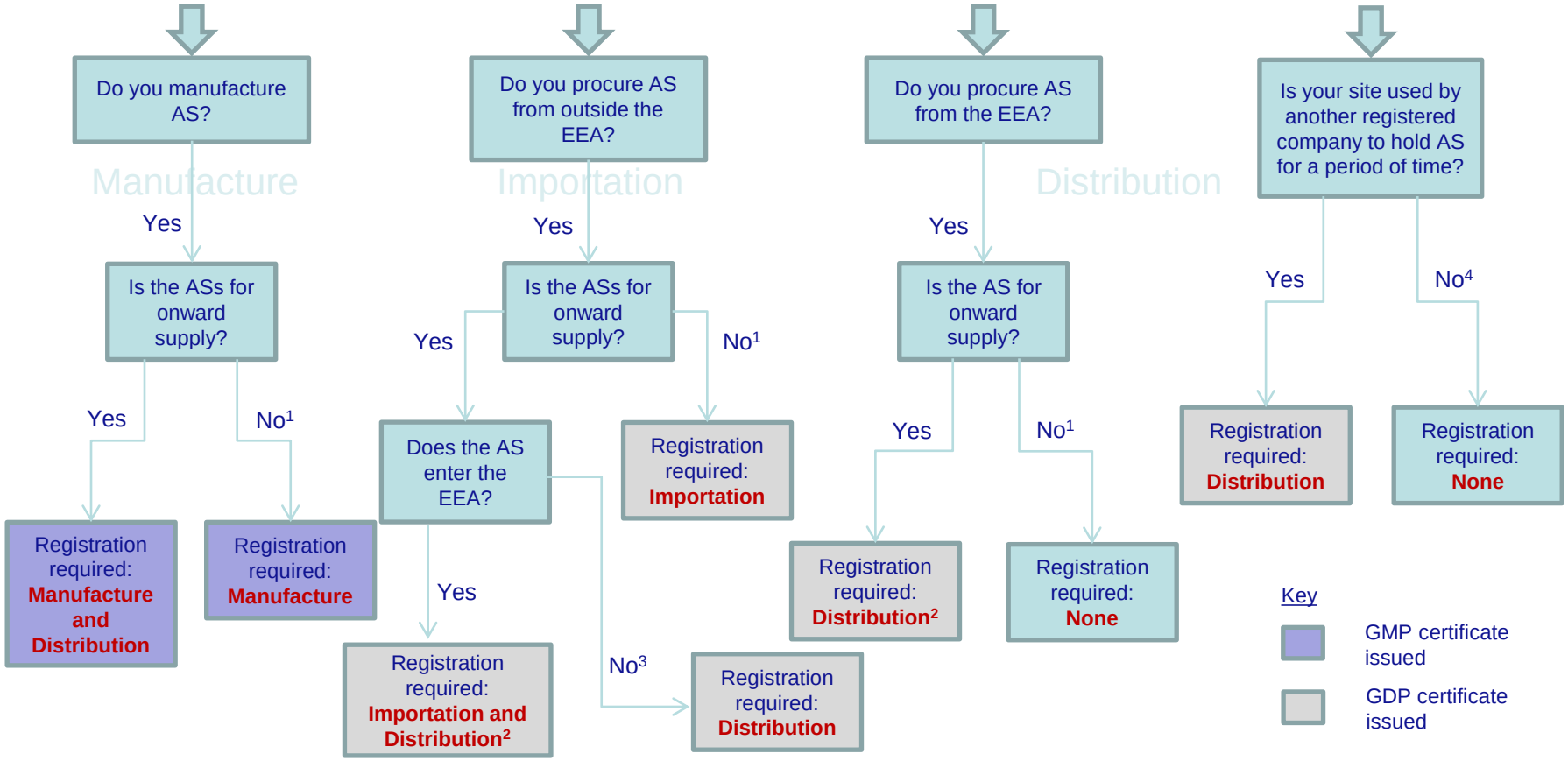
Registration requirements for NI companies involved in the sourcing and supply of an active substance (AS) to be used in the manufacture of human medicines.

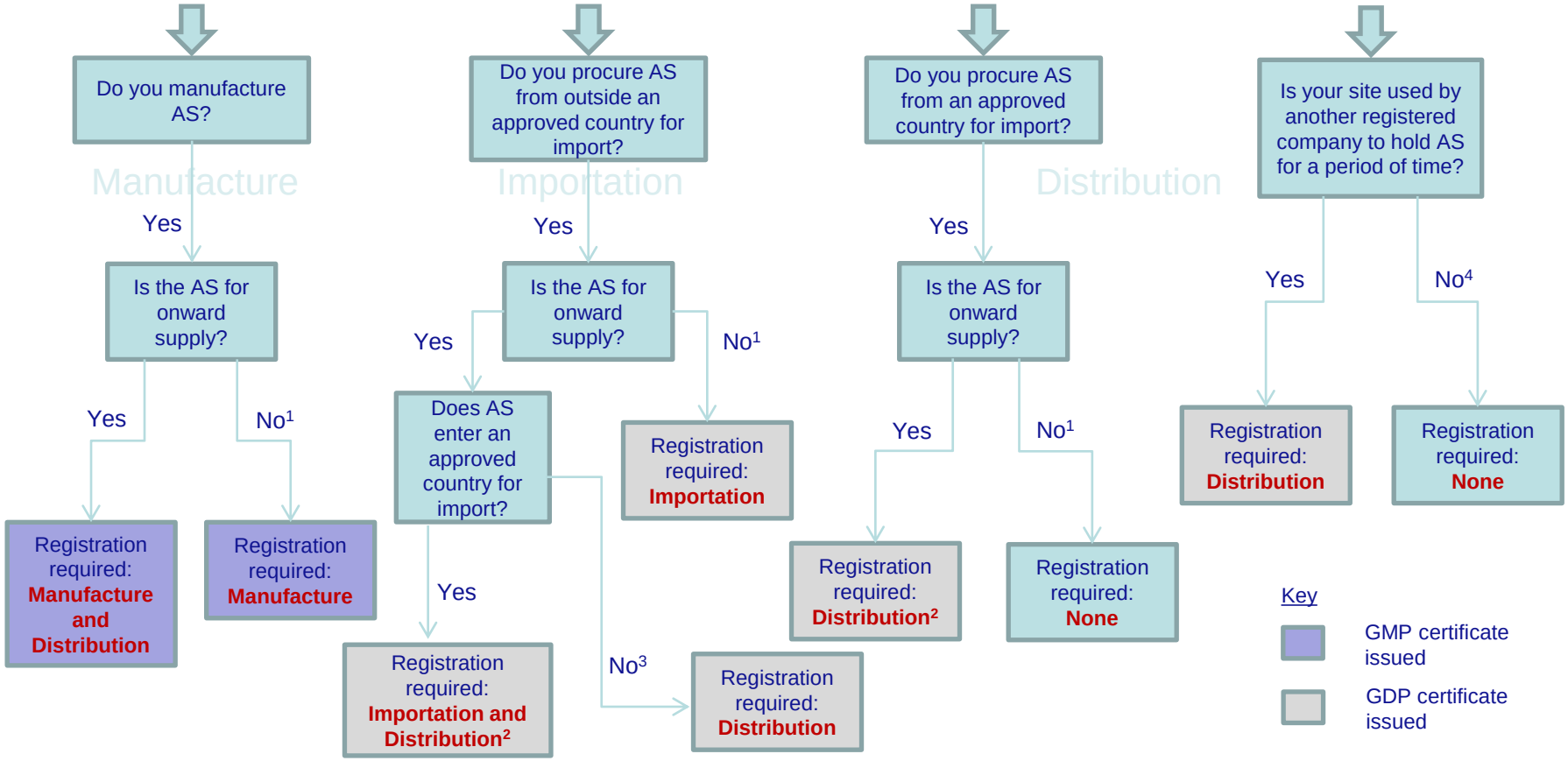
This flowchart may be used to determine the appropriate registration required for UK companies.
Where more than one activity is carried out, the company should register for all activities that apply.



1. Site holds a Manufacturer's Licence and uses the AS in the manufacture of the finished dose form.
2. Where the registration holder contracts out the physical handling of the AS, the company that physically handles the product should be named as a 3rd party site on the registration if they hold the AS and this takes place in the UK.
   In addition, the company should hold its own registration. If the company are based in an approved country for import, they should be registered with the competent authority in that approved country.
3. AS is procured from a country other than an approved country for import are supplied directly to customers based in a country other than an approved country for import.
4. AS is not held (stored) for any length of time and the company are simply contracted to transport the AS.

Registration requirements for GB companies involved in the sourcing and supply of active substance (AS) to be used in the manufacture of human medicines.

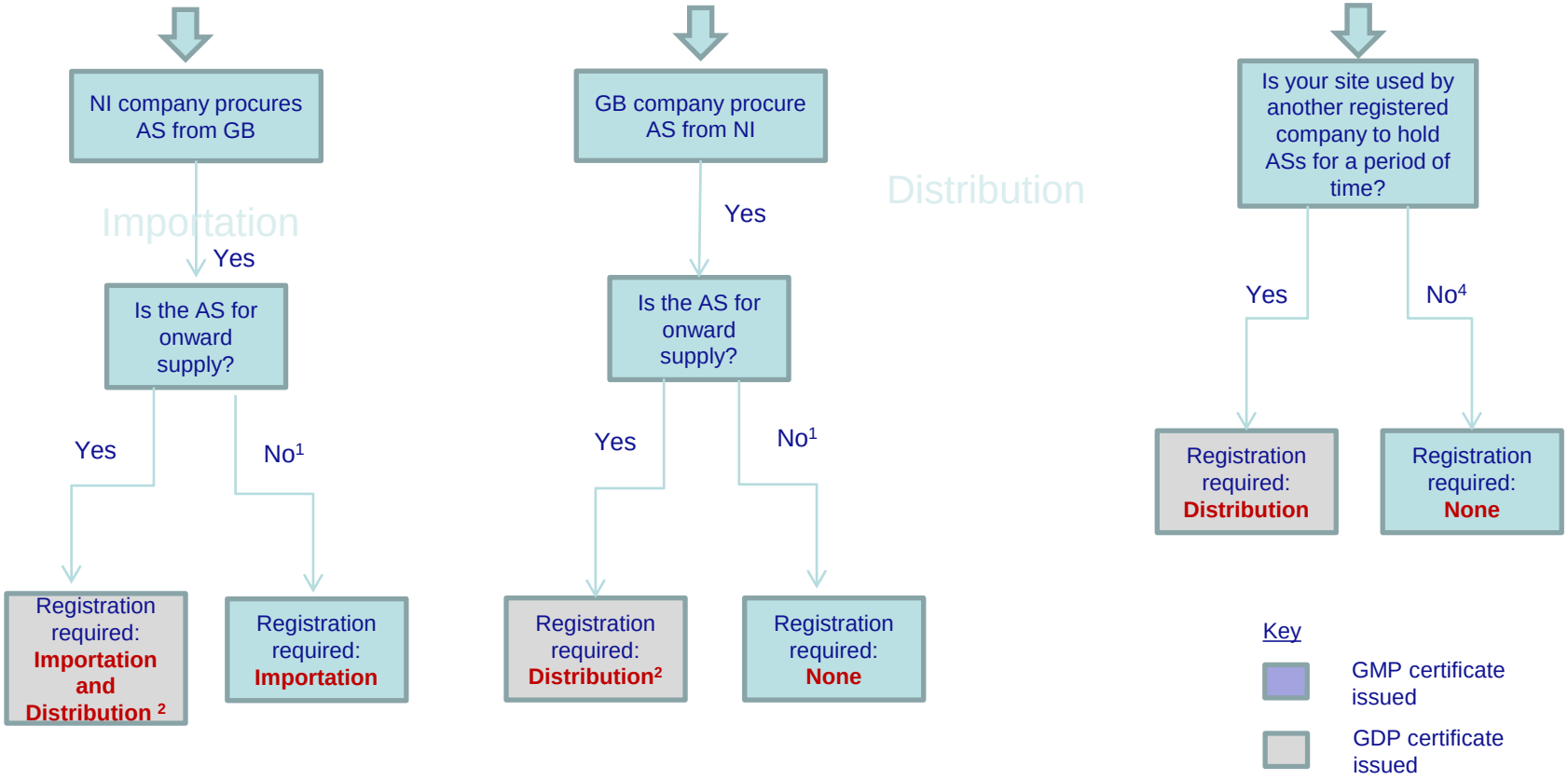
This flowchart may be used to determine the appropriate registration required for UK companies.
Where more than one activity is carried out, the company should register for all activities that apply.



1. Site holds a Manufacturer's Licence and uses the AS in the manufacture of the finished dose form.
2. Where the registration holder contracts out the physical handling of the AS, the company that physically handles the product should be named as a 3rd party site on the registration if they hold the AS and this takes place in the UK.
   In addition, the company should hold its own registration. If the company are based in an approved country for import, they should be registered with the competent authority in that approved country.
3. AS is procured from a country other than an approved country for import are supplied directly to customers based in a country other than an approved country for import.
4. Ass is not held (stored) for any length of time and the company are simply contracted to transport the AS

Registration requirements for companies involved in the sourcing and supply of active substance (AS) between GB and NI to be used in the manufacture of human medicines.

This flowchart may be used to determine the appropriate registration required for UK companies.
Where more than one activity is carried out, the company should register for all activities that apply.



1. Site holds a Manufacturer's Licence and uses the ASs in the manufacture of the finished dose form.
2. Where the registration holder contracts out the physical handling of the AS, the company that physically handles the product should be named as a 3rd party site on the registration if they hold the ASs and this takes place in the UK.
   In addition, the company should hold its own registration. If the company are based in an approved country for import, they should be registered with the competent authority in that approved country.
3. ASs procured from a country other than an approved country for import are supplied directly to customers based in a country other than an approved country for import.
4. ASs are not held (stored) for any length of time and the company are simply contracted to transport the ASs.