 trial sites in Spain, 20 ethics committees will have to give their opinion before the trial can begin, the ministry says.

But under a royal decree that has just been approved by the government, only one ethics committee approval will be required per trial, regardless of the number of centers involved. Moreover, the trial sponsor will be able to discuss the practical details with the trial centers at the same time as the ethics committee and the AEMPS are evaluating the documentation submitted by the sponsor. This will reduce the time taken to start up a trial "and will attract medicine research to our country", according to the ministry.

The new decree also reinforces patient participation in decisions on the conduct of trials by making their presence on ethics committees obligatory for the first time. And it will strengthen non-commercial research by, among other things, creating the status of "sponsor of non-commercial trials". This, the ministry says, will increase clinical research within the national health service and universities which have "good investigators in areas that sometimes are not priorities for the industry."

The new decree will also regulate the Spanish Clinical Trial Register (REec), a public database that can be searched for information on trials authorized in Spain and on the centers where they are being conducted. The register can be accessed at https://reec.aemps.es.

EU Regulation

The EU Clinical Trials Regulation is already in force, but its provisions will probably not apply until the end of December 2017 because the proposed EU clinical trials portal and database must be up and running first. The Regulation will apply to all EU member states equally, although in some areas, such as ethics committee approval, each country will have to put its own procedures in place. Closer collaboration between national regulatory agencies and the ethics committees is seen as vital to ensuring that the trial authorization procedures go as smoothly as possible.

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Source: Ian Schofield, Scrip Regulatory

No. 5

5. EMA and industry brainstorm on dearth of new Alzheimer's drugs

By A Wenzel adapted from an article in scrip regulatory

The European Medicines Agency is working with companies with an interest in Alzheimer's disease in an effort to determine what prevented them from translating potential new products they were developing into marketing authorization applications (MAAs).

The EMA has been involved in an "unprecedented" number of scientific advice meetings in the past ten years with companies developing products targeting Alzheimer's disease, according to the agency's Corinne de Vries. However, this has translated into a "big, fat zero" in terms of the number of MAAs being submitted to the agency, de Vries said.

The EMA wants to know why these products are not coming through its door. In an effort to work out "what went wrong", the agency has had discussions with some of the companies that received the scientific advice, Ms de Vries told the Annual EMA Review of the Year and Outlook for 2016* in London yesterday[1]. This is the first time the EMA has carried out an exercise of this kind, de Vries confirmed to *Scrip Regulatory Affairs*.

de Vries is head of the EMA's Science and Innovation Support Office that was set up in March this year. We believe the scientific advice we gave was correct but we have to ask ourselves whether it was or not, she told the conference.

All the companies that received advice in this area were invited to participate in what de Vries described as a "brainstorming session" with the agency. While many companies engaged, some

did not, the senior EMA official told *SRA*. The exercise, which is still in the data gathering phase, has been "very useful", de Vries noted.

"White spots" and fostering medicines innovation

Down the line the EMA will look at whether this type of exercise should be extended to other areas where there are gaps in medicines innovation. The agency refers to these gaps as "white spots", de Vries noted, ie areas "where we're not expecting anything" in terms of MAAs in the next few years.

The EMA identified the issue with regard to Alzheimer's disease as part of an analysis it carried out to determine not only what might be "coming through our door" in the next few years but also what's not going to come through. The analysis had its limitations – "there were certain areas we couldn't even look at because [they were] too big, it was too much work" – but white spots were identified in, for example, oncology, viral infection and psychiatric disorders.

Relevance of scientific advice

de Vries emphasised that companies that take on board the scientific advice they are given by the agency as they move ahead with development are much more likely to have a "smoother marketing authorization process" than companies that decide to go against the advice. There's a simple explanation for that. "Usually the scientific advice working party is aware of the requirements the CHMP [the EMA scientific committee that evaluates MAAs] is going to have in authorizing the medicine," de Vries said.

This is a growth area at the EMA, de Vries noted, and in the next two years the agency expects the number of scientific advice meetings taking place to increase by around 10%. Some 15 countries are now active in providing scientific advice, including the UK, Austria, Denmark, Belgium, Spain, France, Iceland, Germany, the Netherlands, Lithuania, Finland and Portugal.

** The Annual European Medicines Agency Review of the Year and Outlook for 2016 is organized jointly by the EMA and TOPRA (The Organization for Professionals in Regulatory Affairs).*

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6. About us:

By L. Wenzel

P.SS.T is primarily specialized in the area of Medical Devices and new drug development, beginning with licensing and subsequent planning of pre- and clinical development phases and the respective project management up to marketing authorization applications and pre-marketing activities. Monitoring of clinical studies is as well included in our own services. Additionally we offer resources from our co-operation partners worldwide. We provide scientific services for all sections of healthcare, medicine, medical devise, cosmetics and pharmaceutical industry.

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7. Epilog and list of other interesting articles:

By L. Wenzel

2016, the second year, where we publish the MedDev Newsletter just began. 2015 we started to publish his newsletter in a regular and periodic form. First every 6 weeks and finally we adopted to a 4 weeks' rhythm. This branch is changing so fast. We could publish every week a newsletter and it won't be boring for you to read neither for me to create it. It is not easy to select for our customer circle the right and most interesting articles, because many themes are connected and not independent. There are so many interesting, and in my opinion important news. There is many news from regulations, authorities or changing legal frameworks which influences the daily work a medical affairs professional. This Issue had a focus on the European region, but further (and also former) issues will review also besides of Europe.

To give you some overview about interesting news and themes about Medical Devices is a table listed below. Please notice: Also this a selection from different sources:

- Brazil Takes Over Chair of International Device Forum IMDRF
- WHO Official: 'Excessive' Non-Justified Trails Can Delay Drug Access
- ICH Reformed at Last, Expects More Drug Regulators to Join in
- Oncology Products Benefit Most from Informal Scientific Advice by EMA-FDA Pediatrics cluster
- EMA Widens Stakeholder Access to EU Adverse Drug Reaction Reports
- EU Notified Body Association Appoints Interim President
- Elusive EU Clinical Trials Rules Slip Again – This Time to Late 2018

Most topics or themes are published at EMA's website and the homepages of each national authority. A fine selection can also be find a Scrip Regulatory Affairs .

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