Emerging compliance issue overviews
Market access, pricing, reimbursement and tendering

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Program

• Pricing, reimbursement and procurement
  – UN & WHO
  – EU
  – EU Member State mechanisms
    • Pricing
    • Procurement
    • Reimbursement and other indirect regulation of prices
• Introduction compliance aspects of pricing and reimbursement
• Compliance case studies
Pricing and reimbursement
UN & WHO

• UN Millennium Development Goals
  – In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries (Target 8.E)

• UN MDG Gap Task Force Report 2013:
  – In developing countries, medicines remain costly, insufficiently available at dispensing facilities and often unaffordable
  – Greater international cooperation on policy formation is needed

• WHO Guideline on Country Pharmaceutical Pricing Policies 2013 recommendations for countries to consider e.g.:
  • Tax exemptions/reductions
  • Use of external reference pricing
  • Promotion of use of generic medicines
  • Use of health technology assessment
Pricing and reimbursement
EU

- In the EU, pharmaceutical pricing and reimbursement systems are not harmonised, but are the exclusive competence of the EU Member States:
  - only legislation at EU level is the Transparency Directive.
  - EMA has no authority;
  - many differences between the EU Member States;
  - first steps toward EU harmonised health technology assessment for pricing and reimbursement purposes through:
    - HTA Network: political cooperation between EU Member States (first meeting in October 2013);
    - EUnetHTA: scientific and technical cooperation (first assessment report in September 2013).
Pricing and reimbursement in the EU
Transparency Directive 89/105/EEC

• 1989: Transparency Directive regarding pricing and reimbursement, as national measures could lead to restrictions on free movement of goods in EU
• Decisions on pricing and reimbursement must be:
  – Based on objective and verifiable criteria
  – Communicated to applicant and contain statement of reasons
  – Made within specific timeframe
  – Open to judicial appeal before national courts
• 2012: European Commission proposal for new directive, e.g. with shorter decision-making terms to ensure faster access to medicines
Pricing and reimbursement in the EU
Case study: Transparency Directive

• Netherlands: additional government funding for hospitals for expensive medicinal products. NL MoH decides upon request from hospitals regarding inclusion of active substance for certain indication on list
• Hospital requests, no formal role for pharmaceutical company in decision-making process
• NL Supreme Administrative Court (CBb) ruled (31 March 2014, Mundipharma/NZa) pharmaceutical company does have legal standing to appeal decision regarding refusal to include active substance/indication on list, as it is directly affected in its interests and in view of EU Transparency Directive 89/105/EEC
Pricing, procurement and reimbursement
EU Member States mechanisms (I)

• Pricing:
  – internal reference pricing
    • using the price of similar medicinal products included in a cluster or group
  – generic price linkage
  – discounts
  – external reference pricing
    • compare prices of similar medicinal product in various countries: basket system
    • European Commission review published 2014:
      – all EEA Member States apply external reference pricing, except Sweden and UK;
      – Majority uses external reference pricing as the main systematic criterion for price setting;
      – Others use external reference pricing as supportive criterion, for example during price negotiations (IT) or when there is no alternative product available on the national market (ES)
European Commission: several concerns relating to external reference pricing

• Publicly available prices used for external price referencing are often facial prices which do not take into account the managed entry agreements as those are often confidential

• Identification of the same medicinal product across countries can be difficult due to products being launched with different commercial names, pharmaceutical formulations, dosages and pack sizes
  – technique used by pharmaceutical companies to limit opportunities for external reference pricing?

• Available prices are often heterogenous (ex-factory prices, pharmacy purchasing prices, pharmacy retail prices) making the comparison difficult

• Exchange rate volatility
Pricing, procurement and reimbursement
EU Member States mechanisms (II)

• Procurement:
  – tendering by purchasers: hospitals, governmental bodies, health insurance companies

• Reimbursement:
  – public health insurance
  – reimbursement in-patient use
  – reimbursement out-patient use
Procurement
Joint purchasing of vaccines/medicines in EU

• Procurement of medicinal products is done at EU Member State level or sub-level
• EU Joint Procurement Agreement
  – Approved by European Commission 10 April 2014
  – If cross-border health threat emerges
  – EU Member States can, on a voluntary basis, jointly purchase vaccines and medicines, e.g. vaccines for pandemics such as H1N1, but also countermeasures for other infectious diseases such as botulism, anthrax, hepatitis B or polio
Procurement of medicinal products
EU Member State procedures

• Procurement of medicinal products via:
  – direct negotiations:
    • individual negotiations hospital and supplier/wholesaler.
  – procurement/tender procedures:
    • centralised procedures organised by the competent Ministry, procurement agency or health insurance company;
    • regional procedures organised by regional procurement committees / purchasing groups;
    • individual procedures organised by hospitals.
  – competitive negotiations:
    • requests for price offers from a few selected companies.
  – hybrid approaches:
    • combination of centralised tenders for expensive products and negotiations for other less expensive medicinal products;
    • combination of 1st step national tender and second step of individual negotiations to further reduce prices on local level.
Reimbursement and other indirect regulation of prices

• More indirect policies to reduce prices applied by EU Member States are:
  – the use of positive lists of reimbursed products;
    • possibly with reimbursement limits
  – the use of negative lists of non-reimbursed products;
  – promoting rational use by incentivising generics and implementing bonus schemes:
    • mandatory generic substitution;
    • mandatory prescription by INN;
    • bonuses for HCPs who prescribe in a "rational" or cost-effective manner
Indirect regulation of prices
Compliance restrictions for payers

• Indirect policies by Member States, healthcare insurance companies, other payers vs. Pharmaceutical advertising and inducement
  – for example when offering financial incentive to prescribing physician

• ECJ Damgaard
  – Pharmaceutical advertising rules also apply to others than pharmaceutical companies, e.g. journalists, healthcare insurance companies etc.

• ECJ ABPI
  – Financial incentive schemes by national public health authorities not caught by promotional restrictions
Trends in pricing and reimbursement

• General trend towards risk sharing, cost sharing and other forms of conditional reimbursement that influence the prices of a medicinal product:
  – price-volume arrangements;
  – managed entry agreements:
    • share financial risk of anticipated efficacy of a treatment with a medicinal product or uncertainty regarding a new treatment option;
    • refund if certain pre-defined conditions have not been met, example: phase IV trial outcome.
  – discounts/rebates:
    • rebates/discounts are a preferred option to reductions of official price:
      – such reductions influence negatively reference pricing and, subsequently, prices in other countries.
    • in some EU Member States, inclusion in the positive reimbursement list is possible in practice only after confidential price arrangement between company and payer (example: in specific cases in the Netherlands)
Case study: price arrangements in the Netherlands

- Ministry of Health, Department Price Arrangements for Medicinal Products
- Conditional reimbursement
  - Temporary reimbursement, on the condition that uncertainty regarding therapeutic value and/or cost effectiveness is addressed in post-marketing studies
  - After temporary reimbursement final decision on inclusion in reimbursed health insurance package
- Financial arrangements
  - Improved affordability due to lower cost of new treatment with established effectiveness but with high cost and/or unfavorable cost effectiveness
  - Temporary agreements
  - Confidential if needed
  - No restrictions in prescription for HCPs and no guaranteed volume for company
Compliance issue
Procurement and anti-corruption

• Transparency International:
  – “With price tags running into millions of dollars, health contracts can mean big money for the winning companies. And where costs are high, so are the risks of corruption – particularly when deals are kept away from public scrutiny.”
  – “Health procurement is too important to be kept in the shadows. For both our budget and our safety, the public has to be able to keep watch.”
Compliance issue
Procurement and anti-corruption (II)

• European Commission EU Anti-corruption report 2014:
  – "Healthcare, another sector where corruption vulnerabilities can be seen across the board, in particular regarding procurement and the pharmaceutical industry, has been assessed in more detail in a number of Member States. These countries are currently developing strategies and reforms to tackle healthcare corruption. However, tangible results are scarce so far. Informal payments, and corruption in public procurement and in the pharmaceutical sector remain matters of concern."
  – Healthcare patients have to pay under the table to receive proper medical care.
  – Personal experience with bribery relatively high in Hungary, Slovakia and Poland. The healthcare sector provides the bulk of bribery instances.
Other compliance issues

• Advertising law
  – prohibition of advertising towards non-HCPs and use of economic and other data in tenders

• Rules relating to financial interactions with HCPs (anti-kickback etc)
  – Discounts
  – Sponsoring
  – Fee for service, e.g. for post-approval studies required as condition for conditional reimbursement

• Sunshine laws
  – Disclosure of financial relations with HCPs and HCP organisations
Other compliance issues (II)

• Transparency vs. Confidentiality
  – e.g. price arrangements

• Conflict of interest
  – e.g. former government official who moves to industry

• Pharmacovigilance
  – e.g. in view of conditional reimbursement requiring post-approval data

• Data privacy
  – e.g. in view of patient registries, post-marketing studies

• Competition law
  – cartel prohibition
  – abuse of dominance, e.g. predatory pricing

• Public procurement law
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