

The logo for Hogan Lovells, consisting of the company name in a serif font on a green square background.

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Export Control Considerations for International Advisory Services

Deborah Wei
Hogan Lovells

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Export
Considerations -
Overview

Export Considerations Under the EAR

- When providing international advisory services, a license may be required based on:
 - WHAT: Export classification
 - Is the information/service being provided “technology”?
 - Check the Commerce Control List (“CCL”)
 - WHERE: Destination
 - Where is this going? China? Sanctioned Country?
 - WHO: End-user
 - Who is using it? Restricted Parties? Military or military-intelligence end-user?
 - HOW: End-use
 - How is it being used? Military end-use?
- Level of vetting depends on the above factors and whether any Restricted Parties are involved
 - Activities involving Burma, China, Russia, and Venezuela require increased diligence and vetting under military and military-intelligence end-use/end-user rules



Examples of Activities that May be Export Controlled

- Advisory services projects in China where MGB:
 - Provides technology controlled under EAR99 or higher (i.e., set forth in an ECCN on the Commerce Control List) to any IT Platform or Cloud that is hosted by and accessible to Huawei
 - Provides controlled equipment (e.g., analog-to-digital converters classified under ECCN 3A101 or oscilloscopes classified under ECCN 3A002a) or software to foreign hospital
- Providing detailed technical specifications and instructions related to the production of a vaccine against the yellow fever virus (controlled under ECCN 1C991) to foreign party in U.S. or abroad
- Shipping controlled vectors or plasmids classified under ECCN 1C353 outside the U.S.
- Engagement which involves encryption hardware, software, source code or technology
 - Ex: Supplying or licensing an MGB software platform (whether home-grown or licensed from a third party) if the activities require the download of any software by third parties (i.e. is not strictly cloud-based). Providing/licensing of an MGB software platform solely as cloud-based software as a service (“SaaS”) would not involve an export.
- Having a foreign national employee in the U.S. with an H-1B visa work on a research project or in an area involving access to export-controlled information
- Having foreign national visitors tour labs conducting work with export-controlled technology

Examples of Activities that are NOT Export Controlled

- Certain advisory services provided to foreign hospitals (such as BOE Beijing):
 - Strategic oversight, project management, and partnership collaboration
 - Strategic and operational planning (advising foreign hospital on governance structure)
 - Facility and design planning
 - Center of Excellence development and commissioning
 - Nursing development (including clinical and administrative observerships)
 - Hospital-wide commissioning support
 - Providing training related to lab design, course and curricula development for clinical training programs related to laparoscopic surgery, endoscopic surgery, and surgical energy
 - Providing case scenarios for simulation
 - Recommending names of specific software packages/programs for foreign hospital to purchase
 - Sending experts to a foreign hospital to set up equipment and assist with testing/training of staff
 - Services related to marketing, communications, quality and safety

Examples of Activities that are NOT Export Controlled

- Remote second opinions (telehealth) services to Chinese hospitals/foreign technology companies:
 - MGB physicians would provide written or video-based second opinions to Chinese physicians using either a Chinese telehealth platform provided by the Chinese hospital/technology company or MGB's home-grown telehealth platform. The provision of second opinions related to medical diagnoses would not rise to the level of controlled technology and such activities would not be controlled so long as MGB did not export any software to the foreign hospital or company.
 - Note that using a Chinese-supplied telehealth platform may raise other concerns such as Section 889 restrictions
- Provision of chemotherapy order sets (provided as Microsoft Word document templates) as these templates do not contain information rising to the level of controlled technology
- Provision of any “published” information (e.g., information from journals and other written publications or information that was presented at a conference) to foreign parties



Understanding Restricted Party Lists

Entity List requirements - licensing

- License required for export, reexport, or transfer of any item subject to the EAR to an Entity List entity
- License requirement applies if Entity List entity is any party to the transaction, not just consignee or end user of goods
 - This includes purchaser, intermediate consignee, ultimate consignee, and end user
- Example: Entity List party purchases item subject to the EAR and seeks delivery to another party
 - Even though Entity List party never takes physical possession of the item subject to the EAR, it acts as a party to the transaction as a purchaser
- Example: MGB employee provides technology subject to the EAR to a visiting professor in Boston employed by a Chinese research institute on the Entity List or directly to that institute in China
 - Licensing requirement applies to employees of listed entities wherever located and to the institute itself
 - Hiring ex-employee of an Entity List party is a “red flag”



Entity List v. SDN List

- SDN List has different foreign policy objectives and legal requirements than the Entity List
 - Implemented by OFAC
 - Designations generally made pursuant to executive orders issued by the President
 - Designations can be based on concerns regarding proliferation of WMD, sanctioned countries, narcotrafficking, human rights, undermining democracy or civil liberties, cyber-security, and other foreign policy reasons
- SDN List has a **broader** set of restrictions
 - All activities that directly or indirectly involve an SDN are prohibited under primary U.S. sanctions (where there is a US nexus) absent an exemption or OFAC authorization
 - Secondary sanctions apply to certain SDN programs even where there is no US nexus
- Restrictions extend to any non-listed entity that is owned (at 50% or greater level) or controlled directly or indirectly by a listed party
 - Generally, Entity List license requirements do not per se apply to “legally distinct” entities, including subsidiaries, parent companies, or sister companies. However, such affiliations are a “red flag” requiring additional due diligence.
- U.S. persons must “block” property interests

Entity List v. Other Lists

- **SDN List**

- All activities that directly or indirectly involve an SDN are prohibited under primary U.S. sanctions (where there is a US nexus) absent an exemption or OFAC authorization
- Secondary sanctions apply to certain SDN programs even where there is no US nexus
- Restrictions extend to any non-listed entity that is owned (at 50% or greater level) or controlled directly or indirectly by a listed party

- **BIS Denied Persons List**

- Listed individuals and entities have been denied export privileges
- Any dealings with a party on this list that violate the terms of its denial order are prohibited

- **BIS Unverified List (“UVL List”)**

- Listed parties raise a red flag requiring additional diligence
- Listed parties are ineligible to receive items subject to EAR by means of a license or license exception

- **OFAC Sectoral Sanctions Identifications List (“SSI List”)**

- Targeted restrictions based on the OFAC Directive under which they were designated
- No broad prohibitions on dealings – targeted financial or other restrictions
- No blocking requirement

- **OFAC Foreign Sanctions Evaders (“FSE List”)**

- All transactions prohibited
- No blocking requirement

Military End Use / End User (“MEU”) List

- MEU Rule prohibits export, reexport or transfer of certain items to military end users or for military end uses in China, Russia, and Venezuela without a license
 - Army, navy, marine, air force, or coast guard, as well as national guard/ police, government intelligence or reconnaissance organizations (except those subject to the MIEU rule), or any person or entity whose actions or functions are intended to support military end uses
- Restrictions only apply to the specific items listed in Supplement No. 2 to Part 744 of the EAR
 - Includes certain items subject to low levels of export controls (e.g., 5D992 “mass market” software and 3A991 electronic items)
 - Does not apply to EAR99 items (i.e., most items used by hospitals)
- BIS provided a list of MEU entities but it is not exhaustive
 - U.S. entities must conduct due diligence to confirm counterparty is not an MEU



Military-Intelligence End User (“MIEU”) List

- MIEU Rule prohibits:
 - Export, reexport, and transfer of *any item subject to the EAR* to military-intelligence end users or military-intelligence end uses in China, Russia, Venezuela, Cuba, Iran, North Korea or Syria without a license
 - Applies to EAR99 items (e.g., common medicine and medical supplies such as cotton swabs)
 - Certain transactions by US persons in support of MIEUs or military-intelligence end uses *even if items are not subject to the EAR*.
 - Prohibited activities include performing any contract, service or employment to benefit or assist an MIEU
- MIEUs include any intelligence or reconnaissance organization of the armed services (army, navy, marine, air force or coast guard) or national guard
- BIS provided a list of MIEUs but it is not exhaustive
 - U.S. entities must conduct due diligence to confirm counterparty is not an MIEU

MEU and MIEU Lists – How do they impact MGB?

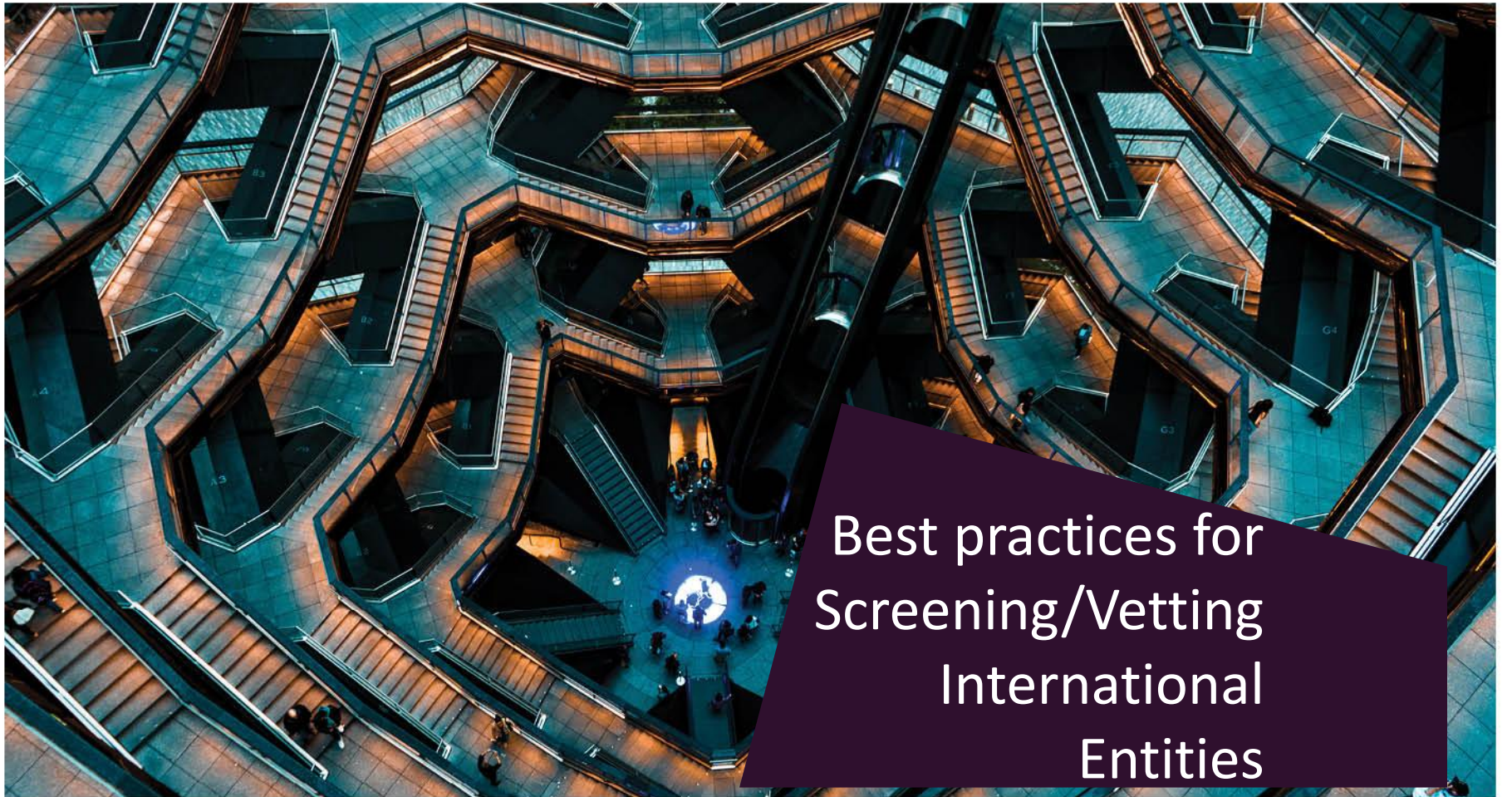
- MIEU is new as of March 2021 – scope of enforcement/interpretation unclear
- MEU List – restrictions apply only to certain items
 - Most common medical items unlikely to be subject to restriction
 - Restrictions do not apply if activities only involve EAR99 items or services only
 - Should also consider reputational and other risks related to engagements with MEUs
- MIEU List – restrictions apply for all items subject to EAR, and even to transactions where no items are being provided
 - Cannot provide any types of items to MIEUs
 - US organizations cannot provide support to MIEUs, including provision of services that benefit or assist an MIEU
 - This is the case even if your services are purely civil end-use
 - Given difficulty of confirming MIEU status some health sector participants are choosing not to engage with potential MIEU hospitals or research institutes as a risk mitigation policy

MEU/MIEU List Due Diligence

- Per BIS guidance, due diligence required to determine whether military hospitals would be considered MEUs or MIEUs. Factors to consider:
 - Actual relationship of hospital to the armed services
 - Patient population served
 - Whether the hospital develops, produces, maintains, or uses military items
- There is no one source for confirming this type of information; need to consider available information from public sources
 - General internet research
 - Databases/data services for reviewing ownership and affiliations (i.e. Kharon, Orbis)
 - Chinese language internet resources - review of entity websites and articles available in Chinese
 - Chinese corporate ownership information (may require assistance from Chinese service provider)
 - Information provided by potential customer (e.g., description of organization, certifications)

Section 889 Considerations

- Section 889(a)(1) of the 2019 National Defense Authorization Act (NDAA) (Pub. L. 115-232) prohibits the U.S. government (USG) from both:
 - **Purchasing** any products or services that use certain prohibited telecommunications equipment or services (Section 889(a)(1)(A)) (“**Part A**”); and
 - Contracting with any entity that itself **uses** products or services that use the prohibited telecommunications equipment or services (Section 889(a)(1)(B)) (“**Part B**”).
- Prohibitions implemented in every USG contract via mandatory Federal Acquisition Regulation (FAR) clauses
- Separate training on Section 889 held March 26



Best practices for
Screening/Vetting
International
Entities

Risk-Based Compliance – key questions

- What is MGB’s risk profile?
 - Look at risks associated with counterparties and location
- Factors to consider in screening:
 - Any parties involved in transaction should be screened (partner hospitals/medical centers, contracting counterparties, banks used for payments, sponsors)
 - Restricted Party screening is conducted by MGB Export Control Officers in Research Compliance
 - Conduct screening at initial stages before a contract is signed
 - Consider rescreening on a regular basis or when terms of agreement are updated
 - Have an escalation and additional due diligence process for assessing any potential “hits”
 - Assess ownership and affiliations
 - Review of publicly available information (news reports, press releases)
 - Transactions with potential restricted party matches should be placed on hold until review is completed
- Have a process if existing counterparties are designated to restricted party list
 - Front-end: contractual clauses allowing termination, certifications
 - Immediate termination of activities with counterparty, stop payments or other financial activities, ensure relevant employees are alerted



Best practices for China

- Research corporate structure of business partners, including any potential affiliations with listed parties
 - As necessary, consult outside advisors to assist with diligence (e.g., Chinese language sources)
 - Understand differences between the lists (“legally distinct” analysis vs. OFAC 50% rule)
 - Examples:
 - West China Hospital
 - Part of Sichuan University, Entity List entity
 - Aral Municipal Li Xiaohua Western Medicine Internal Medicine and Paediatrics Clinic
 - Affiliate of Xinjiang Production and Construction Corps (XPCC), SDN Chinese SOE with many affiliated hospitals
- Have a playbook for resolving any potential Entity List and Restricted Party affiliations
 - End-User/Customer Certifications
 - Contractual Provisions
 - Refresh analysis periodically (e.g., corporate structures in China can change frequently)
- Consider reputational issues and risk appetite prior to entering into engagements, even if transactions are not legally prohibited



Takeaways

- Restricted Party screening is conducted by MGB Export Control Officers in Research Compliance
 - MGB uses the Visual Compliance restricted party screening tool
- All parties to transactions should be screened
- Be alert for affiliations or ownership by restricted parties
- Be alert for potential military end use activities of counterparties, even in purely commercial transactions
- Consider whether advisory services might involve controlled technology
- Consider whether telemedicine services might involve export of controlled technology or constitute a prohibited use of technology restricted by Section 889
- Support export compliance efforts of MGB
 - Screening
 - Due diligence
 - Contractual provisions
 - End use/end user certifications



Export Control
Template Language
for Agreements

Sample Export Controls Contractual Provision for Standard Advisory Service Agreements

1. Notwithstanding any other provision of this Agreement, each Party shall comply with, and retain responsibility for its compliance under this Agreement with all applicable export control laws (*e.g.*, the U.S. Export Administration Regulations (“EAR”)) and economic sanctions programs, including territorial economic sanctions programs currently maintained by the U.S. Treasury Department against Crimea, Cuba, Iran, North Korea, and Syria (collectively, “sanctioned countries”), as well as the restrictions imposed on entities and individuals designated on the Specially Designated Nationals and Blocked Persons List, Entity List, and other restricted parties lists maintained by the U.S. and other governments (collectively, “Restricted Parties”) relating to its respective business, facilities, and the provision of services to third parties (collectively, “Trade Control Laws”). Each Party represents and warrants that it is not a Restricted Party, owned or controlled by a Restricted Party, or entity in a sanctioned country. It shall be in the sole discretion of Mass General Brigham Global Advisory, LLC (“MGBGA”) to refrain from being directly or indirectly involved in the provision of goods, software, services and/or technology that may be prohibited by applicable Trade Control Laws, including against sanctioned countries and Restricted Parties.
2. [Third Party] represents and warrants that (1) It is not a “military end user” within the meaning of Section 744.21 of the Export Administration Regulations; namely, it is not an entity that is part of the national armed services (army, navy, marine, air force, or coast guard), national guard, national police, government intelligence, or reconnaissance organizations, or a person or entity whose actions or functions are intended to support “military end uses” as defined below; and (2) It shall not use the any of the technology or services provided by MGBGA for a “military end use,” including for incorporation into any item described on the U.S. Munitions List at 22 C.F.R. Part 121, International Traffic in Arms Regulations (“USML”), into items classified under Export Control Classification Numbers (“ECCN”) ending in “A018” or under “600 series” ECCNs; or for any item that supports or contributes, directly or indirectly, to the operation, installation, maintenance, repair, overhaul, refurbishing, development or production of military items described on the USML, or classified under ECCNs ending in “A018” or under “600 series” ECCNs.

*Additional provisions may be added for agreements involving Huawei or other Restricted Parties

Questions?

