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Regulatory Roles and Issues in Corporate Transactions

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Teresa Reguly

Partner , IP and Food & Drug Law Practice Group, Torys LLP

CAPRA ACPR

Corporate Transactions

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- A business transaction can take on many forms:
  - Asset deal
  - Share deal
  - Sale of unit/product
  - Merger
  - Amalgamation
  - Arrangement
  - Licensing
  - Financing

Why does this matter from a regulatory perspective?

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- Facility licences to operate the business
  - More than one regulatory body may have jurisdiction over your facility
- Product licences to sell your goods
  - Typically many categories of products are sold
- There could also be regulatory considerations arising from the people who are part of the business
  - Owners may be members of a profession
  - Employees may have professional tied to the business

Corporate Transactions

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- Regulatory issues that may drive or determine the structure of the transaction
  - Operating entities and license holders
    - Tax structuring
  - Need for a Canadian entity to hold a licence
  - Restrictions on ownership for professional corporations
  - Existing relationships with regulators
    - Transfer of licence is discretionary
    - Timing of review of applications

Why does this matter to regulatory affairs?

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- Role of regulatory affairs

  = Make sure it's a smooth transition

  - No impact on business operations
  - Maintain relationship with regulators
  - Working with legal team

Interpreting the Regulations

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- Problem = Regulations may not address the specific transaction
  - Can the seller's licence be transferred to the purchaser?
  - When is a new license needed?
    - Change in name vs. change in applicant
  - Can a purchaser's license be amended?

Interpreting the Regulations

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Ex. Medical Device Regulations

45 A person who wishes to apply for an establishment licence shall submit an application…

(a) the name and address of the establishment;

(b) the name, title and telephone number of the representative of the establishment;

48 If, following the issuance of an establishment licence, there is a change to any of the information submitted in accordance with paragraph 45(a) or (b), the holder of the establishment licence shall submit the new information to the Minister within 15 days of the change.

Interpreting the Regulations

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Health Canada FAQ Drug Establishment Licensing and Fees

If the company name has changed, are we a new company?

Determination of a new company depends on a variety of factors and is made on a case-by-case basis. You may be subject to an inspection and you may be issued a new DEL# depending on your scenario. Please contact the Establishment Licensing, Billing and Invoicing Unit (ELBIU) at DEL_questions_LEPPP@hc-sc.gc.ca.

Marketing Authorizations and Notifications

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- Product licenses are usually easier to manage
  - Drugs: Policy on Changes in Manufacturer's Name and/or Product Name
    - Certification form; Labels; Letter explaining change in business
    - Continue to sell inventory under old label
  - Devices: Fax-Back Amendment Form
    - Attestation
    - Quality System Certificate
  - Cosmetics: Notification within 10 days of a change

What does the Regulatory team need to do?

Step 1 - What's the deal?

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How does the transaction affect the structure of the organization?

Step 2 – Assess Regulatory Assets

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- What licenses does each party currently have?
  - Steps may differ depending on whether the purchaser has an existing licence

Products

Facilities

People

Step 3 – How to Make it Work

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- What is “changing”? How does this impact each license?
  - Name on the door?
  - Name on the product?
  - Employees?
  - Business activities?
- What must be done to effect the change?
  - Transfer or amendment?
  - New licence?
  - Notice?

Step 4 – Order and Timing

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- Consider order of regulatory steps
  - Eg. Update to facility licenses before update to product licenses
- Timing - How long does each step take?
  - Time to prepare/obtain documents for the application
  - Time to review of application by regulatory body
    - Estimate vs. hard date
- When should the step be taken?
  - After signing
  - After closing
  - Before signing

Simple….or not?

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Typical Issues

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- Steps to take are not clear
- Each party has a different position
- Sophistication of the parties
  - Dealing with persons non-familiar with regulatory
  - Past experiences
- Who should be responsible for what
  - When to take actions
  - Communication between parties

Typical Issues

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- Coordination of regulatory bodies
  - Multiple regulatory bodies involved
  - Units within the same regulatory body may not coordinate
- Timing
  - Deal team wants to move faster than regulators
    - Deal drivers – eg. tax
  - Global deal – less flexibility with timing
- Financing/ Side-Deals
  - Impact on transaction

Engaging the Regulator

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- Why meet?
  - Clarity on steps
  - Can help with coordination
  - Can get a ‘set’ date
- Why not?
  - Concern will “slow” the deal
  - Confidentiality of the deal
  - Less control of structure
  - Concerns about what happens if deal does not go through
  - “No-name” calls can be helpful; but can get inconsistent recommendations

What are the corporate lawyers doing?

Due Diligence

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Is it worth it?

- What are the assets?
- What ‘skeletons’ come along?
- What should be left behind?
- How much should the purchase price be?

How do we figure this out?

Due Diligence

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- Review documents provided by the target
  - Disclosure obligations in transfer agreement
- Review public databases
  - Drug product database/MDL database
  - Inspection reports
  - Recalls
  - Adverse reaction database
- Interviews with key employees

Diligence – Typical Questions/Requests

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- List all approved products and pending applications/amendments
- Description of all product recalls, product corrections, advisories
- Copies of adverse reaction/problem reports
- Description of all investigations by governmental authorities
- List of all sites in Canada where the products are handled
- Results/correspondence in relation to site audit
- Description of litigation/ disputes relating to product
- List/description of customer complaints relating to the products
- List of key competitors
- Key commercial agreements relating to the product
- Samples of advertising and promotional campaign materials
- Description of R&D projects or clinical trials relating to the products.

What else are the corporate lawyers doing?

Transaction Agreements

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- Main “Transfer” Agreement
  - The agreement to buy and sell…

- Regulatory representations
  - Have all licenses to run the business
  - Licenses in good standing
  - Not aware of any issues that could impact licences
  - No issues with manufacturing
  - Recalls/corrective action
  - No inquiries/investigations from a regulatory body

Transaction Agreements

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- Covenants regarding the operation of the business in interim period
  - Obligations to maintain licenses, pay fees
  - Requirements to file amendments/update licenses before closing
    - Which party is responsible?
  - Notify party of inquiries from regulatory bodies
    - Cooperation in interim period
- Post-Closing Assistance

Transaction Agreements

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- Schedules to the Agreement
  - Lists of regulatory assets
  - Key employees
  - Excluded assets
    - What is left behind
  - Disclosures to qualify the representations
    - Based on diligence…

Transaction Agreements

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- What happens if purchaser cannot obtain a regulatory licenses by closing?

  = **Need a Transition Agreement**

  Example:

  - Operate business under current licenses
  - Seller provides services to purchaser
    - Purchaser cannot be importer of record
  - Purchaser makes employees available to seller
    - Employees have transferred as of closing
    - Agreements with employees to stay with the company

Transition Agreements

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- Can we avoid using a transition agreement?
  - Valuation considerations
  - Service fees
  - Term of agreement
  - Liability allocation
  - Employee concerns
- Options
  - Delay closing
  - Stockpile inventory
  - Customer arrangements
  - Plead?

At the end of the day…

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Questions?

Thank you!

Teresa Reguly
treguly@torys.com
416-865-7316