MEDICAMENTOS DE BIOTECNOLOGÍA Y BIOSIMILARES

FACTORES A CONSIDERAR EN LA EVALUACIÓN Y SELECCIÓN DE MEDICAMENTOS DE BIOTECNOLOGÍA

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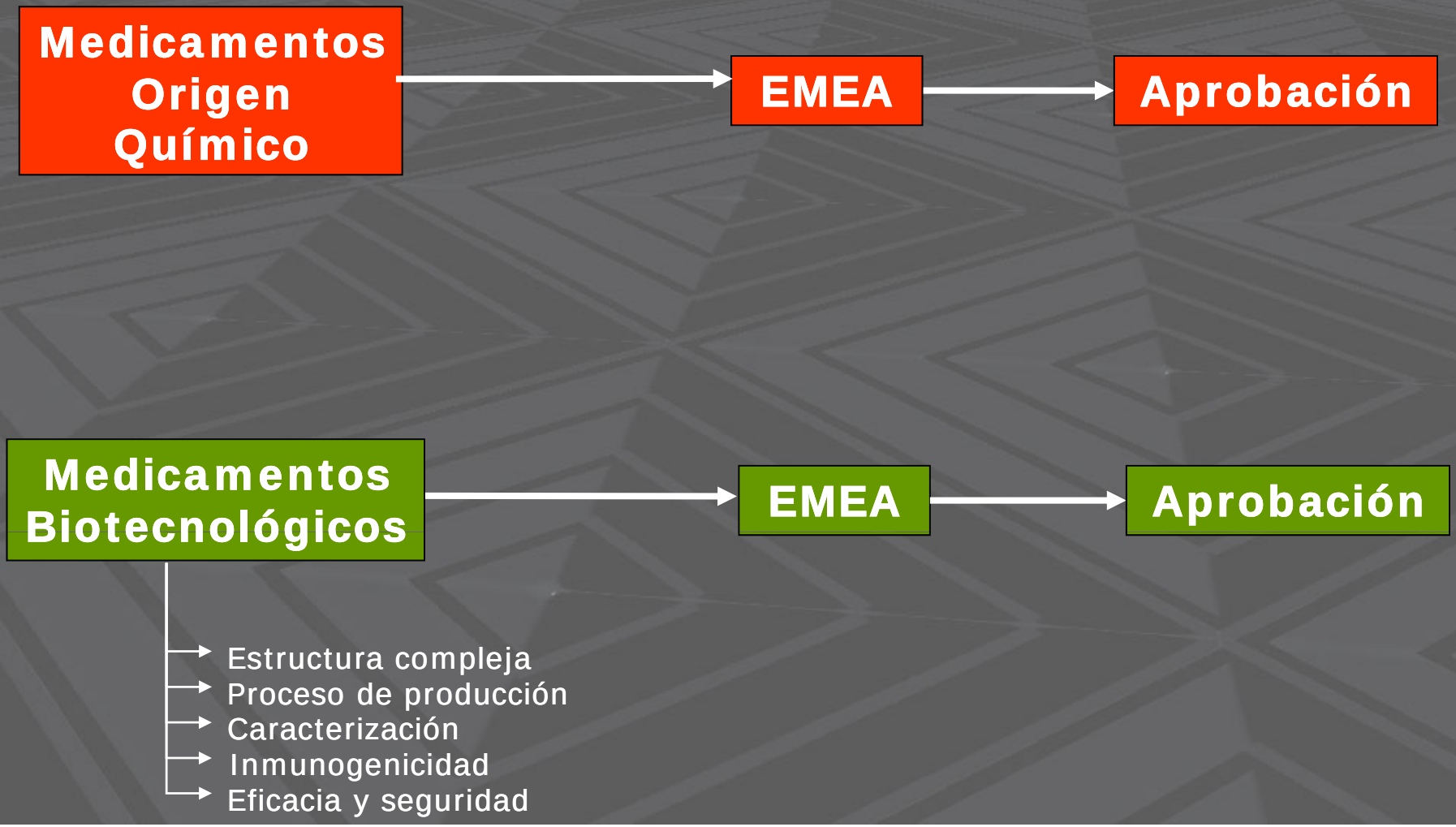
MEDICAMENTOS DE ORIGEN QUÍMICO FRENTE A MEDICAMENTOS BIOTECNOLÓGICOS



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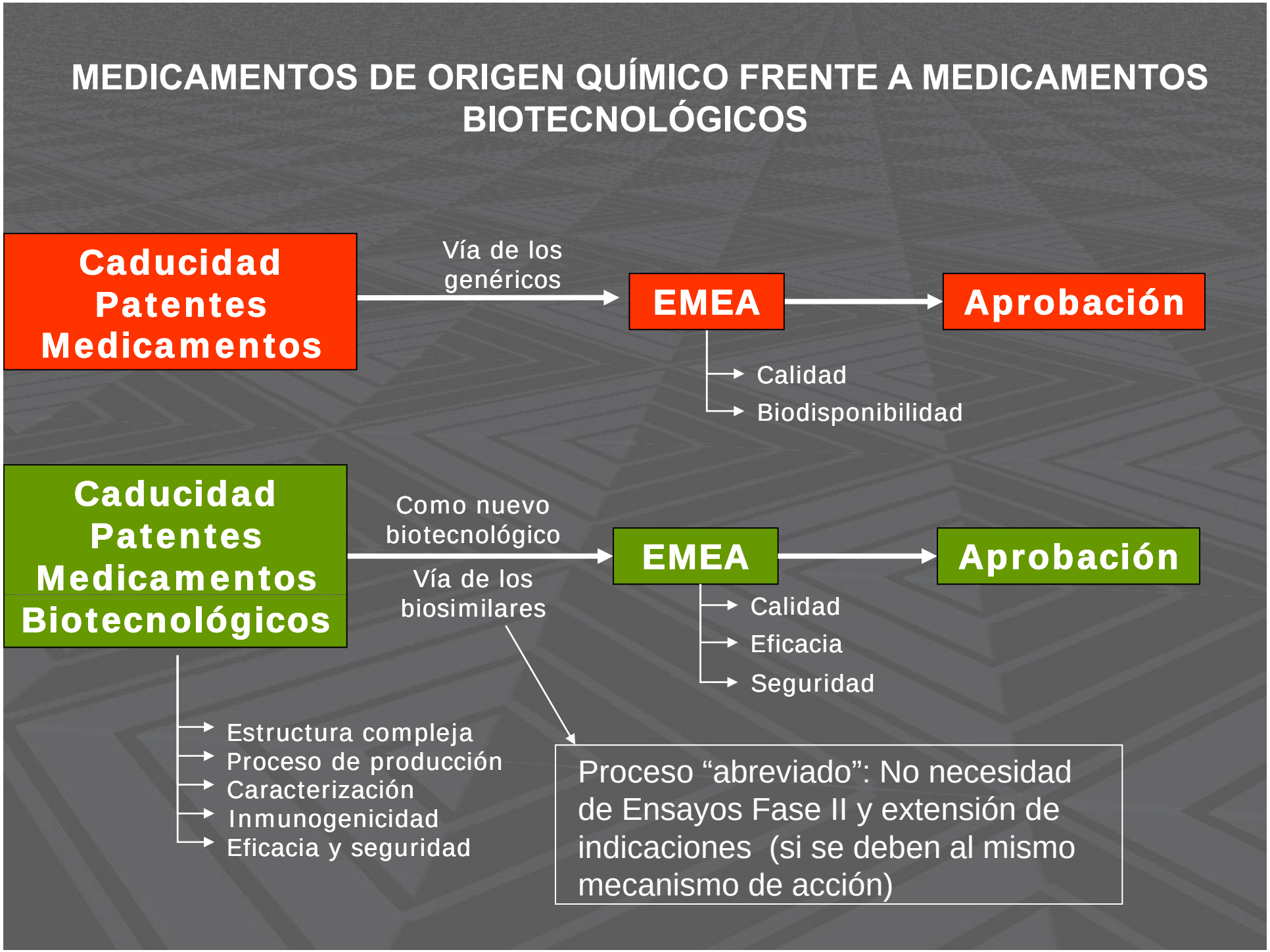


TERMINOLOGÍA

- BOSIMILARES (EUROPA)
- FOLLOW-ON-BIOLOGICS (FOBs en USA).
- SUBSEQUENT ENTRY BIOLOGYCS (CANADÁ).

EN OTROS PAISES Y LUGARES DEL MUNDO: COPIAS QUE NO SIGUEN GUÍAS ESTRICTAS

DEFINICIÓN DE BIOSIMILAR

European Medicines Agency

London, 19 April 2007
Doc. Ref. EMEA/74562/2006

What is a biosimilar medicine?

A biosimilar medicine is a medicine which is similar to a biological medicine that has already been authorised (the 'biological reference medicine'). The active substance of a biosimilar medicine is similar to the one of the biological reference medicine. Biosimilar and biological reference medicines are used in general at the same dose to treat the same disease. Since biosimilar and biological reference medicines are similar but not identical, the decision to treat a patient with a reference or a biosimilar medicine should be taken following the opinion of a qualified healthcare professional.

The name, appearance and packaging of a biosimilar medicine differ to those of the biological reference medicine.

CARACTERÍSTICAS DE LOS BIOSIMILARES

MEDICAMENTOS COMPETENCIA DE MEDICAMENTOS DE BIOTECNOLOGÍA CUYA PATENTE HA FINALIZADO.

FABRICADOS POR TECNOLOGÍA RECOMBINANTE CON LOS MISMOS ESTÁNDARES DE SEGURIDAD QUE LOS BIOTECNOLÓGICOS DE REFERENCIA.

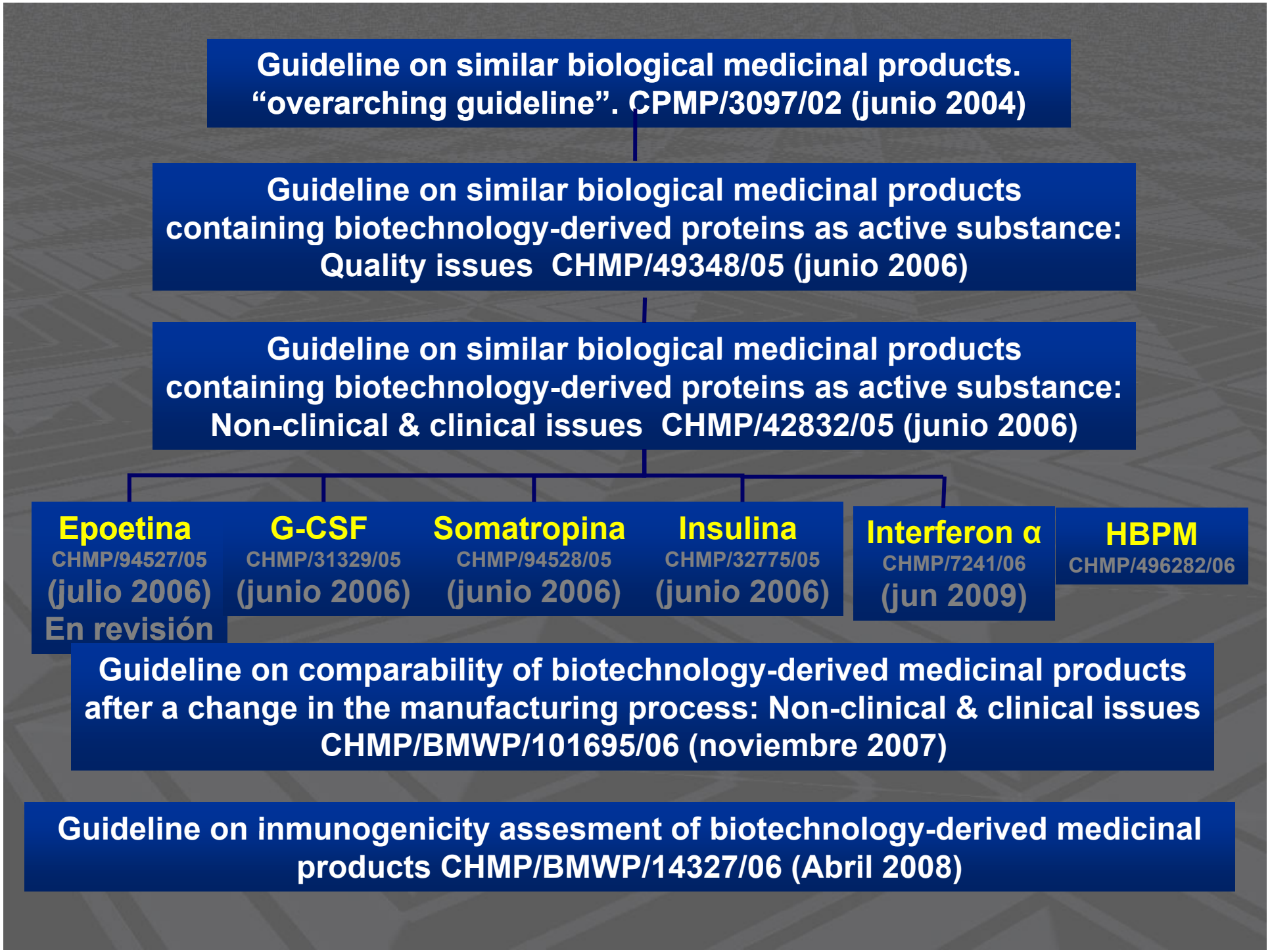
COMPARABLE CON EL MEDICAMENTO DE REFERENCIA EN TÉRMINOS DE EFICACIA, SEGURIDAD Y MECANISMO DE ACCIÓN, COMPROBADO A TRAVÉS DE ENSAYOS PRECLÍNICOS Y CLÍNICOS SIGUIENDO LAS GUÍAS DE LA EMEA

QUE SE UTILIZA EN LAS MISMAS INDICACIONES Y POR LA MISMA VÍA QUE EL FÁRMACO DE REFERENCIA

ES APROBADO POR LA EMEA A TRAVÉS DE UN PROCEDIMIENTO CENTRALIZADO COMO CUALQUIER OTRO MEDICAMENTO DE BIOTECNOLOGÍA.

AUTORIDADES DE LA UE

- **Commission Vice President Günter Verheugen stated: “Biosimilar medicines offer new opportunities, both for the growth of our generic industry and for the control of national healthcare expenditure. Nevertheless, these complex products must comply with the same rigorous standards for quality, safety and efficacy as for any other medicine, for the benefit of European patients.”**


Guideline on similar biological medicinal products. "overarching guideline". CPMP/3097/02 (junio 2004)
Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: Quality issues CHMP/49348/05 (junio 2006)
Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: Non-clinical & clinical issues CHMP/42832/05 (junio 2006)
Epoetina
CHMP/94527/05
(julio 2006)
En revisión
G-CSF
CHMP/31329/05
(junio 2006)
Somatropina
CHMP/94528/05
(junio 2006)
Insulina
CHMP/32775/05
(junio 2006)
Interferon α
CHMP/7241/06
(jun 2009)
HBPM
CHMP/496282/06
Guideline on comparability of biotechnology-derived medicinal products after a change in the manufacturing process: Non-clinical & clinical issues CHMP/BMWP/101695/06 (noviembre 2007)
Guideline on inmunogenicity assesment of biotechnology-derived medicinal products CHMP/BMWP/14327/06 (Abril 2008)

ANTICUERPOS MONOCLONALES

CONCEPT PAPER ON IMMUNOGENICITY ASSESSMENT OF MONOCLONAL ANTIBODIES INTENDED FOR IN VIVO CLINICAL USE.

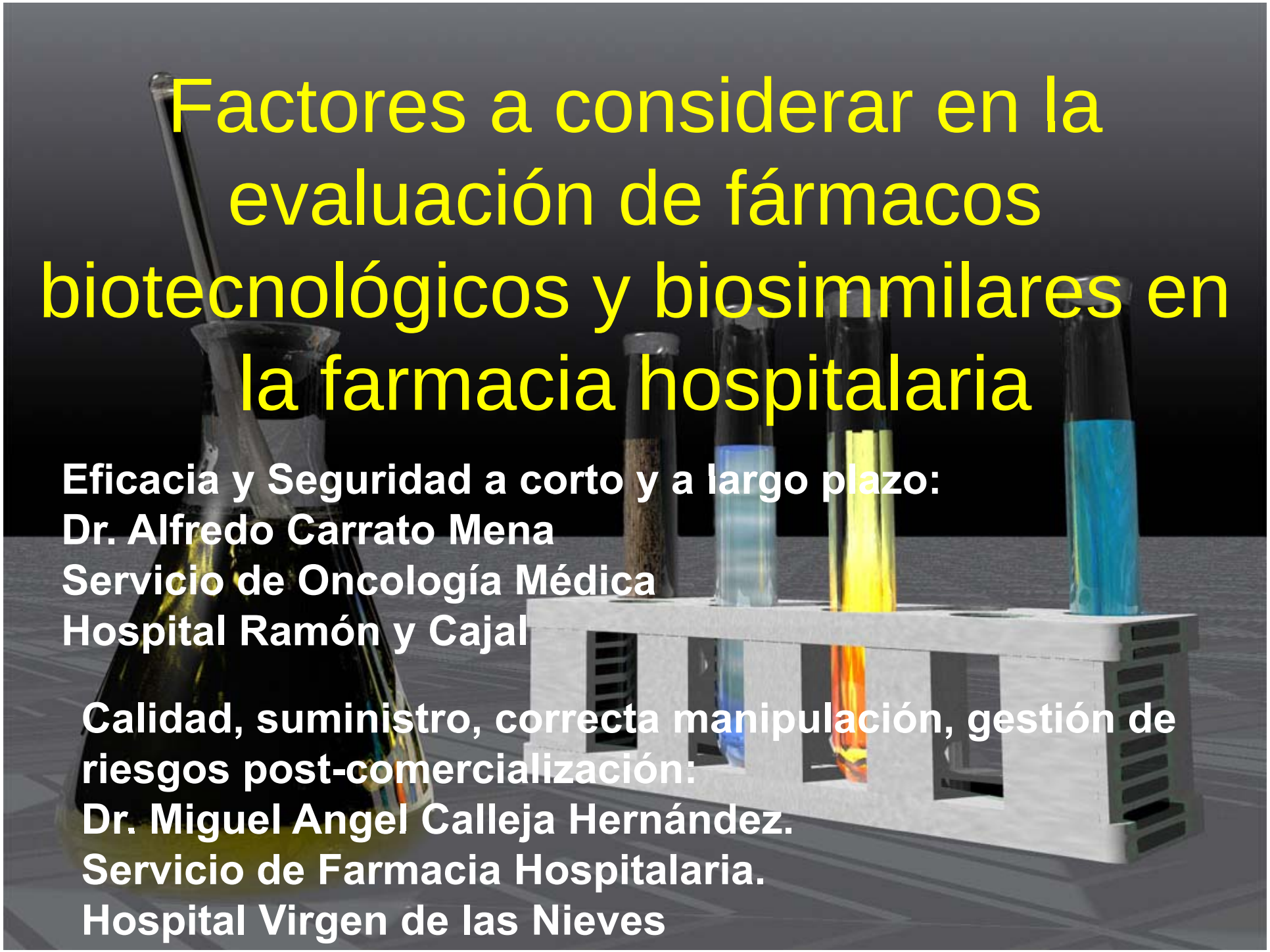
DRAFT AGREED BY BIOSIMILAR MEDICINAL PRODUCTS WORKING PARTY (BMWP)	February 2009
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	March 2009
END OF CONSULTATION (DEADLINE FOR COMMENTS)	June 2009

Unwanted immunogenicity is a significant problem with therapeutic biologicals. The clinical problems associated with unwanted immunogenicity vary in nature and incidence. The importance of the unwanted immunogenicity problem has led to the preparation and adoption of the 'Guideline on Immunogenicity Assessment of Biotechnology-Derived Therapeutic Proteins' by the CHMP (adopted April 2008).

Monoclonal Antibodies (mAbs) comprise a large important class of therapeutic biologicals. Different mAb products share some properties, but may differ in other aspects. Many mAb products are known to be associated with unwanted immunogenicity. Some issues pertaining to unwanted immunogenicity of mAbs differ in important aspects from those generally associated with therapeutic biologicals.

FACTORES A CONSIDERAR EN LA EVALUACIÓN Y SELECCIÓN DE MEDICAMENTOS DE BIOTECNOLOGÍA

- TIPO DE PROTEINA Y SU FORMULACIÓN.
- CONSISTENCIA EN LA FABRICACIÓN.
- FABRICANTE.
- SERIEDAD DEL FABRICANTE EN CUANTO A RESPUESTAS IMPREVISTAS Y PROBLEMAS DE MANEJO Y LOGÍSTICA.
- **EFICACIA CLÍNICA Y SEGURIDAD.**
- **SEGURIDAD POSTMARKETING.**
- **EFICIENCIA Y PRECIO.**
- **INTERCAMBIABILIDAD.**



Factores a considerar en la evaluación de fármacos biotecnológicos y biosimmilares en la farmacia hospitalaria

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