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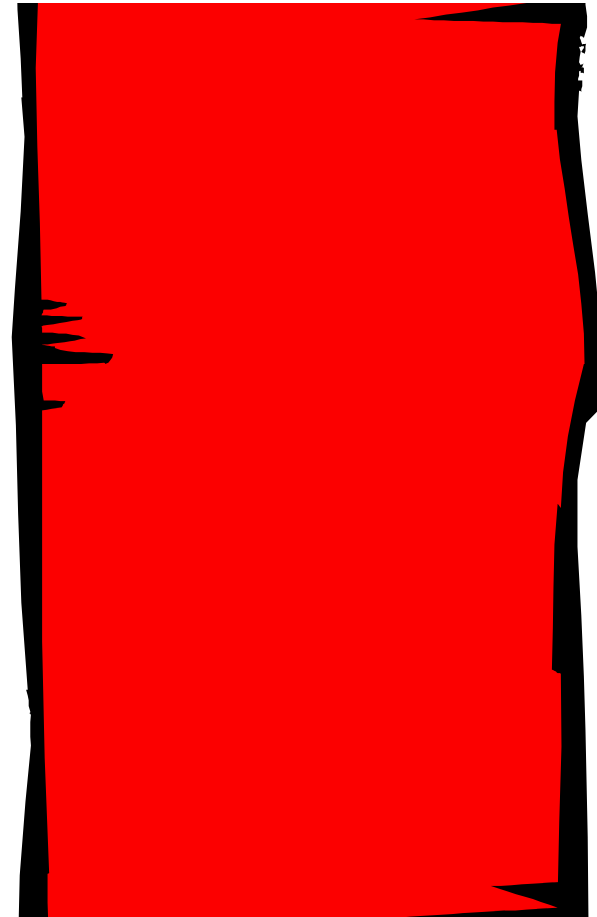
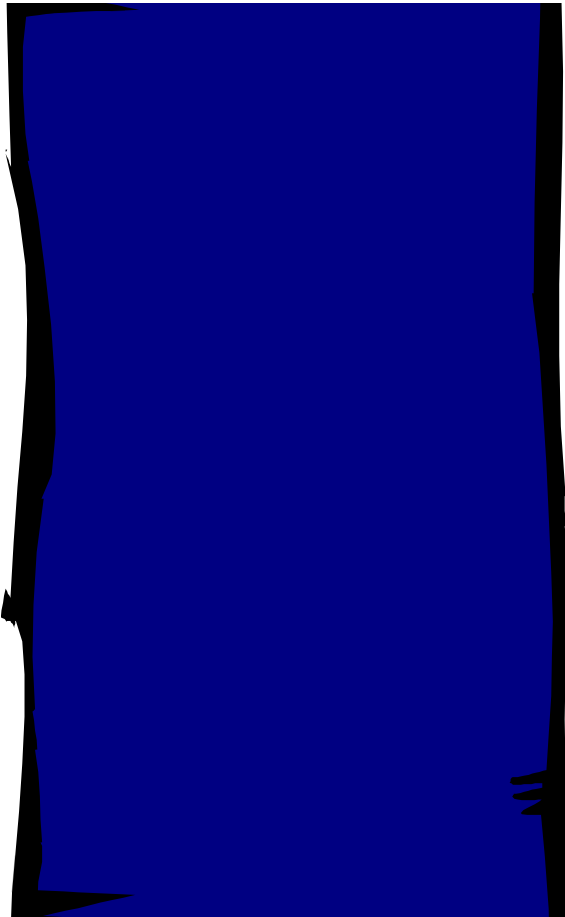
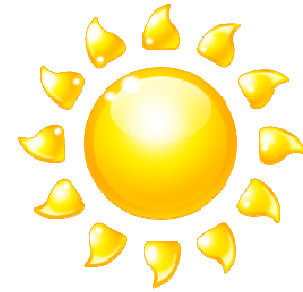
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French Sunshine What Have We Learned?





Loi Bertrand – French Sunshine Act

Covers

- Any company that **manufactures or markets** health products, including **drugs and medical devices**, and other products **under ANSM jurisdiction**; and
- Any company providing services related to the manufacture and sale of those products (*e.g.*, technical, installation, promotional), or otherwise acting on behalf of manufacturers and distributors of covered products.
- ***Applies regardless of whether products are reimbursed by French government payors (unlike the U.S. Sunshine Act).***

ANSM = agence nationale de sécurité de médicaments et produits de santé



Reportable Transactions

- Contracts (“conventions”)

The “**existence and nature**” of all contracts with health care providers, including

- Research agreements
- Consulting Agreements
- Grant agreements

- Benefits (“avantages”)

All **benefits** (transfers of value) in **excess of 10 euros**, including

- Gifts
- Meals
- Travel support
- Cash payments, including rebates and expense reimbursements



Exceptions

Commercial contracts for the **sale of goods and services by covered companies**, and benefits provided pursuant to those contracts, are excluded from the disclosure requirement.

Also, **fees paid to health care providers for services rendered** are not considered “benefits” requiring disclosure. (However, this does not limit the requirement to disclose the “existence and nature” of the contract pursuant to which the services are rendered).



Covered Recipients

Health Care Professionals

Physician, Pharmacist Nurse,
Lab Tech, etc.

Associations of Health Care Professionals

Medical students and other students of health care professions, and associations representing them.

Training Institutions for Health Care Professions

Healthcare Consumer Organizations

Healthcare facilities (including hospitals and clinics)

Foundations and learned societies (including hospital foundations and associations for research and training in a given field) and companies providing consulting services related to medical products.

Media publishers and broadcasters

Publishers of software for prescribing and dispensing drugs



French Sunshine Timeline

- December 29, 2011 – Loi Bertrand
- May 22, 2013 – Final Decree published
Guidance circular June 12, 2013
- August 2, 2013 - guidance that foreign companies must report, even if they do not have French operations
- October 1, 2013
Publication of 2012 and first half 2013 data on websites of companies and *ordres*
- December 19, 2013 – unique website decree published
- February 1 deadline for publication on unique website
January 31, 2014 – MOH announces extension to February 28, 2014



First Publication – October 1, 2013

Data submitted to professional *ordres* and posted on company websites

Note on CNOM website:

It should be noted that in the very tight deadlines imposed upon them, only some companies sent usable information to the College of Physicians. Other manufacturers have sent it in formats that we posted as is. A majority of companies have not sent us any information or sent it in a format that could not be published. So this is an incomplete publication.



Practical Challenges



Navigating Practical Challenges

- Navigating Practical Challenges
 - Inconsistent rules
 - Try to find common elements
 - Comprehensive data gathering
 - Easier to gather more and then filter
 - Document your methodology
 - Tight Timelines
 - Regulations often issued close to the due date for data submission
 - Timelines for reporting short
 - Consider gathering data on a rolling basis
 - Appoint a team to work on gathering data
 - Focus on skill sets
 - Try not to create additional work
 - Leave yourself time to check your data



Navigating Practical Challenges

- Data Privacy
 - Different countries have different rules
 - Get your privacy team involved early
 - Determine what data can be disclosed and how
 - Do you need consent
 - Modify your contracts
 - Customer Concerns
 - Educating your customers
 - Should you share the data with your customers
 - What if there is a dispute



Leveraging the Benefits of Transparency

- Business People like data
 - More effective ways of spending
 - Develop efficiencies
- Use the data as part of your monitoring plan
- Use the data as part of risk assessment
- Use the data to determine resource allocation.



Practical Approaches To Global Transparency Compliance

Global vs. Local Considerations

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Global vs. Local Considerations

- “Considerations”
 - Because there is no one right way
 - Are multiple and complex
- Consideration of Options
 - Informed by priorities and constraints; with reasonable mitigations



Global vs. Local Considerations

- There is no one right way
 - Inevitable tension/competing interests
 - Consistent centralized systems/control = simple, standardized, compliant, expert, leveraged or expensive, inflexible, insensitive to cultural norms?
 - Local control/autonomy = tailored; nuanced; cost savings; relationship focused or uncoordinated; inefficient; chaotic; risky?
 - A middle path of Regional Variation?



Global vs. Local Considerations

- Considerations are Multiple and Complex: External Environment
 - Local language requirements
 - Competitive environment
 - Meal monetary/thresholds
 - Definitions
 - Local language requirements
 - Local privacy laws/norms
 - Local views on confidential commercial info
 - Local anti-competition law
 - Certification requirements
 - Cultural/customer concerns
 - Timelines
 - Level of detail



Global vs. Local Considerations

- **Considerations are Multiple and Complex: Internal Environment**
 - Corporate location
 - Corporate control philosophy
 - Corporate risk tolerance
 - Budget
 - Certifiers/sub-certifiers
 - Cross-company communications and project execution history
 - Comfort with translations and local operating units
 - Where key corporate expertise/experience resides
 - Relationships with regulators
 - Operational time zones
 - Current number of systems; integration; efficiencies
 - Data capture/entry
 - Data pull/compilation
 - “Big Picture” records/IT projects
 - Reliance on vendors



Global vs. Local Considerations

Options Informed by Priorities and Constraints; With Reasonable Mitigations

- Corporate mission and values
- Short-term and Long-term goals; strategic planning prioritization and resourcing
- Thorough analysis; alignment; execution
- Reasonable mitigations
- Continuous learning and adjustment



Questions?

Thank you!