

Data and market exclusivity under the regulatory regime

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data/marketing exclusivity can be a key facet in protecting marketed products because:

- patent litigation may lead to patents being knocked out
- occasionally the basic patent has expired before the product is launched
- in any event it provides an additional layer of protection

research based companies



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it is important to understand data exclusivity
to plan marketing applications & ensure
product launches asap

generic companies



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- at least **£500 MILLION**
- extensive work
- may take 10 years
- regulatory approval is required before a pharmaceutical product can be marketed
- data showing the product is safe & efficacious must be submitted



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- a GENERIC product can gain marketing approval by relying on the data filed by the originator
- these applications are called ABRIDGED or ABBREVIATED marketing applications
- evidence that the generic product is BIOEQUIVALENT to the original product must be submitted
- governments recognised that incentives were needed for innovators to bring new products and/or improved products to the market



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- WTO member countries are required by TRIPs Art 39.3 to protect “regulatory” data:

Members when requiring, as a condition of approving the marketing of a pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origin of which involves a considerable effort shall protect such data against unfair commercial use. In addition, Members will protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

data exclusivity was provided



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- it is a short period in which others cannot rely on the originators data
- it is INDEPENDENT of the patent system
- it is complementary to the patent system
- it does NOT prevent other parties developing a copy of the product
- it does NOT prevent the others obtaining marketing approval for their copy of the drug if they generate all the data required independently
- the provisions in each country/region are different

what is data exclusivity?



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- different law applies to applications made:
 - **pre 30 October 2005** (for products submitted via Mutual Recognition & National procedures Directive 2001/83/EC)
 - or
 - **pre 20 November 2005** (for products submitted via Central Authorisation Procedure Regulation No. 2309/93)

what is the period?



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there is now a harmonised period of protection in Europe the so-called **8+2+1** period of data & marketing exclusivity provided for new drugs & new combinations of drugs

EU Directive 2001/83/EC as amended by 2004/27/EC or Regulation 726/2004 now applies

what is the period?



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- an application (generic) relying on the original data can only be made after the product has been authorised for **8 years**
- if approved, the generic can only be placed on the market when the product has been authorised for **10 years (8+2)**
- the period of 10 years is extended to 11 years (8+2+1) if a new indication of significant clinical benefit is registered in the first 8 year period



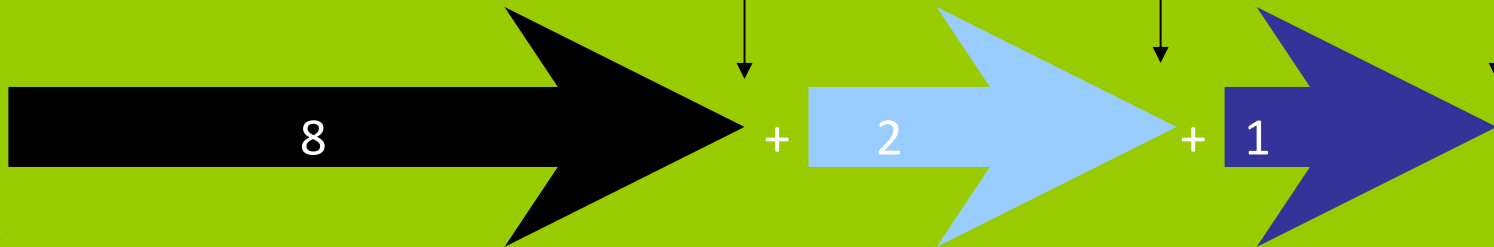
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years

8

10

11



marketing
authorisation

- “significant clinical benefit” seems to be an onerous standard
- **no** further period of exclusivity is available for:
 - new formulations
 - new routes of administration
 - new salts, solvates, polymorphs, esters or separated enantiomer of the previously approved racemates



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- orphan drug status in Europe is given to:
“medicinal products intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 people in the community”

EU Directive 847/2000/EC

- if no satisfactory “treatment” is authorised

what is orphan drug status?



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- the period of exclusivity for drugs given orphan drug status is 10 years
- in this period no marketing application for a similar product will be accepted (nor will marketing extensions for the same indication be accepted)



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REGULATION (EC) No 141/2000 Article 8

Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to Regulation (EEC) No 2309/93 or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition laid down..... and without prejudice to intellectual property law or any other provision of Community law, the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product.



- the 10 year period of exclusivity can be reduced to 6 years if by the end of the 5th year the requirements for orphan drug status are no longer satisfied
- the orphan drug exclusivity may also be negated if:
 - permission is given by the rights holder, or
 - the rights holder cannot supply demand, or
 - the second product is more effective, safer or clinically superior in another way



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designed as an
incentive to
develop
formulations &
provide
prescribing
information to
meet the needs
of children



what is paediatric exclusivity?



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the Regulation on Medicines for Paediatric Use provides three separate incentives:

- a **6 months** further patent term extension (this does NOT apply to drugs given orphan drug status)
- products where the patent(s) have expired, which are the subject of a Paediatric Use Marketing Application (PUMA) obtain a period of data & marketing exclusivity of **8+2** years
- orphan drugs obtain a further 2 year period of marketing exclusivity (**10+2** years)

what are the incentives?



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- the Regulation came into force **26 January 2007**
- from **26 July 2008** all marketing applications for new medicines, including orphan drugs, must contain the results & information of an agreed Paediatric Investigation Plan (PIP)
- from **29 January 2009** all marketing applications for new indications or new formulations including new routes of administration (line extensions) must contain the results & information of an agreed Paediatric Investigation Plan (PIP)

what are the obligations?



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- information from PIP is incorporated in summary of product characteristics (in marketing authorisation)
- product authorised in all member states
- provided-1 year marketing exclusivity was NOT obtained based on new paediatric indication
- there is a relevant SPC or a patent eligible for same
- extension application made not later than 2 years before expiry of SPC
- **transitional provision**-until Jan 2012 extension application possible up to 6 months before expiry

6 mth extension will apply where:



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- the extension application must be made to National Patent Offices
- it must contain a copy of the statement from the Marketing Authorisation as proof of completion of an agreed PIP
- proof of authorisation in all Member States may be required

how to obtain the 6 mth extension:



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- established products no longer protected by patents, which are the subject of a Paediatric Use Marketing Application (PUMA), obtain a period of data & marketing exclusivity of **8+2** years
- orphan drugs obtain a further 2 year period of marketing exclusivity



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- historically the period of data protection in Europe was between 6 & 10 years depending on the route used for the marketing application
- now it is a standard 8+2 (10 years) regardless of the route
- however, generic applications can be made from year 8 and generic product can be launched immediately after 10 years
- thus there is no “lag” time for generic products
- 6 months extension of patent term can be valuable

research based companies



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- vital to apply/benefit from appropriate extensions
- for existing products still protected by SPCs or eligible for same, review whether it is appropriate to do further clinical trials to be able to benefit from the new provisions
- EU Commission promised to make funding available for research into paediatric use of off-patent medicines
- EMEA (EMA) was to develop a network/expertise & database for paediatric clinical trials

research based companies



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- some compensation-a generic marketing application can now be made at 8 years and once approved the generic product can be launched immediately after 10 years
- in separate legislation (Directive 2004/27/EC) an exemption to patent infringement was created for work undertaken in furtherance of an abridged application for marketing approval

generic companies



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if a research based company intends to discontinue a medicine that has benefited from the financial incentives of the Regulation the company must either:

- transfer the marketing authorisation to a third party

or

- allow a third party to use the relevant data to support an abridged application

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questions????



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