



WHITE PAPER

Managing Copyright Compliance: A Closer Look at the Pharmaceutical and Life Science Industries

**RightsDirect**

A Copyright Clearance Center Subsidiary



Now that the rapid exchange of scientific research and product information across international borders has become commonplace, rightsholders and users of published materials face an increasingly complex set of issues involving re-use rights, permissions, restrictions and fees.

Copyright laws vary from one country to the next, making the resulting mix of obligations difficult to reconcile and enforce, especially for global, research-driven organizations with employees working in different countries.

To complicate matters further, the methods of information exchange have moved beyond traditional ink and paper to incorporate new tools like laptops, tablets, smartphones and collaboration platforms. In a short time, the digital age has transformed both the experience and the speed in which knowledge workers collaborate with colleagues — from across the hallway to across the globe.

The pharmaceutical and life sciences industries are certainly no different in this respect. Research and information professionals depend on their ability to quickly disseminate critical information for a variety of reasons — to accelerate drug discovery, to keep physicians and patients informed, to communicate with government regulatory authorities and to monitor the safety of drugs in the pipeline and in the marketplace. The challenge, especially for the medical affairs professional, corporate librarian or pharmacovigilance team, becomes sharing business-critical content in a timely fashion while at the same time respecting the rights of the content rightsholders.

What Is Copyright?

Simply stated, copyright refers to the legal framework that governs the rights of content creators (authors, artists and publishers) in their creative works, and the consumption of content by users. The copyright process assigns exclusive legal rights to works that qualify for protection. Its main intent is to promote the development of culture, literature and creative expression by entitling copyright holders to financial and other benefits. Copyright provides an incentive for creators to continue developing the books, journals, images, videos and other content that we all depend on. Moreover, it ensures protection of the intellectual property rights at the core of any content-producing enterprise. And by complying with copyright, users demonstrate respect for the intellectual property of others.

While there is no such thing as international copyright law, more than 160 countries have ratified a treaty — the Berne Convention — that sets minimum standards for the protection of the creators and holders of rights in copyrighted print and digital works around the world. But the implementation of common standards into national law is left to the participating countries, creating a fragmented legal environment and a challenge to ensure copyright compliance across borders.

For those with direct responsibility for managing the flow of information within their research-driven organizations, it is important to be clear about these general concepts of copyright protection. In order to minimize potential infringement risk, information professionals need to

recognize the most common barriers to compliance, and be familiar with established models for how permissions are aggregated and made available to end users.

Copyright Awareness in the Workplace Varies

Researchers and other knowledge workers tend to forward information to their peers quite often. Yet many of them are unaware of their responsibilities when it comes to using copyrighted material.

A recent survey by research and advisory firm Outsell, Inc. revealed that 42 percent of surveyed workers share content with their immediate teams on a weekly basis. On average, these employees reported forwarding published content at least once a week and often multiple times a week or daily.

But the majority of respondents — 75 percent — believed that if they can access content online for free, then they

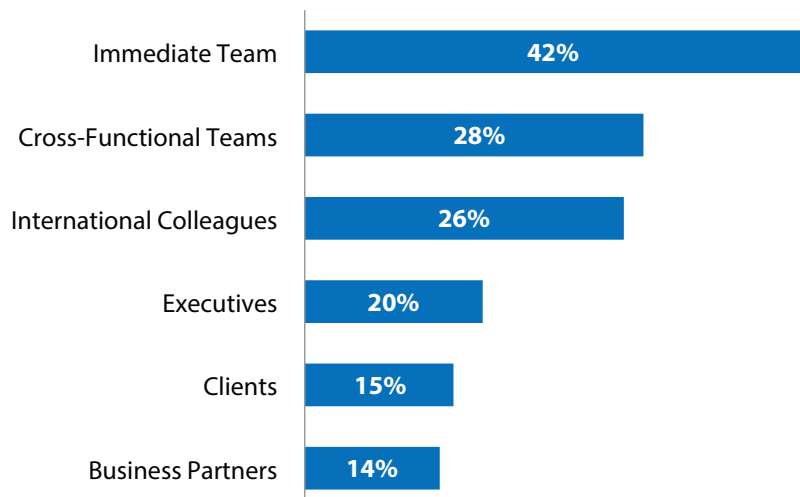
What is protected by copyright?

The Berne Convention sets minimum standards for copyrighted works. The detailed list of categories may slightly vary from country to country, but usually the following are included:

- TEXT AND LITERARY WORKS
- COMPUTER SOFTWARE
- IMAGES, GRAPHICS AND SCULPTURES
- SOUND RECORDINGS
- MOVIES AND AUDIOVISUAL WORKS
- DRAMATIC WORKS AND ACCOMPANYING MUSIC
- DANCE

are free to share it without the permission of the copyright holder. Not many of them knew that there might be terms and conditions related to sharing that online content. For example, while an Open Access title may be free to download and access via the internet, there may also be specific terms prohibiting the re-use of the article for commercial purposes.

Sharing Content

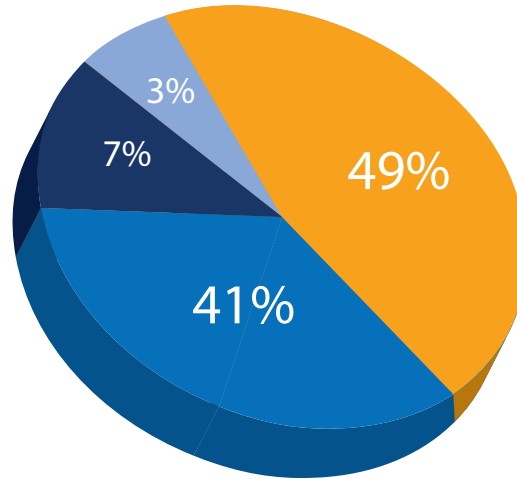


Source: RightsDirect Information Consumption and Use Survey - UK and Europe 2014
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“ 51% of surveyed workers either lack a copyright policy or awareness of it.”

Source: RightsDirect Information Consumption and Use Survey - UK and Europe 2014. Copyright 2014 Outsell, Inc. <http://www.outsellinc.com>

Copyright Awareness in the Workplace



■ Aware of Copyright Policy ■ Unsure of Policy Details ■ Don't Know of Policy ■ No Policy

Some organizations adopt copyright policies to educate and guide their employees on copyright compliance. For those organizations where a copyright policy exists, awareness among employees tended to vary considerably. The same Outsell study revealed that only 49 percent of respondents were even aware of their own organization's copyright policy. Of the rest, 41 percent were not certain of the details, and a further 10 percent were either unaware of a policy, or said that such a policy did not exist.

Perhaps most disappointing, more than half of workers surveyed said they lack awareness of existing policies or simply don't have a policy in the first place. As the evidence suggests, low organizational awareness of copyright issues is the norm, and presents daunting challenges for senior management, compliance officers and information specialists.

Content Sharing Habits and Challenges

In order for pharmaceutical and life sciences workers to perform well, collaboration is critical. Sharing published scientific content from journals, books, newspapers and magazines throughout the organization and across borders is crucial to the ongoing exchange of ideas.

According to Outsell, email is the preferred tool for employees. 76 percent of surveyed employees say they forward content to co-workers and others via email attachment. Nearly half of them reported cutting and pasting the material into an email before sending. Collaboration tools such as Lotus Notes®, Microsoft Sharepoint® and company intranet sites are commonly used by companies to capture, annotate, store and share information in a single location.



But who is most likely to be sharing and storing this content, and for what purposes? The following scenarios are based on interviews conducted by RightsDirect with information specialists at several global pharmaceutical companies, and serve to demonstrate how and why content is shared both internally and externally:

Sharing key research findings with R&D project members — The staff of corporate libraries (also known as knowledge centers or scientific information centers) plays a key role in the licensing-in and distribution of scientific content to their R&D colleagues. Fast dissemination of the latest scientific articles enhances productivity and can often speed the pace of drug discovery.

Maintaining pharmacovigilance databases of company products — Drug monitoring helps ensure the safety of drugs in the development pipeline and those already approved for marketing. Storing published information about the company's products in up-to-date databases allows the pharmacovigilance department to quickly distribute time-sensitive information as an early warning tool for the detection, assessment and prevention of possible adverse effects.

Responding to requests for scientific information from customers — Medical affairs departments are often asked to provide patients, doctors and other healthcare professionals with scientifically-validated information, including full text articles from peer-reviewed journals. These published works typically come with specific permissions and restrictions guiding how they can be distributed.

Keeping regulatory authorities informed — As the agencies responsible for the scientific evaluation of medicines used in their jurisdictions, the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require that any adverse reactions to medicines be promptly reported by the manufacturers and applications for new drugs be submitted properly. Using copies of previously published material in the process of obtaining regulatory clearance for drugs and medicines is where copyright compliance becomes important.

Displaying information for educational purposes — The sharing of published product information on tablets and smartphones is a vital sales tool, whether for display during an individual sales call or for showcasing at a large medical conference. However, some employees may not be fully aware of the license limitations that apply to the re-use or redistribution of these materials.

What all these scenarios have in common is the ongoing need to distribute copyrighted materials to perform a required business task. But often copyright is perceived by employees more as an interruption to the exchange of information rather than as a facilitator of it.



Copyright Compliance and the Socially Responsible Company

Trust in a company's commitment to the public good often takes decades to build. Yet it can be ruined in minutes through a seemingly minor misstep that results in unwanted scrutiny from regulators, governments, customers and the media.

These days, consumers are paying closer attention to corporate practices and policies than ever before. According to a recent study¹ by APCO Worldwide Inc., the majority of the public (71 percent) say they care more about a company's behavior today than they did just ten years ago.

As business activities become increasingly complex, a growing number of companies are voluntarily embracing

the value of fostering an enterprise-wide culture of integrity and transparency. This heightened focus on corporate social responsibility (CSR) is slowly expanding to include a greater awareness of — and respect for — copyrighted material and the intellectual property rights of others.

For years, global organizations have been working to protect their own intellectual property from misuse or misappropriation by others. It only makes sense, then, to extend and expand this same respect and protection to include materials produced and distributed by others.

But to do this, companies need to have the right policies, training, processes and monitoring tools in place in order to have any chance of succeeding. Naming a point person for copyright issues in the organization is critical, as is the proper implementation of copyright guidelines.

How to create a copyright compliance policy

Internal copyright guidelines can decrease your risk of copyright violation. When crafting a copyright policy, adhere to the following steps:

- ✓ **TAP YOUR ORGANIZATION FOR INPUT** Helpful suggestions can come from any department
- ✓ **ESTABLISH YOUR POLICY OBJECTIVE** Be clear on why your organization is implementing a copyright policy
- ✓ **DEFINE COPYRIGHT** Make sure to give concise definitions and examples
- ✓ **ADDRESS INTERNATIONAL COPYRIGHT ISSUES** Your guidelines should cover the countries you operate in
- ✓ **CLARIFY COPYRIGHT FORMATS** When it comes to copyright, multiple formats are protected
- ✓ **OUTLINE COMPLIANCE PROCEDURES** Name point-of-contact and lay out steps to request permissions
- ✓ **HANDLE COPYRIGHT INFRINGEMENT PROPERLY** Encourage employees to act responsibly
- ✓ **PROMOTE YOUR POLICY** Don't hide it in manuals, advertise on the corporate intranet and issue periodic reminders.

¹ APCO Worldwide Inc., Champion Brand Study 2013 — <http://apcoworldwide.com/champion/#/1>

Looking to find more information on copyright in one place?

Visit the [CCC Education Portal](http://www.copyright.com/education)
<http://www.copyright.com/education>

Learn more about [Events and Webinars](http://www.rightsdirect.com/rd/events)
<http://www.rightsdirect.com/rd/events>

RightsDirect and CCC offer a variety of copyright resources:

- Regular Webinars
- Online Certificates
- Special Seminars
- White Papers
- Educational Videos

Visit www.rightsdirect.com or www.copyright.com to learn more.

Making Copyright Compliance Easy

While technology has made it easy to find and use content, obtaining copyright permissions can be a difficult, time-consuming and expensive endeavor. Subscriptions and access to publisher databases provide basic usage rights, but sharing rights granted by publishers differ. Some publishers do not offer licenses permitting employees to share published content legally at all. And clearing permissions individually one publisher at a time can prove to be quite challenging for multinational organizations.

A better and more comprehensive solution is an annual repertory license that simplifies the licensing of content and helps researchers and other knowledge workers to use copyrighted materials without having to seek multiple individual permissions.

The [Multinational Copyright License](#) offered by RightsDirect, an international subsidiary of Copyright Clearance Center (CCC), allows cross-border sharing of copyrighted materials throughout the entire organization. The license covers more than 950 million rights from over 12,000 international publishers, representing a broad range of content types and authorized use cases. With a [Multinational Copyright License](#) in place, medical professionals in pharmaceutical companies and

healthcare organizations can lawfully re-use content within their organization in a variety of ways that typically occur every day:

- Share digital and print content such as full-text scientific articles within the organization
- Provide single digital or print copies of an article to healthcare professionals who request them
- Store articles for records, projects and pharmacovigilance databases
- Submit copies of articles to government agencies for regulatory filings

Pharmaceutical and life science companies can benefit from a consistent set of permissions across all participating rightsholders and reduced time pursuing permissions individually while at the same time respecting the intellectual property of others and demonstrating their commitment to conducting business in a socially responsible manner.

Copyright Education

RightsDirect and its parent company CCC offer copyright education programs and assist with corporate compliance campaigns. This incorporates instructor-led trainings, group discussions, question and answer sessions and analysis of real-world scenarios. In addition, CCC offers regular webinars and online certificate programs on the basics of copyright in a global environment.

About RightsDirect

RightsDirect provides licensing solutions that make copyright compliance easy, allowing companies to re-use and share the most relevant digital content across borders. With RightsDirect copyright licenses and complementary information management tools, users can instantly check license coverage, manage permissions and optimize content workflow in one integrated solution.

Based in Amsterdam, RightsDirect is a wholly owned subsidiary of Copyright Clearance Center (CCC). Working in partnership with the world's leading publishers and collecting societies, we compensate participating rightsholders for the re-use of their works. Together, CCC and RightsDirect serve more than 35,000 companies and over 12,000 publishers around the globe. For more information, please visit www.rightsdirect.com.



FINDING THE RIGHT SOLUTION:

10 QUESTIONS TO ASK

Pharmaceutical and life sciences organizations should ask the following questions to help determine the copyright compliance-readiness of their employees' information sharing practices:

1. What rights are included or excluded with the content typically shared? Are additional licenses necessary to cover secondary use?
2. Are the same re-use rights and permissions included when content is acquired through direct publisher subscriptions versus document delivery?
3. How much time and resources does it take to clear permissions individually?
4. Which is the more cost-effective licensing acquisition method — pay-per-use or repertory license?
5. How difficult will it be to explain the coverage terms of available licenses to employees?
6. Will the license allow sharing digital and print content within the company?
7. Will the organization be allowed to reproduce content in employee communications?
8. Can a single, responsive digital or print copy of an article be provided to doctors, patients or other customers who request it?
9. Will the license permit to store articles internally for records, projects and in publications database?
10. Does the license include the right to submit photocopied and digital copies of articles to government agencies for regulatory filings?



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