

A&L Goodbody

Pharma Managers Series - Prescribers Update

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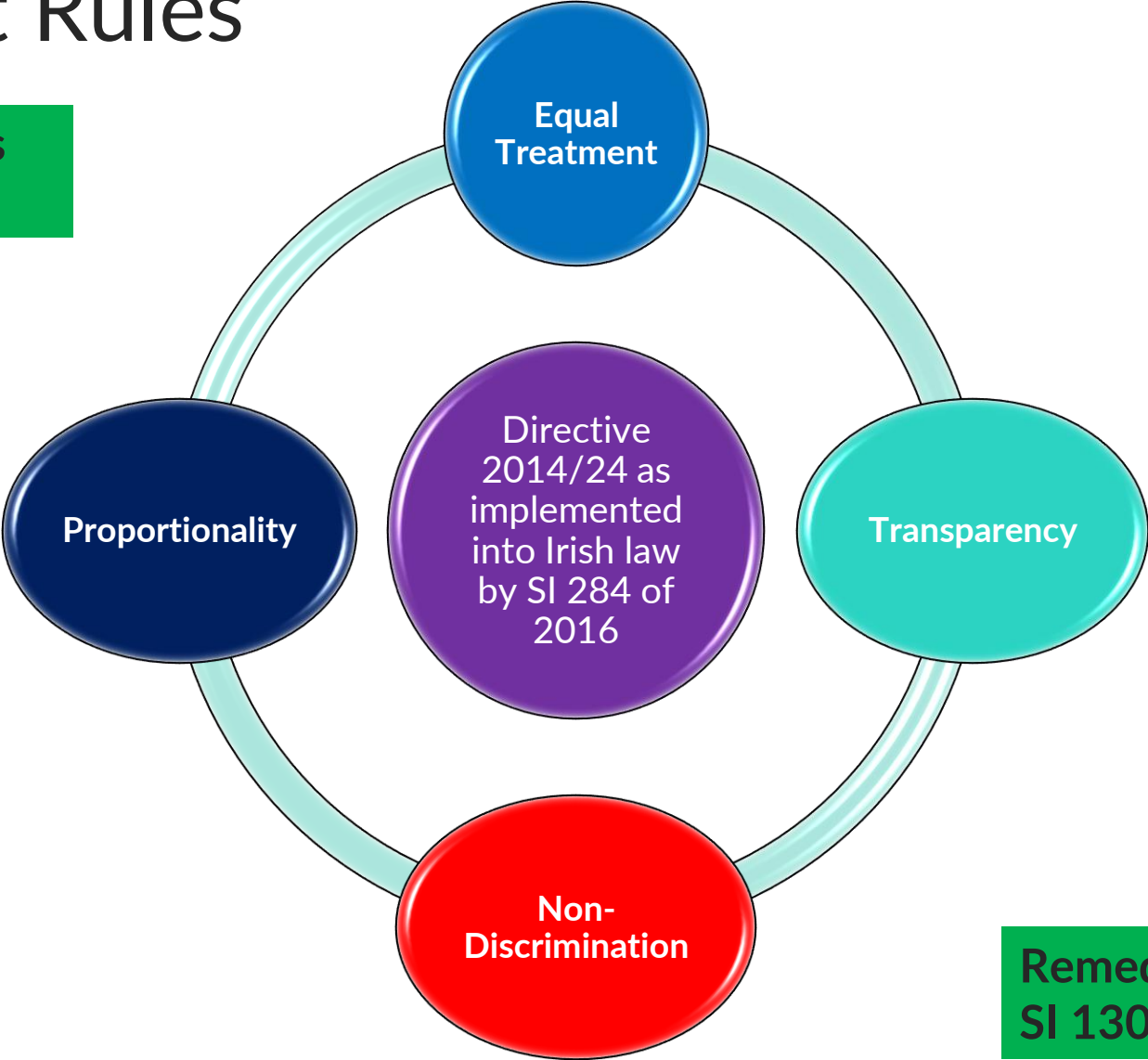


Agenda

- 1 Procurement Rules
- 2 Procurement Processes
- 3 Recent Procurement Case Law in the Pharma Sector
- 4 Review Procedures

Procurement Rules

Government Guidelines



Remedies Regulations
SI 130 of 2010

Public Sector Thresholds (excl. VAT)

OJEU NOTICE & PROCUREMENT REGULATIONS APPLY	
Goods & Services	€221,000 (non-central Gov bodies) €144,000 (central Government bodies)
Works	€5,548,000
Light Touch Regime for certain specified services	€750,000

Government Guidelines

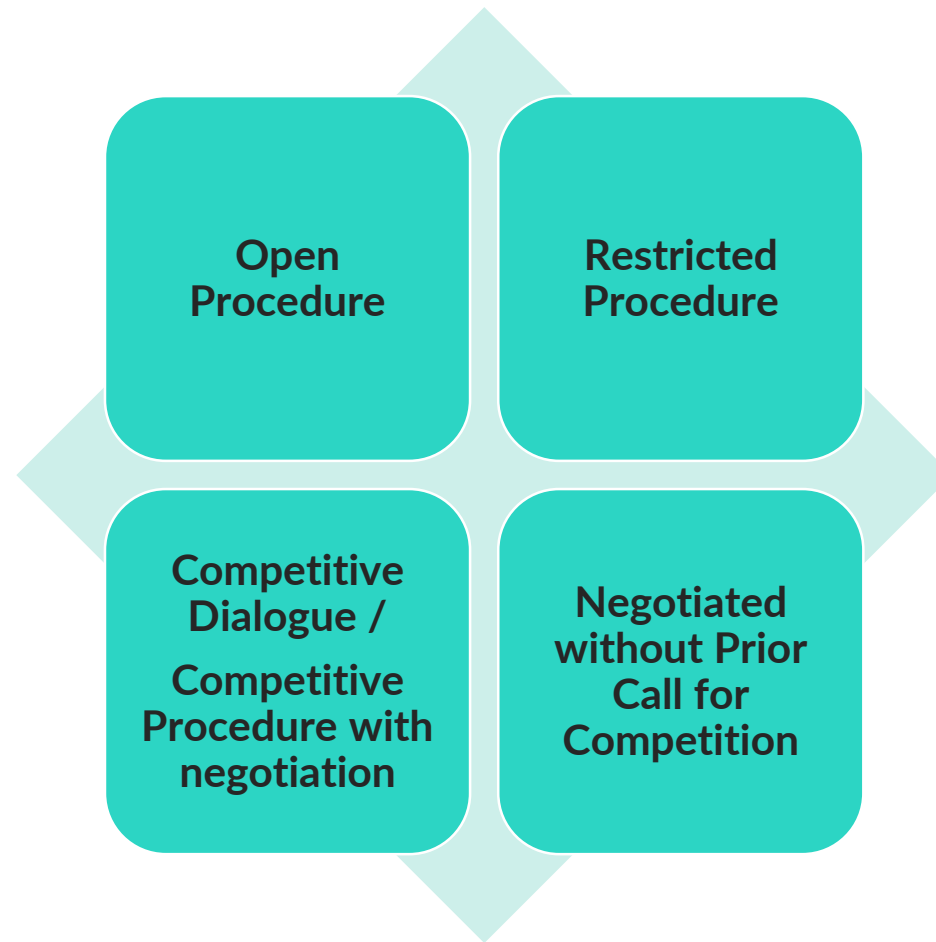
Public Procurement Guidelines for Goods and Services (2017)

- www.ogp.gov.ie
- References potential derogations e.g. para 139:-
“There are derogations from the application of the mandatory exclusions for overriding requirements in the public interest, e.g. provision of vaccines in emergency public health scenario.”

Code of Practice for the Governance of State Bodies (2016)

- Competitive tendering should be standard procedure in the procurement process of State bodies (para. 8.17)
- Non-competitive procurement should be reported in the Chairperson’s comprehensive report to the Minister (para. 8.16)

Procurement Processes



Negotiated Procedure – relevant grounds

Negotiated Procedure

No tenders received in open/restricted procedure & initial contract conditions not substantially altered

Only one supplier because competition is absent for technical reasons

Only one supplier because of the protection of exclusive rights (e.g. IPR)

Extreme urgency brought about by unforeseeable events & time limits for standard procedures can't be met

Systematic recourse to negotiated procedure not justifiable

Case C-328/92, *Commission v Spain*, para.18:

- » *" 18.... having regard to the freedom of doctors to prescribe pharmaceutical products, to which the Spanish Government refers, an urgent need for a particular pharmaceutical speciality may well arise in a hospital pharmacy; however, that freedom to prescribe pharmaceutical products cannot justify a priori systematic recourse to the single-tender procedure for all supplies of pharmaceutical products and specialities to hospitals. Moreover, even if the requirement of urgency were considered to have been satisfied in a particular case, Article 6(1)(d) would not necessarily apply. The Court has consistently held that, in order to rely on the derogation provided by that provision, all the conditions it lays down must be satisfied cumulatively (see, with respect to the corresponding provision applicable to public works contracts, the judgment in Case C-24/91 *Commission v Spain* [1992] ECR I-1989, paragraph 13)."*

Potential Procurement Approaches

- Framework Agreement (single or multi-supplier)
- Dynamic Purchasing System

Recent Procurement Case Law in Pharma Sector

- Sanofi Aventis Ireland Ltd t/a Sanofi Pasteur v HSE [2018] IEHC 566 judgment of the High Court of 22 October 2018
- Roche Lietuva UAB (Case C-413/17) ECLI:EU:C:2018:865
- AbbVie Ltd v NHS Commissioning Board [2019] EWHC 61 (TCC) judgment of the High Court of England and Wales of 18 January 2019

Review procedures

- All interested parties (“eligible persons”) have a right of review before the High Court
- Remedies Regulations sets out the remedies regime for above threshold challenges
- **Standstill:** 14 days (electronic means) or 16 days (non electronic means) from day after regret letters are sent
- **Review Period:** 30 days from date of publication of notification letter or when the bidder knew or ought to have known of the alleged infringement (except for ineffectiveness)
- **Automatic Suspension:** If no contract concluded, there is an automatic suspension preventing conclusion of contract after proceedings commenced; Court has power to lift the suspension if an application is made
- **Procedure:** Set out in Order 84(a) Rules of Superior Courts for above threshold contracts; for below threshold contracts, just normal judicial review procedure under Order 84



Thank you
